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Extended EHR@EU Data Space for Primary Use - Xt-EHR

Proposal number: 101128085

Stakeholder Consultation

DRAFT

D6.1 Patient Summary: Implementation guides on EEHRxF, functional and technical requirements and specifications for EHR systems

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EXECUTIVE SUMMARY

The aim of this deliverable is to establish the requirements and specifications for Electronic Health Record (EHR) systems to support the exchange and interoperability of the Patient Summary. This document is part of the broader initiative under the European Health Data Space (EHDS) Regulation, which seeks to enhance healthcare quality, ensure patient safety, and facilitate the seamless and secure exchange of health data across healthcare institutions and borders as well as accessibility of EHR for patients.

The deliverable includes elements in accordance with Article 15 of the EHDS regulation, namely harmonised datasets containing electronic health data and defining structures, coding systems, and value sets to be used as well as technical interoperability specifications. All this is to enable the transmission of personal electronic health data between different software applications, devices which means between different healthcare providers. The successful transmission will be achieved by focusing on the requirements for interoperable and safe exchange of for example Patient Summaries. This includes a thorough review of the European Electronic Health Record Exchange Format, EEHRxF, as well as of different specific functional and technical requirements and specifications, developed under eHealth Network and EU-funded projects, such as the existing eHealth Network Guidelines, deployed (or planning to be deployed) under the MyHealth@EU Infrastructure. In addition, the International Patient Summary (IPS CEN ISO 27269), has been taken into consideration in order to align requirements on EHR systems according to EHDS.

The majority of use cases in this deliverable aims to support national and cross-border exchange of Patient Summary, meaning the support of both national health data sharing and cross-border exchange of data between the country of origin (country A) and the country of treatment (country B). In addition to these use cases is the patient perspective and his/her access to the Patient Summary in accordance with the patient rights of the EHDS regulation.

In addition to the above, the T6.1 deliverable, also includes an assessment done to investigate the compliance and readiness of Member States to share data, as a reference to include in the continued work on conformity levels and requirements.

With the use cases perspective as a starting point this document provides logical models that define how data should be structured and exchanged. This resource is provided in some detail in this deliverable, but the full representation is provided externally to this document. These models are based on previously established European work as well as international standards, such as HL7 FHIR, ISO/CEN International Patient Summary (IPS) and are designed to be adaptable to local, regional, national and cross-border contexts.

The effort has been done in close collaboration with eHealth Network and its subgroups, as well as MyHealth@EU communities and other Xt-EHR work packages and tasks (WP4, WP5, WP7, WP8 and Task 6.2 of WP6).

The feedback from the stakeholder consultation will inform the final deliverable, in which we will define, formalise and list suggested functional and non-functional (technical) requirements as well as related specifications for implementing the patient summary in the EEHRxF under the scope of the EHDS Regulation.

List of Figures

Abbreviations

ATC code	Anatomical Therapeutic Chemical code
CDA	Clinical Document Architecture
EC	European Commission
EEHRxF	European Electronic Health Record Exchange Format
EHDS	European Health Data Space
eHDSI	eHealth Digital Service Infrastructure
EHR	Electronic Health Record
eP/eD	ePrescription/ eDispensation
EU	European Union
FHIR	Fast Healthcare Interoperability Resources
GDPR	General Data Protection Regulation
HCP	Health Care Provider
HL7	Health Level 7
HP	Health Professional
ICD	International Classification of Diseases (ICD)
IPS	International Patient Summary
IHE	Integrating the Healthcare Enterprise
IHE XDS	IHE cross document sharing
LOINC	Logical Observation Identifiers Names and Codes
MS	Member State
NSCR	National Shared Care Record
NPU	Nomenclature for Properties and Units
OMOP	Observational Medical Outcomes Partnership
OpenEHR	Open specifications, clinical models and software that can be used to create standards, and build information and interoperability solutions for healthcare
PS	Patient Summary
SNOMED CT	Systematized Nomenclature of Medicine Clinical Terms
WP	Work Package

TERMS AND DEFINITIONS

Term	Definition	Reference
'cross-border healthca	"healthcare provided or prescribed in a Member State other than the Member State of affiliation"	Article 3 of Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare
MyHealth@EU	''the brand under which the electronic cross-border health services – ePrescriptions, Patient Summaries, Medical test results, Discharge records and Medical images – are being made available in European countries to protect and assist	MyHealth@EU website

	travellers. These services enable citizens in Europe to benefit from healthcare in their country of travel in the same way that they benefit in their country of residence.''	
Interoperability component	A software component of the EHR system which sends and receives personal electronic health data of priority categories for primary use in the European electronic health record exchange format (EEHRxF), and which is independent from the logging component of the EHR system.	European Health Data Space (EHDS) regulation (Article 2, point (n))
'Member State of affiliation	" (i) for persons referred to in point (b)(i), the Member State that is competent to grant to the insured person a prior authorisation to receive appropriate treatment outside the Member State of residence according to Regulations (EC) No 883/2004 and (EC) No 987/2009; (ii) for persons referred to in point (b)(ii), the Member State that is competent to grant to the insured person a prior authorisation to receive appropriate treatment in another Member State according to Regulation (EC) No 859/2003 or Regulation (EU) No 1231/2010. If no Member State is competent according to those Regulations, the Member State of affiliation shall be the Member State where the person is insured or has the rights to sickness benefits according to the legislation of that Member State;"	Article 3 of Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare
'Member State of treatment'	"The Member State on whose territory healthcare is actually provided to the patient. In the case of telemedicine, healthcare is considered to be provided in the Member State	Article 3 of Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare

	where the healthcare provider is established"	
'interoperability'	"the ability of organisations as well as software applications or devices from the same manufacturer or different manufacturers to interact, involving the exchange of information and knowledge without changing the content of the data between these organisations, software applications or devices, through the processes they support;"	Article 2 – Definitions, Proposal for a Regulation on the European Health Data Space - Analysis of the final compromise text with a view to agreement.
'health professional'	"a doctor of medicine, a nurse responsible for general care, a dental practitioner, a midwife or a pharmacist within the meaning of Directive 2005/36/EC, or another professional exercising activities in the healthcare sector which are restricted to a regulated profession as defined in Article 3(1)(a) of Directive 2005/36/EC, or a person considered to be a health professional according to the legislation of the Member State of treatment"	Article 3 of Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare
'patient'	"any natural person who seeks to receive or receives healthcare in a Member State"	Article 3 of Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare
'patient summary'	''An identifiable "data set of essential and understandable health information" that is made available "at the point of care to deliver safe patient care during unscheduled care [and planned care] with its maximal impact in the unscheduled care"; it can also be defined at a high level as: "the minimum set of information needed to assure Health Care Coordination and the continuity of care"	eHDSI Glossary
'Electronic Dispensatio	"Information on the supply of a medicinal product to a natural person by a pharmacy based on an electronic prescription"	Annex I of the Regulation on the European Health Data Space

Cross-border services	eHealth Network apply to the cross-border exchange of health data. These guidelines are: Patient Summary, ePrescription/eDispensation, Laboratory results, Medical imaging studies and reports and Hospital Discharge reports. They aim to support the safe and efficient provisioning of care services in another Member State. These guidelines could also serve as a guiding principle for the national implementations of laboratory result reports.	eHealth Network https://health.ec.europa.eu/ehealth-digital-health-and-care/digital-health-and-care/eu-cooperation/ehealth-network_en
EEHRxF	European electronic health record exchange format. As specified further in EHDS regulation article 15, the, European electronic health record exchange format shall be commonly used, machine-readable and allow transmission of personal electronic health data between different software applications, devices and healthcare providers.	REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the European Health Data Space and amending Directive 2011/24/EU and Regulation (EU) 2024/2847
EHR (Electronic health record)	electronic health record' or 'EHR' means a collection of electronic health data related to a natural person and collected in the health system, processed for the purpose of the provision of healthcare;	
Producers	Producer refers to the 'Health data holder' and is any natural or legal person, public authority, agency or other body … which collects, stores and manages electronic health data, and makes it available for primary or secondary use under the EHDS framework.	Regulation (EU) 2025/327 on the European Health Data Space (EHDS), Articles 2(2)(n), and 35-37,43.
Consumer	Consumer refers to the 'Health data user' and is any natural or legal person … which has been granted lawful access to electronic health data for secondary use pursuant to a data	Regulation (EU) 2025/327 on the European Health Data Space (EHDS), Articles 2(2)(n), 11, 12, and Directive 2011/24/EU, Article 3.

	permit, a health data request approval or an access approval by an authorised participant in HealthData@EU. For primary use a consumer refers to the entity, such as a health professional, healthcare provider or Member State of treatment, that accesses and uses personal electronic health data for the purpose of providing healthcare to a natural person under their care. This consumer role is fulfilled by the EHR system or interoperability component receiving the data, in compliance with the access rights and obligations defined under the European Health Data Space Regulation.	

126

127

1 AIM OF THIS DOCUMENT

The aim of this document is to establish the requirements and specifications for Electronic Health Record (EHR) systems to support the exchange and interoperability of PS across the European Union. This document is part of the broader initiative under the European Health Data Space (EHDS) regulation, which seeks to enhance healthcare quality, ensure patient safety, and facilitate the seamless and secure exchange of health data across healthcare institutions and borders as well as accessibility of EHR for patients.

2 SCOPE AND INTERDEPENDENCIES

2.1 Scope

The scope of this document is to propose a specification of electronic health data related to PS to support the implementing acts on the European EHR exchange Format (EEHRxF) under EHDS. The PS has a starting point, already implemented guidelines, including, but not limited to, MyHealth@EU services and data sets for PS with the aim of supporting MS towards the EHDS. The work package provides harmonized datasets, coding systems and values to be used in datasets and technical interoperability specifications and data quality requirements for EHR systems. National and cross-border exchange of patient summaries will be facilitated by developing common specifications and the EEHRxF according to the EHDS Regulation.

In this document, we outline the suggested functional and technical specifications for EEHRxF in the category of "PS". As outlined in the EHDS regulation, the EEHRxF shall allow for different profiles (fx FHIR) for its use at the level of EHR systems and at the level of the national contact points for digital health in MyHealth@EU for cross-border data exchange. The specifications suggested in this document are general and will apply as a basis to which all profiles should adhere. In accordance with the EHDS regulation, the specifications apply to both producers and consumers of data.

It is also important to note that the EHDS Regulation applies to both the category of PS as a whole and to the individual data entries included in this category. For example, given that allergy and intolerances status is part of a PS, the requirements linked to the PS should also apply to such allergy and intolerances status even if it is processed separately from the PS as a whole, to facilitate its inclusion in the PS.

In addition, it is set out to describe the landscape of the final deliverable. Understanding what is implementable in a foreseeable future while also progressing results requires a proper understanding of the journey up until now and the starting point for all Member States.

2.2 Out of scope

This will not be a legally or normative binding document, it serves as a technical deliverable to support implementers and policymakers.

It does not address the broader governance or operational policies related to national infrastructure.

It does not include implementation planning for Patient Summary, ePrescription, eDispensation, medical imaging, or medical test results, except where such components are referenced for alignment or interoperability.

2.3 Interdependencies

There is an overlap between the different prioritised categories of electronic health data listed in the EHDS Regulation. PS-related health data exist as elements in all parts of the EEHRxF, as defined by the eHealth Network guidelines. Therefore, a significant part of this task's work is to consider the overlap between these categories and to align and adopt the specifications on all levels from functional to technical. This work is done in collaboration with other tasks of different Work Packages, namely WP4 (Sustainability and cross-border interoperability) WP5 (General requirements for EHRs and system interfaces), WP6 (Electronic prescriptions and PS towards EHDS), and WP7 (New services for EHR systems towards EHDS). These interdependencies ensure that the PS deliverable is coherent within the broader Xt-EHR ecosystem and aligned with both national and EU-level strategic goals.

The work in WP 5, 6, and 7 aims to support the concerned implementing acts which will need to include some framework of assessment of conformity of EHR systems. Such frameworks will include, as a basis, detailed criteria on the level of subsets or individual data elements in the harmonised datasets. Those criteria will then be input to and subject to discussions with WP8 (Certification and Labelling framework).

More broadly, strong interdependencies exist with the eHealth Network sub-groups of Semantic and Technical Interoperability, as for the already mentioned eHN Guidelines and the Technical Interoperability requirements, as for the MyHealth@EU specifications and assets, as for ISO / CEN International Patient Summary specifications and HL7 FHIR IPS Implementation Guides.

3 INTENDED USE

The intended use of this document is to support the development of EHDS implementing acts by specifying harmonised data sets, code systems and values, as well as technical specifications. These artefacts are also aimed at providing guidance for the development, implementation, and deployment of EHR systems capable of generating, sharing, and processing patient summaries in a standardized format within and across EU Member States. This document is intended for EHR system developers, healthcare providers, policymakers, and other stakeholders involved in the management and exchange of health data. By adhering to the future specifications, stakeholders will be able to ensure that patient summaries are interoperable, secure, and useful for enhancing patient care and facilitating cross-border healthcare.

The intended use also includes providing a baseline for conformance assessment, and a reference for the evolution from CDA to FHIR, in alignment with the broader goals of the MyHealth@EU initiative. This section is not included in this document as it is still under development and will be part of the final deliverable.

4 INTRODUCTION

The Xt-EHR Joint Action (JA09) aligns with the European Commission's commitment to a "Europe fit for the digital age" and further with the objectives of the EU4Health Programme by enhancing health systems. This project aims to develop requirements, guidelines, specifications, and implementation guides to prepare the implementation of the EEHRxF and key assets for primary use data and thus to foster the interoperability and exchange of health data across the European Union, in readiness for the impending EHDS regulation.

This work encompasses the comprehensive primary use of health data to achieve several pivotal objectives. Through a concerted effort focused on quality data, robust infrastructure, and capacity-building initiatives, the broader agenda for a single market for digital goods and services can be effectively realized while safeguarding data protection and ensuring the free movement of people across borders. The project aims to impact all stakeholders in the process of digital transformation in healthcare based on a standard-based health information exchange. Through Xt-EHR, the interoperability and cross-border exchange of different types of health data will be promoted by proposing the necessary implementation guidelines for the implementation of new services that will complement the eHN guidelines and the MyHealth@EU initiative. Moreover, Member States will need to foster the adoption of interoperable EEHRxF in national systems to comply with EHDS provisions, particularly to support patients' rights to obtain priority categories of EHR health data in an interoperable format.

Work package 6 of Xt-EHR aims to develop the EEHRxF for patient summaries and for electronic prescriptions and electronic dispensations. Within WP6, Task 6.1 aims to develop the EEHRxF specifically for patient summaries. Patient summaries have been used in many of the EU Member States for a decade or more, and the infrastructure to support cross-border sharing of electronic patient summaries as well as prescriptions and dispensations, have been available since 2011[1], while MyHealth@EU Routine Operation started in 2019[2]. Several projects and bodies have performed analysis of the state of play with patient summaries in Europe[3].

5 METHODOLOGY

The methodology applied in the development of this document has taken into account the vast amount of information and specifications related to PS that is available. PS is a well-defined and well-used structure that has been a priority and an evaluation process for European and national EU Member States projects for decades. The work of this group has been focusing on assessing:

- eHN Guidelines and MyHealth@EU requirements and specifications as a starting point.
- ISO 27269 - International Patient Summary (IPS) – gaps and potential improvements available.
- Perform an overview of conformity to perform a gap analysis and identify potential improvements to the specifications based on a survey on conformity performed by the PS Cluster working group.
- Identifying relevant sources that can enhance the primary eHN guidelines for PS.
- Collaboration with Standards Development Organisations (SDOs) in sharing requirements to support development of implementable specifications, in particular collaboration with HL7 Europe and IHE to support the development of a HL7 FHIR Implementation guide. As part of this is looking at what is available as FHIR IPS implementation guide

[1] In epSOS Large Scale Pilot, cross-border exchange started in November 2011 between Italy and Greece, followed by Spain and other MSs

[2] First EU citizens using ePrescriptions in other EU country under eHDSI and MyHealth@EU.

[3] Bruthans, J., & Jiráková, K. (2023). The current state and usage of European electronic cross-border health services (eHDSI). Journal of Medical Systems, 47(1), 21.

- Development of logical models for PS, based on available sources and in discussion with Task 6.1 contributors.
- Identification of the source requirement for each data element in the models.
- Identification of the preferred code systems and associated value sets creation rules and contents.
- Application of a conformity model, based on the HL7 FHIR Implementation obligation framework. (for future deliverable, not part of this document)

The resources used for this work were:

- eHealth Network guideline on Patient Summary, release 3.4
- Additional eHealth Network guidelines
  - Laboratory Result Reports, version 1.1
  - Hospital Discharge Reports, version 1.1
  - Medical imaging studies and reports, version 1.1
- MyHealth@EU Requirements Catalogue, version 9.0.0, 2025-03-24
- MyHealth@EU CDA Implementation Guide, version 9.0.0
- Standards from Standards Development Organizations
- HL7 Europe FHIR Implementation Guide (joint project with Xt-EHR)
- ISO/DIS 27269:2024 and 2025 International Patient Summary (2025 released shortly before document was ready so only limited alignment)

The development of the PS logical model was subject to certain constraints, particularly the requirement to maintain alignment with models common to all tasks. As a result, the common models may be temporarily misaligned between documents and changes may occur during the project due to the continuous alignment effort continuously between tasks working on different EHDS priority categories.

Additional information about the source documents. The requirements catalogue is maintained within the European Commission document management which also means that they are available only with authorisation. Any request to access documents shall therefore me communicated with DG Sante.

6 STATE OF THE PLAY OF THE PATIENT SUMMARY IMPLEMENTATION

6.1 Overall context of the Patient Summary

The concept of PS has been part of various international standardisation efforts, including those by IHE, HL7 and CEN/ISO. Building on the former global initiatives (IHE Patient Care Coordination (PCC) and IHE Continuity of Care Document (CCD)), the European Patient Summary was developed to support the continuity of care across borders. Its development was initiated in the epSOS Large Scale Pilot, where it was one of the two initial documents—alongside ePrescription/eDispensation—to be exchanged between electronic health records across EU Participating Nations.

The initial purpose of the PS was to provide continuity of care to a patient in case of emergency and unplanned care. The project ultimately aimed to strike a balance between clinical usefulness, interoperability, and national feasibility, to allow for cross-border exchange. Also in epSOS, other PS cases were developed: 112-Emergency, specific for emergency situations, Medication Related Overview (MRO), to provide info to pharmacists for an informed dispensation, Health Care Encounter Report, to return information on new findings, procedures and therapies, after an encounter while abroad (a sort of precursor of the Discharge Report) , and the Patient Access, the possibility for a patient to request his PS, into a selected languages (further developed and piloted in PATHeD Project).

The CEN International Patient Summary was developed starting from the epSOS, and subsequently from the European Patient Summary. Later, the European Patient Summary evolved into the ISO IPS.

The European Patient Summary in MyHealth@EU and in XpanDH discusses the possibility of addressing rare diseases, planned care, and possible new organisation per phase of pathology, as requested, e.g., by Oncologists.

6.2 Analysis of existing specifications

To support implementation and alignment across Europe, a set of specifications and guidelines has been developed over time. Two key reference documents in this regard are:

- The eHealth Network guidelines, or eHN guidelines
- The eHealth Digital Service Infrastructure (eHDSI), subsequently referred to as MyHealth@EU, Specifications and Assets.

The guidelines are legally non-binding since the eHealth Network (eHN) is not a co-legislator/authority but a Member States voluntary board to implement the EC/Dir 2011/24 on cross-border healthcare and, in particular, Art. 14 on eHealth. However, the adoption by the eHN members represents the commitment from Member States to use them to create convergence plans at the national level.

Starting from Version 3, the eHN Guidelines are project and technology independent, to allow a broader adoption at the national level. Cardinalities are not specified, nor the Value Sets, but just the preferred code systems are indicated.

MyHealth@EU was always a voluntary initiative, meaning that Member States could join if they wanted. However, when joining the initiative, the Member States were obliged to use the MyHealth@EU

specifications based on the requirements set by the eHN guidelines. With the entry into force of the EHDS Regulation, it is now mandatory for all Member States to join MyHealth@EU, according to the set time plan and specifications that are under development.

MyHealth@EU specifications and assets are project-specific and technology-specific. In particular, the PS is currently implemented as HL7 CDA R2, Level 3 (structured and coded) and Level 1 (structured header and embedded PDF type A).

From 2029 onwards, participation in MyHealth@EU will be mandatory for all Member States, and the specifications will be legally binding. At that point, the eHN guidelines will be phased out and integrated into the official European Electronic Health Record Exchange Format (EEHRxF) specifications

As indicated in Section 5, the current specifications are the following:

- the Patient Summary Guidelines, v3.4 as the most recent version[4].
- the MyHealth@EU specifications and assets in Routine Operation referring to the so-called Wave 7. Wave 8 will enter Routine Operation in Q4 2025.
- The last released specification and assets, still in Pre-Production Testing are Wave 9: In this task we will consider the Requirements Catalogue, v9.0.00[5] as the most recent version. The Master Value Set Catalogue, MVC9.0.0[6], and the CDA Implementation Guide 9.0.0[7].

6.3 Patient Summary questionnaires

During the first months of the Joint Action, WP6 performed a comprehensive analysis of the state-of-the-art of the PS in the Union. This work was made possible by liaising with the eHDSI PS Cluster workgroup and expanding their excellent work. The PS Cluster working group consists of 22 MS interested in the implementation of the PS. The goal of the activity of WP6 was twofold:

1. Understand whether and how the MS are complying with the current eHN Guidelines and eHDSI Requirements Catalogue.
2. Perform a gap analysis and identify potential improvements to the specifications, which will support WP6 in the refinement of the specifications.

In order to pursue these goals, WP6 performed a thorough analysis of the PS Questionnaire, which the PS Cluster workgroup asked MS early 2024 to take part in. This survey collected information about the availability of coded data and the national characteristics of PS, which is divided into three sections: “Patient data/patient identification”, “Patient clinical data” and “PS data”.

In July 2024, 18 countries out of 22 included in the survey have responded to the PS Questionnaire, with a response rate of 82%. The results of the questionnaire are to be found in Annex 1

[4] https://health.ec.europa.eu/ehealth-digital-health-and-care/digital-health-and-care/eu-cooperation/ehealth-network_en#ehealth-network-guidelines

[5] MyHealth@EU Requirements Catalogue v9.0.00 (EC internal resource with restricted access)

[6] eHDSI/MyHealth@EU Master Value Catalogue (EC internal resource with restricted access)

[7] https://art-decor.ehdsi.eu/publication/epsos-html-20250519T123531/index.html

6.3.1 Key outcomes and proposals based on the questionnaire results

The analysis of the PS Questionnaire responses reported in the previous paragraphs leads to the conclusion that there is an overall low conformance to the current PS specifications among the MSs' EHR systems, with specific issues related to the data quality.

For this reason, a proposal could be to identify an alternative set of specifications in which the cardinality of the requirements related to the lowest conformance rate among the MSs could be relaxed. The relaxation of the requirements in the set of specifications aims to enable a wider exchange of data across the EHRs of the EU, in line with the objectives of the EHDS Regulation, to let the data flow and data actually follow the patients. The set of specifications containing requirements characterised by a lower degree of cardinality will be detailed at a later stage. The data model proposed in the dedicated section does not consider, for now, this possible relaxation of some data elements.

Change Proposal by eHDSI/MyHealth@EU, which will eventually occur or have already occurred, will be taken into consideration in the case they would provide content to be integrated in the current version of the PS.

An additional source of evolution of the PS is represented by the analysis of the convergence between the European PS and the International Patient Summary. The comparison which was undertaken during the project has shown that IPS could bring out opportunities for the production or revision of data elements in the EPS.

To promote the exchange of the PS across the MSs, the transmission of the PS as a simple Original Clinical Document could be taken into consideration for these EHR systems with a low conformance degree to the set of specifications, as well as the transmission of unstructured data. This proposal shall be discussed only after outcomes concerning the implementation of an EHR conformance model are produced by the Xt-EHR joint working group, including the participants of all the Work Packages.

The low level of conformance at this stage needs to be kept in mind when revising the requirements and especially when considering the different ways of implementation. We must have a short-term and a long-term goal to work with, as the targets of EHDS are both to achieve cross-border and national Patient Summary data sharing. In regard to national patient summaries, there will be an impact between the introduction of the cross-border PS and the convergence of the national, but there is still a level of adoption which will most likely be done differently between countries.

7 ANALYSIS OF RELEVANT GUIDELINES, SPECIFICATIONS AND STANDARDS

As described above, the creation of the PS is a long-term endeavour. The outcomes of these projects were multiple, and in the next sections, we highlight the most important outcomes regarding products.

7.1 eHealth Network Guidelines

The purpose of an eHealth Network guideline is to describe business requirements for interoperable sharing of health data. The guideline aims to facilitate the sharing of health data across national borders within the EU/EEA as well as to support all Member States in their respective national eHealth priorities. The guideline also aims to be a single point of strategic-level decision-making. The guideline is developed with the aim of being applicable and useful for further elaboration and detailing during implementation activities, such as in setting use-case specific technical requirements or when developing implementation guides.

Use cases supported are developed inside the individual guidelines themselves. Initially, the first two guidelines, PS and electronic prescriptions, supported sharing health data of a patient from the country of affiliation (referred to as "Country A") with a healthcare professional in the country of treatment (referred to as "Country B"), with some exceptions, but guideline versions after 2019 aim to support both domestic and cross-border use cases.

Currently, the guideline documents are developed by the eHealth Network subgroups and the decision to adopt a guideline is made by the eHealth Network. During 2024 the eHealth Network subgroups performed an assessment of the consistency of existing guidelines both regarding the textual sections and the data sets.

Changes to improve consistency between guidelines were adopted at the November 2024 meeting of eHealth Network. The analysis of dataset consistency has been provided for use by Xt-EHR in the reuse of the guidelines for developing harmonised data sets

7.2 MyHealth@EU

MyHealth@EU is the European eHealth digital service infrastructure that facilitates cross-border health data exchange between Member States. It plays a pivotal role in ensuring that EU citizens will be able to access healthcare services seamlessly across borders, fostering cooperation among health systems in the digital era. The platform is an essential component of the EU's broader agenda to promote a Digital Single Market in health, allowing citizens to receive healthcare services even while travelling or living in other EU countries. Originally launched under the eHDSI (eHealth Digital Service Infrastructure), it facilitates the secure and interoperable exchange of patient data across Member States. Patient Summaries and ePrescriptions are the primary services currently supported, with future expansions aligned to the EHDS Regulation.

The role of MyHealth@EU in PS Interoperability is significant. MyHealth@EU builds on the eHealth Network Guidelines, with further defined business and clinical requirements. The result, the MyHealth@EU Requirements Catalogue, specifies the functional and technical criteria to enable cross-border implementations. Within WP6, MyHealth@EU provides a key reference framework for Conformity

assessment, ensuring Member States' systems meet common interoperability standards. Semantic alignment: through defined code systems and value sets. Implementation models: using HL7 CDA, FHIR, and logical data models proposed in this document. The PS in MyHealth@EU is governed by structured formats (e.g., CDA, and now evolving towards FHIR).

The MyHealth@EU infrastructure requires National Contact Points for eHealth (NCPeHs) that must ensure compatibility with the MyHealth@EU exchange formats, provide structured, coded clinical data as per conformant categories defined in the MyHealth@EU catalogue and transition from CDA to FHIR-based implementations where applicable (guided by HL7 Europe and IHE)[8].

In the following table, the sections constituting the PS are shown, classified by the optionality attributed to them by MyHealth@EU. According to the definitions provided in the MyHealth@EU Requirements Catalogue, sections classified as "Basic" must be present in the PS, while sections classified as "Extended" can be omitted entirely.

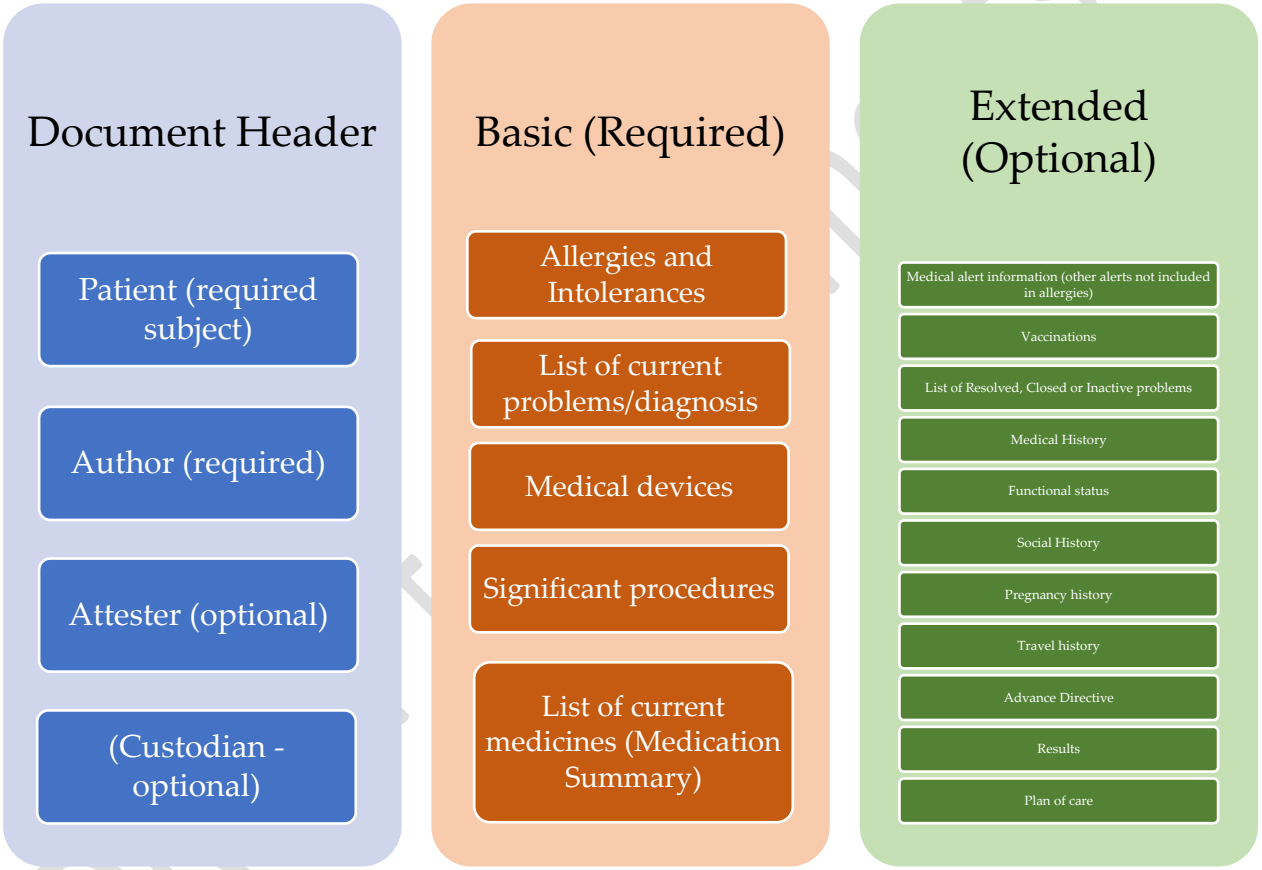

Figure 1 - Sections of the PS according to the optionality attributed by MyHealth@EU.

[8] MyHealth@EU Requirements Catalogue v8.0.00
Change Proposals CP086–CP091
eHDSI Technical Specifications (current and archived)
HL7 FHIR Implementation Guide (Joint Action contributions)
eHN PS Guidelines v3.3

7.3 Convergence towards ISO 27269 International Patient Summary (IPS)

As part of the work undertaken, the IPS has been identified as a qualified source to assess the usefulness of the work of this task under Xt-EHR, preparing for this document. As previously mentioned, IPS was derived from EU PS, but follows different trajectories. In the last three years, the process to align EU PS and IPS was started in the eHN Guidelines and MyHealth@EU. Ensuring that international and European specifications are aligned will be important for future data sharing with countries not using the EU PS and for MS that have implemented IPS. The use of the IPS elements is subject to ISO's ownership and has hence been carefully assessed to ensure copyrights are respected.

The IPS is composed of the sections described in the following table according to their optionality classification.

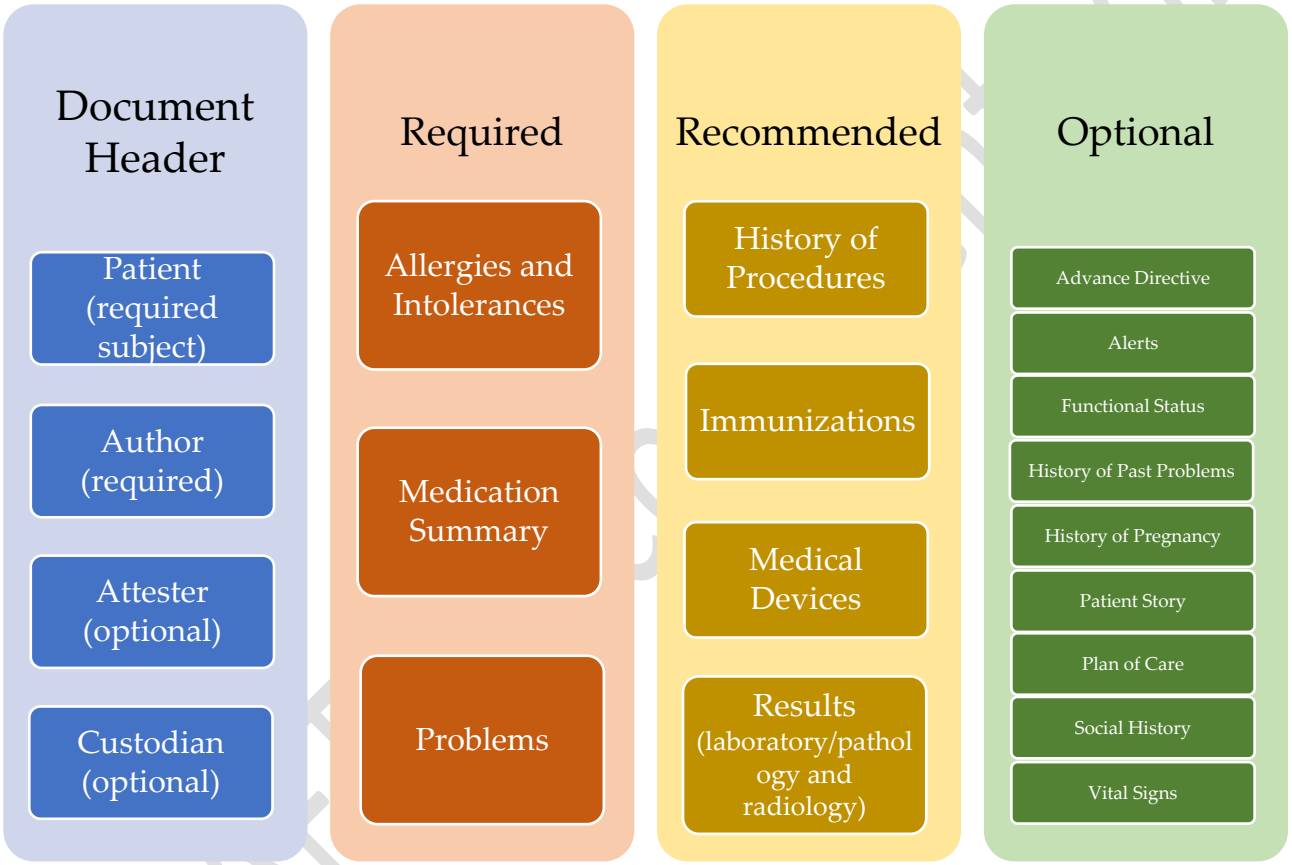

Figure 2 - Sections of the Patient Summary according to the optionality attributed by ISO IPS

The current effort in eHN Guidelines and MyHealth@EU is to get the alignment between the EUPS and the IPS.

The same effort is performed in Xt-EHR T6.1, in an attempt to find a common agreed solution as input to the Implementing Act and associated Implementation Guides.

7.4 European Health Data Space (EHDS) Regulation (EU) 2025/327

On 11 February 2025, the European Parliament and the Council adopted Regulation (EU) 2025/327 on the European Health Data Space (EHDS). This landmark legislation aims to enhance patient access to and control

over their own electronic health data, foster data interoperability, and enable secure cross-border sharing of health information. The EHDS Regulation provides a robust legal basis for both the primary use of electronic health data – supporting continuity of care across Member States – and the secondary use of such data, including research, innovation, policy development, public health emergency response, and official statistics.

This document acknowledges the EHDS framework and specifically aligns Patient Summary (PS) requirements with:

- **Article 15**, mandating the development of the European Electronic Health Record Exchange Format (EEHRxF);
- **Article 36**, outlining general requirements for EHR systems in terms of interoperability and security;
- Other provisions ensuring that patients have immediate electronic access to personal health data while respecting confidentiality, data minimisation, and the right to mask sensitive information if national law allows.

The EHDS Regulation introduces a common legal and technical framework for sharing personal electronic health data within the Union. Key elements influencing PS include:

1. **Primary vs. Secondary Use**
   a. Primary use covers direct patient care, guaranteeing that natural persons can easily access and share their PS with authorised providers (Recital (9), Article 6).
   b. Secondary use addresses how aggregated or pseudonymized PS data may be leveraged for research, innovation, policymaking, and other societal benefits (Recitals (52)–(55).
2. **Cross-Border Infrastructure: MyHealth@EU**
   a. The EHDS mandates that Member States connect to MyHealth@EU for cross-border health data exchange (Recitals (33)– (34), Article 11), ensuring PS can be transmitted securely whenever patients receive treatment abroad.
3. **Conformity Assessment of EHR Systems**
   a. Under Chapter III of the Regulation, EHR systems – including those generating or handling PS – may be subject to a self-certification scheme if they process "priority categories of electronic health data" (Recitals (36)– (40).
4. **Patient Rights and Access Control**
   a. The Regulation reinforces the immediate, free-of-charge, machine-readable access to PS for patients (Articles 3-4), plus restricting of access to particularly sensitive data elements for health professionals (Recitals (17)– (18), Article 8, Article 10).
5. **Rights and obligations of Health Professionals**
   a. The regulation enforces obligation of healthcare providers and professionals to record and update the PS (articles 11-12)
   b. Healthcare providers and health professionals are obliged to register the PS
6. **Obligations of Member States**
   a. Member States shall establish electronic access services for patients to access the PS (Article 4)
   b. Member States shall establish health professional access services enabling access to the PS (Article 12)

8 USE CASES

The following use cases aim to reflect the logic of the eHealth Network guidelines while aligning with the objectives of the European Health Data Space (EHDS). They also incorporate the diversity of contexts in which the Patient Summary (PS) may be used.

Each use case provides a brief explanation of its purpose, relevance, situation, context, key actor, and functional process steps.

These scenarios reflect a high level of consensus on what constitutes essential European eHealth services, as established in Directive 2011/24/EU on the application of patient's rights in cross-border healthcare.

To support interpretation and comparison, all use cases are presented following a common structure and can be mapped onto key stages of the PS lifecycle: creation, access, update, and use across borders.

The following figure has been created to provide a simplified representation of the PS lifecycle. The specific details are further described in the use case tables presented below.

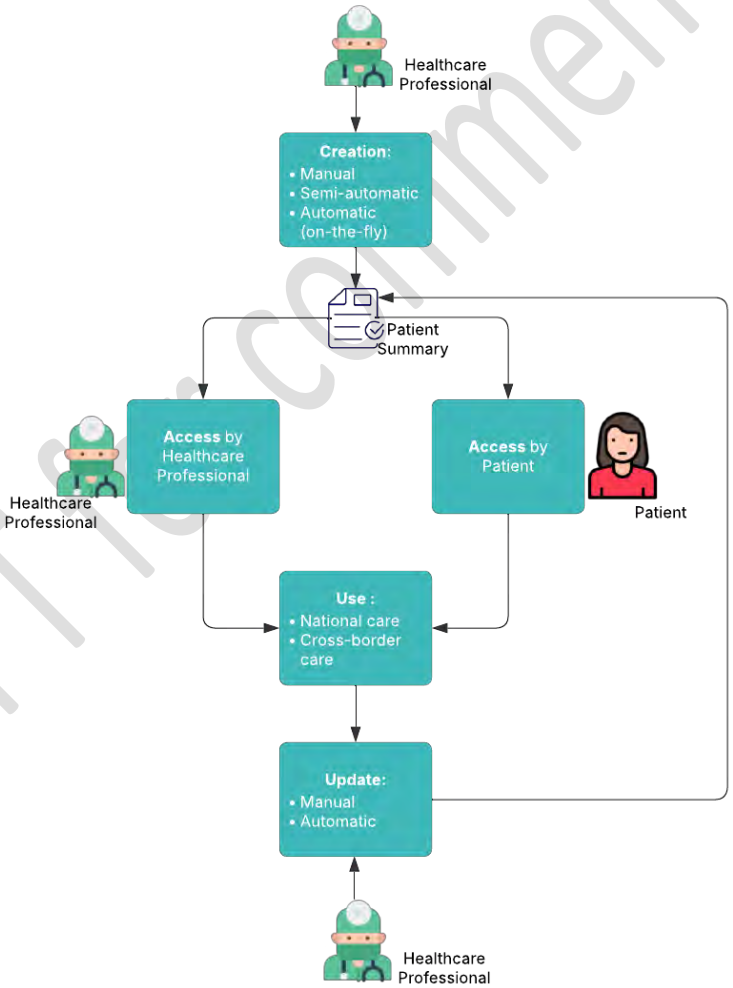

Figure 3 Image of process of the PS

eHN PS Guidelines Release 1 covered the Unplanned Care. This was defined by Emergency Health Professionals and GPs as a synthetic document. Data elements were selected to be concise and easily

implementable according to the MSs realities, providing acceptable coverage of the cases to be addressed, indicating the minimum mandatory data set, called "Basic", which allow to classify a clinical document as a PS, and the maximum data set, called "Extended", to be translatable for cross-border use.

eHN PS Guidelines Release 2 began to focus on usability for planned care, providing a roadmap for MSs to implement.

In Release 3 of this guideline, additions were made to fill existing gaps (e.g. increased support for the treatment of patients with rare conditions) as well as to extend the planned care context that requires a wider range of information that can be presented to the health professional in country B. This can, e.g. include some elements for the continuity of care to achieve better health outcomes. Planned Care documents require completeness and higher granularity to transfer all relevant information for the specific pathology, necessitating a wider range of detail for already specified elements from Release 2, such as laboratory findings and results.

Lessons learned from the experience of the COVID-19 Pandemic show that in case of health care emergencies immediate collection of data on citizens/patients is key to monitor the emergency and to identifying possible solutions. Having a visible and comprehensive PS definition at the European level can serve as the starting point for data collection standardised at the European level. Moreover, it may foster compliant implementations at the national and regional levels. Therefore, consensus on the PS should be promoted, and its visibility should be enhanced.

8.1 Actors

This chapter describes actors involved in PS workflows. Actors represent abstract roles performed by business actors (healthcare roles) or technical actors (systems and applications). This actor model follows the approach outlined by relevant Integrating the Healthcare Enterprise (IHE) profiles such as Cross-Enterprise Document Sharing (XDS) and Patient Care Coordination (PCC).

8.1.1 Business actors

Patient summary Creator - An actor responsible for generating and finalising the Patient Summary (PS). Typically, this role corresponds to hospital-based or clinic-based information systems, which assemble structured clinical and administrative data into a PS, and Health Professionals (HP) who manually build the PS, selecting the clinical info to be included.

Patient summary Data holder - An actor responsible for storing the PS (i.e. the PS Custodian), maintaining them securely, and facilitating their access and retrieval by healthcare providers or patients. This can be as a Technical Actor, a repository that can be regional, national, or cross-border. The PS Repository publishes metadata and responds to retrieval requests from consumers.

Patient Summary Consumer - The final user of the PS, typically representing clinical or patient-facing applications. This actor retrieves, views, and processes PS information for clinical follow-up, continuity of care, or patient self-management purposes.

8.1.2 Technical actors

To support the expected functionalities a set of specific technical actors are defined. These actors focus on the preservation, exchange of data and semantic assets to provide interoperability – they represent atomic functionalities that may be implemented in different configurations depending on the situation and architecture – for cross-border, national or internal EHR system exchange.

Document Source - The Document Source creates and submits a structured PS. It sends these documents and associated metadata to the Document Repository for storage and indexing, enabling future retrieval by authorised healthcare providers, or patients and/or their legal representatives.

Document Repository - The Document Repository securely stores PS. It maintains document persistence, assigns unique identifiers, and facilitates secure retrieval by Document Consumers. It registers stored documents with a Document Registry, ensuring their visibility within document-sharing infrastructures.

Document Registry - The Document Registry maintains metadata about each stored PS. This includes indexing information, patient identifiers, clinical coding data, and document locations (links to repositories). It handles queries from Document Consumers and enforces data access policies according to applicable regulations.

Document Consumer - The Document Consumer queries Document Registries based on patient identifiers, clinical criteria, or document attributes, retrieving the desired PS from repositories. Typical implementations include healthcare provider EHR applications, cross-border health data portals, or patient health record applications.

8.2 List of relevant Use Cases

8.2.1 Create the Patient Summary

Title	Manual creation of Patient Summary by Health Professional (HP)
Purpose	Creating a PS by a HP
Relevance	Provision of concise and curated information on patient's medical background for sharing on a regional, national or cross-border scale. Manual creation remains relevant when the healthcare organisation assigns to the Health Professional in charge for that patient, the task of concentrator of the patient's clinical info. Furthermore, in many current situations where EHR systems are not fully integrated. It also supports flexibility, allowing health professionals to prioritise and profile the relevant information for that specific patient. Data portability between the different sources of clinical information and the system to support the creation / create the PS shall be guaranteed.

Domain	Patient Summary
Situation	National, regional or cross-border
Context	Patient is regularly treated by HP (e.g. general practitioner) who is well acquainted with patient's medical history and has access to patient's health records. The PS is based on the HP's comprehensive knowledge of the patient's health evolution over time and may be adapted to its intended clinical purpose. This may include planned care scenarios in which the PS is prepared by the HP to support upcoming consultations, referrals or procedures. Data portability between the different sources of clinical information and the system to create the PS shall be guaranteed, directly or through transformation / transcoding and mapping univocal, reliable and repeatable processes.
Information	Patient Summary
Participants	Citizen/Patient HP in the patient's country of origin
Functional process steps	The patient is treated by a HP (e.g. general practitioner, family doctor) The HP reviews the patient's health records and identifies content that falls under the category of PS. The HP creates a PS based on the available information. The HP selects and refines the information, removing redundancies and adjusting content to the clinical context and purpose. Depending on the clinical scenario, the HP may find it useful to organise or highlight information according to specific needs (e.g., structuring data in a specific order in extensive reports, or highlighting information to support safe dispensation). Depending on the capability of the local EHR system, national digital infrastructures and availability of EHR, the process of creation can be facilitated by semi-automatic steps. For example, the HP can tag the relevant existing records and include them in the PS. The EHR system may perform automatic look-up for relevant records and automatically generate a draft PS. The HP reviews the PS and creates the final (curated and personalised) version. The HP authorises (and digitally signs) the PS.

	The PS is made available to authorized healthcare providers and HPs.

547

Title	Automatic (on-the-fly) creation of Patient Summary
Purpose	Creating a PS by means of automatic collection and compilation of relevant records from multiple sources.
Relevance	Provision of concise information on patient's medical background for sharing on a regional, national or cross-border scale. This approach supports scalability and helps ensure that the information is up to date when needed. It is particularly useful where time is a critical factor in unplanned or emergency care, where prior preparation is not possible. Being independent from HPs, this approach has historically mostly been used to facilitate PS creation, regardless the availability and commitment to create and maintain the PS.
Domain	Patient Summary
Situation	National or regional, cross-border
Context	Patients are treated - by different healthcare providers and HPs. Important information on medical background is encountered at various stages and locations alongside the patient's pathway and recorded within the provision of healthcare services. The information categorised as PS is timely recorded in the local EHR system. Depending on the digital health infrastructure and national regulations, the PS record is submitted to the central national/regional EHR repository. Automatic creation of PS is provided by means of a dedicated national/regional EHR system. The automatically generated PS includes all relevant records from all relevant sources (authors).
Information	Patient Summary
Participants	Citizen/Patient Healthcare providers and HPs in the patient's country of affiliation (country A) - providing original (single) PS records. PS Authoring Institution: Digital health authority or other authorised entity in Country A – Provides the sources of information for the creation of the PS: document creator / signing authority Optionally: Healthcare providers and HPs in patient's country of treatment – initiating automatic creation of PS

Functional process steps	The patient is taken care of by a healthcare provider organisation. The HP who provides treatment registers in an EHR what is relevant for the given healthcare service. The HP is the author of this (single) record, and the healthcare provider is the author organisation. The PS is created from the information recorded in the EHR system automatically. Depending on the digital health infrastructure, the record may be submitted to a centralised EHR system (national/regional EHR platform or repository). Creation of the PS is initiated within the respective national/regional EHR system. The process depends on national infrastructures and regulations. The following options may apply: - Creation is triggered upon detection of a new PS Record (a new updated version of PS is created), - Creation is triggered upon request for PS (an up-to date PS is created upon query/retrieve) by health professional or, where applicable, the patient. - Scheduled creation / update of PS (regular schedule for system procedures for collecting relevant records and generation of PS) Where supported by the system, automatic generation of PS may apply contextual structuring based on known clinical scenarios such as oncology, or chronic disease to improve usability and clinical relevance. The compiled PS is authorised (and digitally signed/sealed) by PS Author Institution Before finalising the compilation, a QA check step will be performed to detect duplicate or conflicting data across different sources, depending on system capabilities. In the potential case of cross-border use, the structure and content of the generated PS may vary to align with conformance requirements and language standards. The automatically generated PS is available and accessible to authorised healthcare providers and HP. Automatically created PS shall be stored for traceability and look-up in case of the need to legal backward reconstruction of that specific snapshot.

548

549

8.2.2 Request of the Patient Summary

Title	Patient Summary sharing on a national scale
Purpose	Accessing /downloading PS for the purpose of care on a national level by a HP in the MS of affiliation.
Relevance	Patients are treated by different health care providers, often across regions or institutions. Access to PS shall be provided to authorized HPs irrespective of the healthcare institution or location of care. This access supports continuity of care and is particularly relevant in unplanned/emergency situations or when the patient is unable to provide accurate health information. It is also relevant for patients with chronic conditions or multimorbidity, whose care often involves multiple providers. PS can be downloaded, to allow storage in another system, safeguarding the data portability, if EEHRxF specifications are respected. Access/download to PS is relevant in diverse clinical contexts, such as planned and unplanned care, emergency situations involving unconscious patients. It has also been proposed to provide partial access to pharmacists, for supporting correct medication dispensation (e.g. about known allergies): Medication Summary was defined for this specific purpose, as a subset of the PS. If the PS as a whole is used for a purpose different from the provision of care, that has to be made clearly evident to patients, in order to allow them the informed, specific decision to allow that access.
Domain	Patient Summary
Situation	National (regional, cross-institutional)
Context	Different health care providers may use different EHR systems. Nevertheless, access to PS shall be possible for the health professional for the purpose of treatment by means of health professional access services in accordance with EHDS Article 12. Note: EHDS compliant EHR systems (EHDS Article 3) will provide the access by default. Healthcare providers and professionals using existing (not yet compliant) EHR systems may use the health professional access service provided by Member State.
Information	Patient Summary
Participants	Individual/Patient HP in patient's country of affiliation (country A)

Functional process steps	The patient is treated by a HP The HP is identified, authenticated and authorised The patient is identified in accordance with Member State's regulations The PS is electronically transferred from the originating EHR system to the HP at the given healthcare provider Rules on access to PS shall apply regarding Member State's national regulations (e.g. accessible only to authorized HPs; conditions as regards type of medical service, referral, etc,) The HP retrieves the PS and uses it to provide health care services.

552

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Title	Patient Summary sharing on a cross-border scale
Purpose	Sharing information about the medical background and history of a patient from their country of affiliation (Country A) with a HP in the country of treatment (Country B).
Relevance	Many people request medical help when travelling, working, or living abroad. Information about the medical background and history of a patient (health data) from their country of affiliation should be available to both citizens and health professionals in Europe (in their preferred Union language), to ensure continuity of care, avoid adverse events and support safe decision-making. Treating patients without access to relevant medical history is hazardous and inefficient. Benefits include improved quality of care and patient safety, reduced effort in gathering/exchanging health information, and access to up-to-date information to treat and care for a patient. Access to PS is relevant across various clinical scenarios where up-to-date and structured health data is critical, including emergency care, pathology specific treatment (e.g. in oncology, cluster medical data per stage of the pathology). In the case of Emergency, it was suggested by Emergency doctor, to provide a special PS view, by displaying first the Alert, or specific elements flagged as information important in emergency condition, when time is one of the most critical assets. This concept of Alerts is included in the eHN Guidelines and IPS, but still to be implemented. It would be advisable to consider the possibility of providing display tools able to sort the medical data by relevance/urgency.

Domain	Patient Summary
Situation	Cross-border
Context	Different countries operate different health care systems, support their own culture for healthcare provision, and may use different (or several different) language(s) and possibly different clinical vocabularies and legal basis for the data processing. This raises challenges (e.g. in semantic interoperability) for the support of cross-border exchange of health data and may result in limitations in the use of patients' medical information during patient treatment and care process in different European countries. A PS provides health information on important aspects such as allergies, current medication, previous and current illnesses and surgeries, lifestyle indicators etc. These are necessary for the proper treatment and care of a patient, especially when there is a language barrier between the HP and the patient. Two Use Cases are possible with regards to the Patient Summary (PS). The first is the one in which an occasional visitor needs his/her PS in country B for emergency, unplanned or planned care. The second is the one in which the person is a regular visitor in country B (i.e. someone who lives in one MS but works in another MS). The distinguishing characteristic is that the HP may have some information available from previous encounters in this type of regular visitor. Both, a PS from country A and one from country B, could be consulted. Here the Use Case of the occasional visitor is described.
Information	Patient Summary
Participants	Citizen/Patient HP in patient's country of affiliation (country A) HP in country of treatment (country B)
Functional process steps	(With the reservation that preconditions are met) The patient consults a HP in country B The HP is identified, authenticated and authorised The patient is identified (identity confirmed by country A) HP provides information to the patient on how personal health data in the PS will be collected and processed. The PS is electronically transferred from the patient's country of affiliation (country A) to the HP in the country that she/he is visiting (the "country of treatment/country B)") in a secure way, and the HP has to show to the patients/citizens the processing of their personal health data before

	consulting their PS in their affiliation country language (this document is called PIN (patient information notice)) The HP retrieves the PS and uses it to provide health care service. The PS should be presented to the HP in an understandable way regarding language, structure and vocabularies. The coded elements should be translated in the Country B language, or at least made available in English,

554

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Title	Request for the Patient Summary by the Patient or patient's representative
Purpose	Access to PS by means of electronic health data service (EHDS Article 4)
Relevance	Provision of access to PS to natural person (read access only, download in EEHRxF). Access to the PS by the patient or their representative is essential for transparency, supporting patient autonomy and continuity of care. It enables individuals to better understand their health status, prepare for consultations and share their information when seeking care across different places or institutions.
Domain	Patient Summary
Situation	National or regional, cross-border
Context	Patients (or their legal representatives/proxies) have the right to access their PS and obtain (download) the PS in the EEHRxF by means of electronic health data service (patient portal and/or mobile application). The availability and features of these services may vary depending on the country. Actual usage may be influenced by the patient's (or representative's) digital literacy. This access is particularly useful in situations where patients need to consult their records before a medical appointment, coordinate care across different providers or carry their health information while traveling. Not just for cross-border use, it may be relevant to request the PS in a language different from the official Country of Affiliation. Several cases apply: Country A has more than one language, or the citizen is a foreigner, affiliated to Country A, but he does not fully understand the local language, or the citizen is planning to visit another Country: he would get the PS in the language of the Country where he foresees to be, with the medical legal validity of an officially release clinical document. The document may be

	handed to a HP in Country B, in case the citizen needs care. This last case is also called "Patient Mediated Access".
Information	Patient Summary
Participants	Patient /patient's representative
Functional process steps	Patient (or their legal representative/proxy) signs in the patient portal or mobile application. Depending on the system, authentication may require a national eID or other secure login methods. Patient requests their EHR and selects PS. Patient accesses the content of their PS. Information should support patient readability. While the PS is primarily intended for clinical use, complementary explanations, meaningful labels or additional language support could be considered to improve patient understanding. Patient may decide to retrieve (download) the Patient Summary. The PS is provided in the EEHRxF and may be stored in the EUDI Wallet[9] when supported. - Downloaded files may be used for sharing with other healthcare providers, for personal reference or when seeking care abroad.

556

557 8.2.3 Update the Patient Summary

Title	Update the Patient Summary after provision of healthcare service
Purpose	Update the PS with the latest relevant information after an Encounter, a Procedure, a Treatment/Therapy
Relevance	Update of PS, registration of new information Update of the PS is essential to ensure that clinical decisions are based on the most accurate information. Lack of updates may lead to outdated or missing information being shared, increasing the risk of medical errors, duplication of tests or inadequate treatment.
Domain	Patient Summary
Situation	National or regional, cross-border
Context	PS needs to include up-to date information at a given time to remain clinically useful. Wherever pertinent information is registered, the PS needs to be updated.

[9] EU Digital Identity Wallet Home - EU Digital Identity Wallet -

Information	Patient Summary
Participants	Patient Health professional
Functional process steps	Patient is treated by HP. The HP who provides the treatment encounters new information which is relevant for PS (e.g. medical procedure, vaccination, allergy). HP updates the PS. Note: The operational procedure of updating PS may depend on both capabilities of national digital health infrastructures and organization of healthcare. The following possibilities may apply: - The PS is updated on-the fly, no manual action needs to be taken by health professional. - The update may be performed (semi)automatically in the EHR system. For example, when HP completes and updates a Discharge Report or records a vaccination record in the EHR system, the EHR system may automatically create an updated version of PS - If the PS is created manually, not all HPs are authorised to make an update. The health professional who treats the patient only registers relevant (pertinent) information (e.g. discharge summary). HPs who are authorised to edit the PS (e.g. patient's general practitioner) receive an automatic notification every time the relevant information is available. In many cases, the EHR serves as a primary source of information for updating the PS. Where supported, its completion may trigger an automated update or a notification to the professional responsible for maintaining the PS. In all cases, it is important to ensure traceability of updates and clarity in version control.

558

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Title	Automatic update of the Patient Summary after provision of healthcare service
Purpose	Update the PS with the latest relevant information
Relevance	Update of PS, registration of new relevant information

Domain	Patient Summary
Situation	National or regional, potential cross-border
Context	PS needs to include up-to date information at a given time. Wherever pertinent information is registered, the PS needs to be updated. Automatic updates ensure that the PS remains clinically accurate and reduces the burden on health professionals.
Information	Patient Summary
Participants	Patient Health professional
Functional process steps	Patient is treated by health professional. The HP who provides the treatment registers new information that is relevant for PS (e.g. diagnosis, medical procedure, vaccination, allergy). The update is performed automatically upon receipt of new information (or notification that new relevant information was recorded). The detailed technical procedure depends on the Member State's digital infrastructure. The following options may apply: No need for explicit update, the information will be automatically included upon a new request for PS Notification on new information. Upon notification, a retrieval of new information is performed, and a new version of PS is generated.

560

Title	Patient's request to rectify the PS and/or inclusion of patient's provided information
Purpose	Update the PS with patient's provided information
Relevance	Request to rectify info may avoid propagation of mistakes Patient's provided input may help clinical decisions
Domain	Patient Summary
Situation	National or regional, potential cross-border
Context	PS needs to include up-to date, correct information at a given time. Wherever pertinent information is registered, the PS needs to be updated. Patient's provided information shall always be clearly identifiable within the PS, not to affect the medical legal validity of the original PS.

	Inclusion of patient's provided info, as rectification of previous information, or as additional reported condition shall always be performed by HP authorised to update and sign the PS.
Information	Patient Summary
Participants	Patient Health professional (HP)
Functional process steps	Patient is treated by HP. The HP who provides the treatment registers new information that is relevant for PS (e.g. diagnosis, medical procedure, vaccination, allergy). The patient, who requested the PS, may recognise some data are not properly recorded, or new relevant information, from the patient perspective, might be added. A controlled process shall be made available to the patient to provide both requests of rectification and provision of the additional information. The HP in charge shall take actions if the provided information is recognised as relevant to fix errors/incompleteness, and/or include them as "patient's provided information. Differences in the procedures may apply according to MSs specificities.

9 IMPLEMENTATION GUIDES

This deliverable is developed in alignment with the European Health Data Space (EHDS) Regulation, which provides the legal foundation for interoperable health data exchange across the EU. In accordance with Article 15 of the EHDS Regulation, Task 6.1 of Xt-EHR focuses on the development of implementation guides for Patient Summary (PS) as part of the harmonised categories of electronic health data outlined in Article 14 and Annex I.

The implementation guides developed under this task will contribute directly to the advancement of the European Electronic Health Record Exchange Format (EEHRxF). They are designed to support both national and cross-border use of Patient Summaries by specifying how EHR systems should structure, process, and exchange this document type in a way that ensures interoperability, security, semantic alignment, and legal compliance. These guides will serve as a practical reference for implementers and system manufacturers preparing for the adoption of implementing acts defining common specifications for EHR systems under the EHDS. Particular attention is given to ensuring consistency with HL7 FHIR-based exchange models, the integration of terminologies such as SNOMED CT and ICD-10.

The specifications of this deliverable, D6.1, will be using the deliverables D5.1[10] and D5.2[11] as a starting point, including the common metadata framework. Xt-EHR Task 6.1 work is observable in two different implementation guides:

- Datasets in the form of logical models are provided in Xt-EHR Logical Information Models Implementation Guide (see 9.3.3).

  Xt-EHR logical models (link provided below)

- HL7 FHIR data exchange specifications will be available at a later stage provided in HL7 Europe Patient Summary Implementation Guide

The implementation guides are interrelated – all FHIR profiles will be based on the logical models provided in the Xt-EHR guide, and mapping from logical models to FHIR profiles is provided in the HL7 Europe FHIR implementation guides.

Xt-EHR logical information models implementation guide content is covered below in the "Data Sets" chapter (see 9.3.3).

9.1 Business and functional specifications

The specifications in this deliverable support use cases related to what EHR Systems used by health professionals need to provide functions for recording, editing, updating and storing of PS records. In case the PS is created by compilation of multiple sources, the generating system shall be connected to all relevant EHR systems and provide functions for collecting, compiling, updating, storing and retrieval.

According to EHDS, the Patient has a right to access their data from the PS as well as other prioritised categories of health data. This is specified in deliverable 5.1. All data sources (EHR systems containing PS records) need to provide interfaces to patient access services (electronic health data access service, EHDS Article 4) in order to provide access to and download of PS records. This requirement is mandatory for all EHR systems subject of Chapter 3 of EHDS regulation. For existing EHR systems, these interfaces can be provided indirectly via mapping services (e.g. healthcare providers, regional and national intermediate systems); it is worth noting that such services are not included in this project.

9.1.1 Structure and free text

The balance between the high level of structure and the possibility to add free-text information to the datasets has been a constant concern in the discussions leading up to the logical models. Where a larger extent of free text data elements in addition to structured and/or coded data elements would facilitate implementation, it also poses challenges for checking conformity, doing translation and/or transcoding (within or across Member State borders), and for overall reuse of data.

[10] D5.1: Technical Requirements for EHRs and key system interfaces

[11] D5.2: Technical requirements for EEHRxF metadata

In the development of the logical models, the need for a pattern with free text as a fallback mechanism—used when structured and coded data cannot or should not be provided—was addressed. There are several variations of this pattern.

When coded data elements are expected, generally CodeableConcept as a data type from HL7 FHIR is used, and the free-text alternative is available as an in-built mechanism of that data type.

To allow specification of further details using free text, additional string-typed element is added.

For highly structured datasets, it is also possible to provide a summary text element to be used as an alternative or complement to the structured and/or coded data elements. Examples are "comment" data elements throughout the models or text, which can be a summary of the information when structured data cannot be provided.

9.1.2 Conformity

To assess conformity to the models presented here, each data element needs to be assigned a conformity level for each context in which data is produced or consumed. In this document only the cardinality is included and the level of conformity will be included at a later version of the document as this is a model being produced by the Xt-EHR project at large and not specific to PS.

9.1.2.1 Conformity of code systems and value sets

At this point no value sets or code systems are marked as mandatory or preferred. However, the technical frameworks and different profiles (e.g. for cross-border) might impose such requirements. We welcome feedback on the need for and potential consequences of stating preferred or required code systems/value sets for certain information elements.

9.1.3 General requirements, Requirements specific to domain

Technical solutions for managing Patient Summary (PS) shall comply fully with Chapter III and Annex II of the EHDS Regulation (EU 2025/327). Annex II provides essential requirements for harmonised software components of EHR systems, especially concerning interoperability, data security, logging, and functional capabilities.

In the context of PS, it is essential to recognise that clinical information included in PS must be structured consistently to ensure accurate interpretation across healthcare settings. Information must always be clearly associated with standardised clinical terminologies, including proper coding of diagnoses (e.g., ICD-10), procedures (e.g., SNOMED CT), medications, and follow-up instructions. Results from different sources or care episodes should be clearly differentiated, linked appropriately to the care context, and displayed in a structured manner that avoids misinterpretation or clinical ambiguity.

9.2 Semantic specifications (code systems and value sets)

Exchanging PS data across European countries requires the use of standardised code systems to ensure interoperability. eHealth Network guidelines outline the preferred code systems for cross-border services visible fx within the MyHealth@EU, such as ICD, SNOMED CT, Orphanet, ICF[12], LOINC, NPU etc.

The Use Cases require the ability to convey both meaning and context in the PS to enable safe, high-quality care. For that purpose, along with the dataset structure, preferred code systems provide concepts that will be understood by both the provider and the receiver of the PS. Different code systems are used by Member States. The strategic long-term goal is to gradually reduce fragmentation and converge on the use of international code systems across Europe. In the future, also considering the expected wider use of new and emerging international standards such as the International Classification for Diseases 11th Revision (ICD-11), SNOMED CT or the International Classification of Health Interventions (ICHI). Likewise, the ISO Identification of Medicinal Products (IDMP) suite of standards should be used for medicinal products identification, as soon as made available by the EMA[13] and National Competent Authorities joint SPOR (Substances, Products, Organisations, Referential) Project.

For a number of data elements one or more preferred code systems has been defined. This has been identified as a challenge which has been raised with the eHealth Network and work is being undertaken to investigate and recommend a good way forward to make implementation less challenging.

During the process a discussion around the change of code systems and value sets was initiated and this will carry on in the eHealth Network subgroup on semantics. It is important to state that there needs to be a clear governance process and principles established for the specification of code systems. An example on this is what is already defined in the eHealth Network Guidelines around the future transfer from ICD-10 to ICD-11. The guideline states that there will be a change from ICD-10 to ICD-11 but that this is to be considered in relation to the set principles for changing. These principles do exist, but they need to be reviewed and potentially updated to reflect the current and future need.

9.2.1 Value sets

In the context of MyHealth@EU, the Master Value Sets Catalogue (MVC) is a collection of terms, used in the context of exchanging data on current MyHealth@EU services. Value Sets based on International standard code systems such as ICD-10, SNOMED CT, ATC Classification, EDQM[14] Standard Terms, or UCUM[15], EMA SPOR SMS, Orphanet, and others. This catalogue was collaboratively created by multinational teams under the epSOS large-scale pilot and is now maintained by the eHDSI community of semantic experts. These value sets are included in the work of the project. The specification has also included value sets from FHIR IPS where needed and assessed for contributions.

9.2.1.1 Long-term maintenance of the value sets and other interoperability assets

All semantic specifications, including code systems and value sets, require continuous maintenance and evolution over time to remain clinically relevant and compliant with regulatory changes. This maintenance

[12] ICF: International Classification of Functioning, Disability and Health

[13] EMA: European Medicine Agency

[14] EDQM: European Directorate for Quality of Medicines & Health Care

[15] UCUM: Unified Code for Units of Measure

demands sustained engagement from clinical experts and authoritative standards bodies. Currently, such maintenance is partially provided by volunteer-driven groups, standards bodies, and expert communities, including:

- WHO Collaborating Centres (ICD-10 maintenance)
- SNOMED International (SNOMED CT management and governance)
- HL7 Europe and HL7 International (HL7 standards, FHIR profiles, terminology management)
- European Medicines Agency and WHO Collaborating Centre for Drug Statistics Methodology (ATC coding)

To ensure sustainable and authoritative semantic maintenance, dedicated European-level initiatives or organisations with sufficient resources and clinical expertise should be established or strengthened. Collaboration with these entities will ensure long-term compliance, interoperability, and clinical validity of discharge-related semantic resources.

As indicated by the results of the analysis of member states readiness for use of agreed code systems for cross-border exchange (see 10.1), the terminology landscape in the EU is not harmonized. The gradual harmonization of use of terminologies in the EU will take time and expectations are that member states will continue to use national code systems, or international code systems used in ways specific to individual member states in areas where standard terminologies cannot be agreed. The progress towards wider standardization of terminologies will be in part driven by the regulation as adoption and implementation can be agreed between member states.

As mentioned, maintaining the EEHRxF will require a robust management process for code systems and standards, with clear version control and analysis. This management process will involve defined roles and responsibilities for overseeing updates, a systematic review process to evaluate changes, and a validation mechanism to ensure the quality of the updates. Additionally, if multiple code systems are in use, it will be crucial to ensure proper mapping between national and international code systems to guarantee compatibility with the EU single market. A detailed mapping strategy, ideally supported by automated tools, will help align the systems and address potential discrepancies. Regular monitoring will ensure that national code systems stay synchronized with international standards over time. Achieving convergence on agreed-upon code systems and standards will be essential for promoting interoperability across the EU. A well-defined roadmap, with clear phases, timelines, and stakeholder engagement, will help guide the adoption of these standards. This roadmap will also include communication and training resources to ensure stakeholders can navigate the changes and understand the EU's long-term vision for healthcare interoperability.

9.3 Technical specifications

The technical specifications detailed in this section are tailored explicitly for PS within Electronic Health Record (EHR) systems, focusing on interoperability across EU Member States. These specifications define data capture, storage, and transmission formats compatible with existing EHR systems and enable integration with emerging digital healthcare technologies.

9.3.1 Data model

Data models described here provide a formal, computable representation of the PS dataset. This deliverable employs both conceptual and logical data models, each serving different purposes:

- Conceptual Model – captures the overarching clinical concepts and interactions within the continuity of care domain, supporting high-level understanding among clinical stakeholders.
- Logical Model – defines detailed and structured data elements, their relationships, and constraints necessary for technical implementers and software developers.

Common for all specifications related to services is that there is a header which is needed where there is a data model defined which is the same in all deliverables (more details in deliverable T5.2). The models below show the core content of the PS.

There is an overall Xt-EHR logical model, a joint effort between WP4, WP5, WP6 and WP7, as there are a number of common models across the different specifications. This deliverable includes the PS structure only, as proposed in the logical model. A detailed logical data model has been created and can be inspected online at the following address:

https://xt-ehr.github.io/xt-ehr-common/branches/stakeholder-consultation-D6-1/

9.3.2 About Patient Summary data models

PS consists of several sections, some of which are suggested to be mandatory to support. For each mandatory section, implementers should, as a minimum, be able to produce a generated narrative text of the content, as well as certain structured elements. There are only a few elements that are suggested as required at this point.

While the overall use cases for exchanging a Patient Summary (PS), as defined in MyHealth@EU specifications and ISO IPS standard remain consistent—typically aiming to support patients' access to their own data, and transfer of data between systems and cross-border care (both emergency access, and continuity of care)—it is acknowledged that, in practice, implementers will need to support multiple variants of these use cases, depending on the context.

In some cases, only a subset of the clinical data included in the PS (e.g. only medications, allergies, or vaccinations) will be relevant or exchanged. As such, each section of the PS is described and handled independently, with clear guidance on both the narrative and structured data elements expected for that section. As mentioned, data elements common to several services exist: an agreement among the various services has been achieved in order to take advantage of such modularity, by replicating, as far as possible, the common data model in the different services: the clear advantage is the interoperability of data among the services, and the reduced cost for multiplying specifications and implementations.

In alignment with the work carried out under the task T6.2 (ePrescription/eDispensation) the information elements and value sets suggested are mainly taken from eHN PS Guideline, MyHealth@EU specifications, ISO International Patient Summary (IPS) and HL7 FHIR IPS. Some additions or adjustments have been made, based on input from the working group of this deliverable. These are described in each section.

The main changes of the proposed EEHRxF logical model compared with the eHN Guideline are:

- The structure has been flattened to facilitate implementation of only parts of the PS and better support a data-centric approach. The result is that all sections are at the same level, not having the grouper-sections "Alerts", "Medical problems", "Medical history", and "Patient provided data" as in the eHN guideline.

- All content sections are kept the same as in the Guideline. However, we do suggest that the two problem sections be combined into one. This is to better support different use cases and current available data. See under the section 9.3.5.2 "Problems" for more information.

- In line with the International Patient Summary and MyHealth@EU specifications, there is an empty list reason elements (also called "Null Flavor") for all sections that are suggested to be mandatory.

- Each section has a narrative text element. This is in line with International Patient Summary implementation guide, and to support the right for natural persons to get the content in an easily readable format (Article 3 in the EHDS regulation).

- In addition to top level preferred code systems, which in many cases are not meant to be implemented in full, value sets that are in use in the MyHealth@EU and HL7 Europe specifications have been added as examples. Also included are some value sets based on suggestions from participating Member States.

- The logical models have cardinality, and repeatable elements are split into their own models, which are often reused between different priority categories (e.g. problems, procedures). The individual information elements in these reusable models are based on the Guideline, unless otherwise stated.

9.3.3 Datasets

The datasets below were developed based on requirements identified in the sources listed above (see chapter 5). The definitions of the datasets are provided in the Xt-EHR Logical Information Models Implementation Guide in the form of logical models. For each model a figure as well as tables are presented in this document, the tables are available in Annex I. The tables describe the source of requirements and relationship to the eHealth Network guidelines, MyHealth@EU Requirements Catalogue, International Patient Summary, followed by a more detailed description for each data element respectively.

The columns of the detailed descriptions table are as follows:

- Number – a number indicating the hierarchical position within the model. This number is not necessarily unique or stable over time.
- Data element – the name of the data element and its path in the logical model
- Description – a description of the data element
- Data type – the data type of the value(s) of the data element
- Cardinality – the minimum and maximum number of occurrences of a value of a data element
- Preferred code system – the recommended code system for data elements with a coded datatype/Associated Value Sets (if existing and meaningful).

In the Unified Modelling Language (UML diagrams), the choice datatypes are represented using a diamond form with the alternative types referenced by dashed lines.

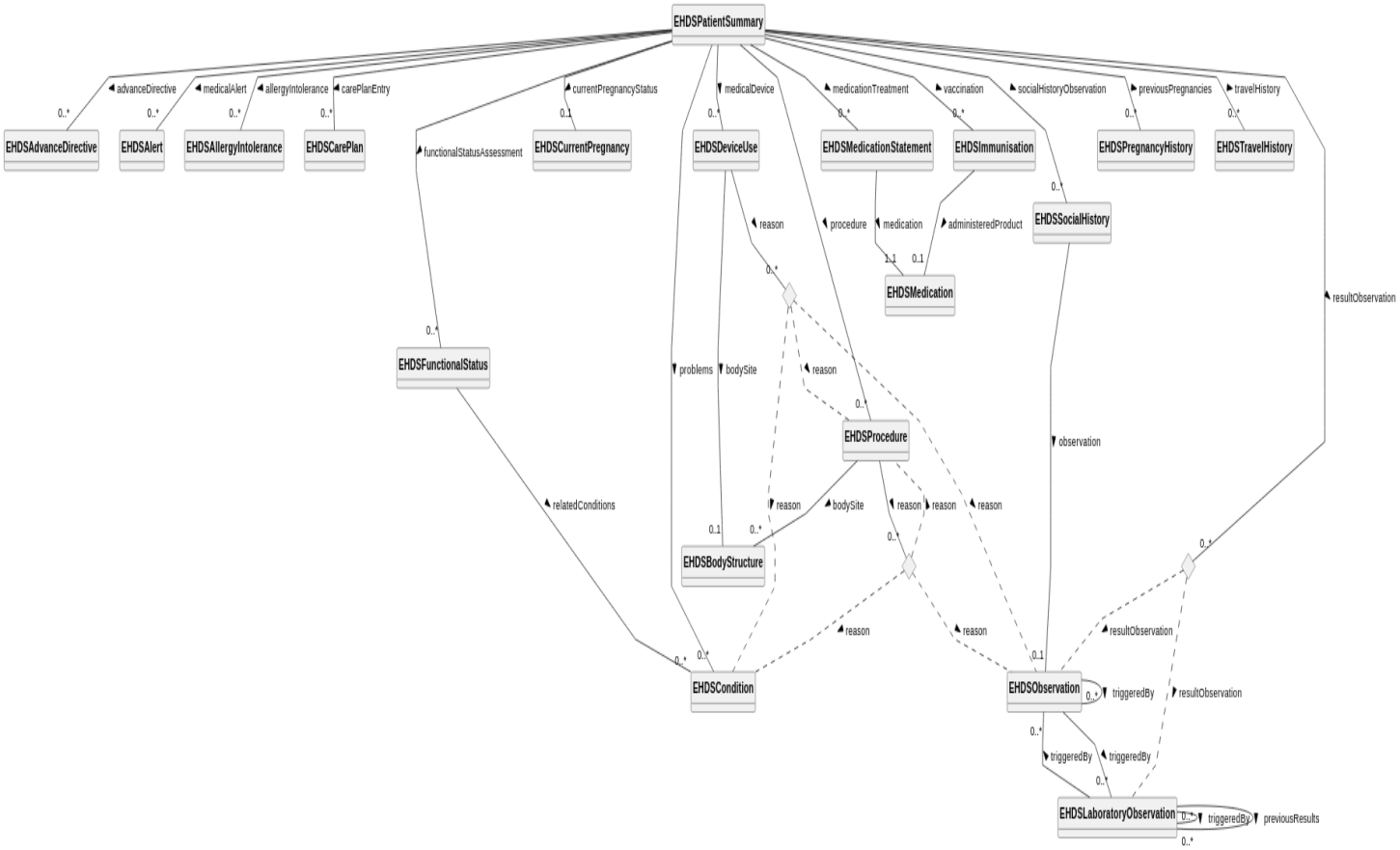
9.3.3.1 *Readers guide*

- Empty list reason in mandatory sections

For the mandatory section, there is an element called Empty list reason. This is to allow systems that have no content to exchange, to give a reason why the content is empty. This is the same as how the information models in the IPS are specified, and identical to the current FHIR International Patient Summary Implementation guide (2.0.0). The MyHealth@EU specification, on the other hand, is modelled in a slightly different way, by expecting an empty list reason in the field in the content model where you would normally find a problem, procedure, or allergy code. To comply with the MyHealth@EU specifications, even systems that have no data in a mandatory category would have to implement and exchange data using the content model. The way it is done in the MyHealth@EU specification is less of a problem for the National Contact Points, which would only have to implement it once, and really should implement the content models, than it would be for all EHR systems, which by design might not have data included in the content models, or have this data only for a few patients. In an earlier version of FHIR IPS IG (1.1.0), empty list reasons were implemented the same way as in the current MyHealth@EU, but it was changed after substantial feedback from implementers. We therefore suggest that EEHRxF follow the modelling development of FHIR IPS.

9.3.4 Summary overview of all sections

Below, you will find conceptual models for the different sections of the PS, starting with a general overview and then a more detailed view of the individual models.



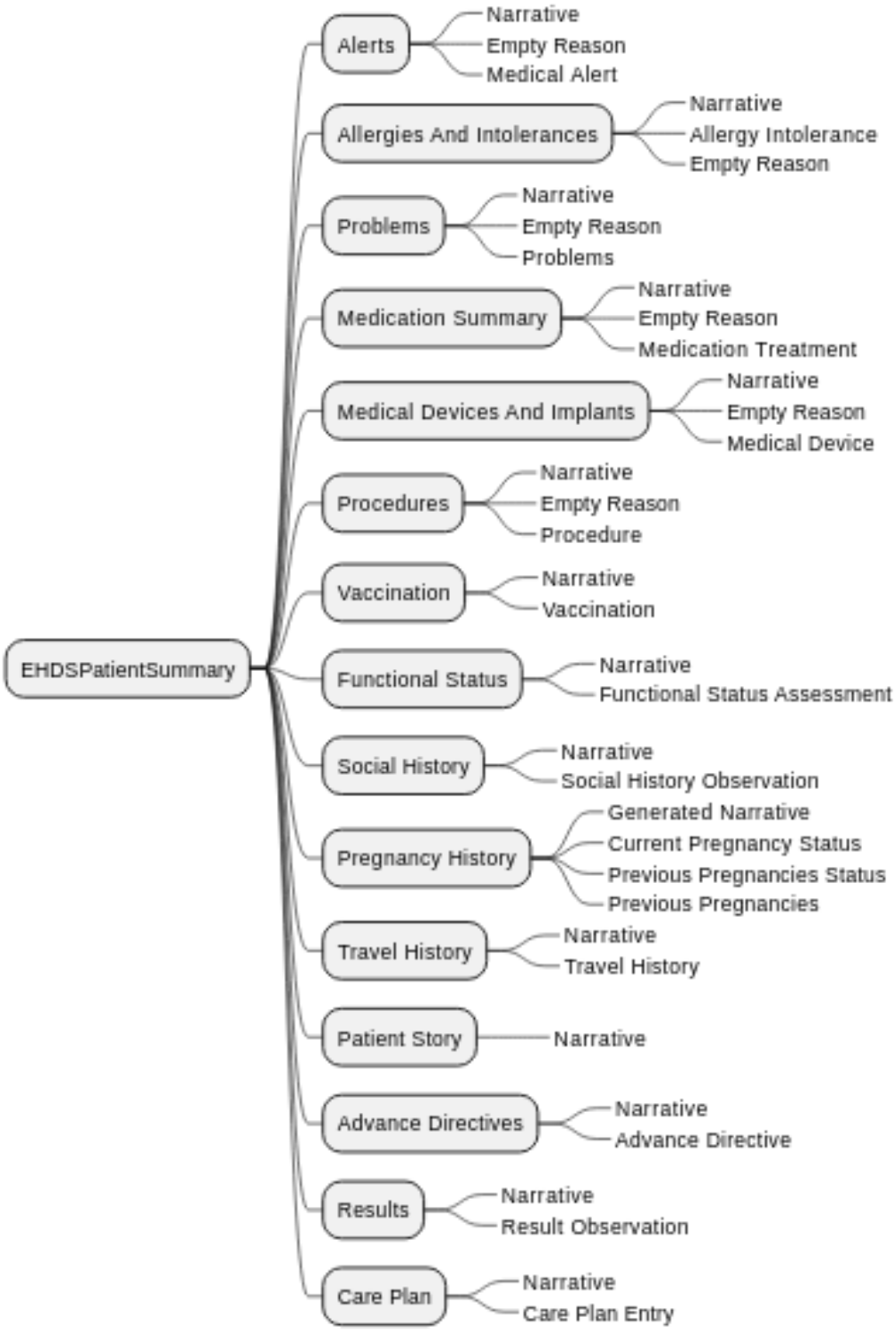


Figure 4 - Table with summary overview of all sections

9.3.5 Detailed models

9.3.5.1 Alerts

9.3.5.1.1 Alerts Model

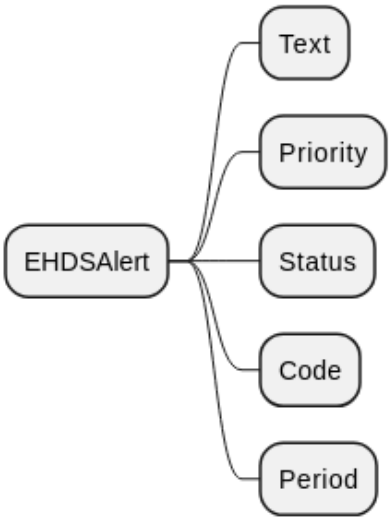


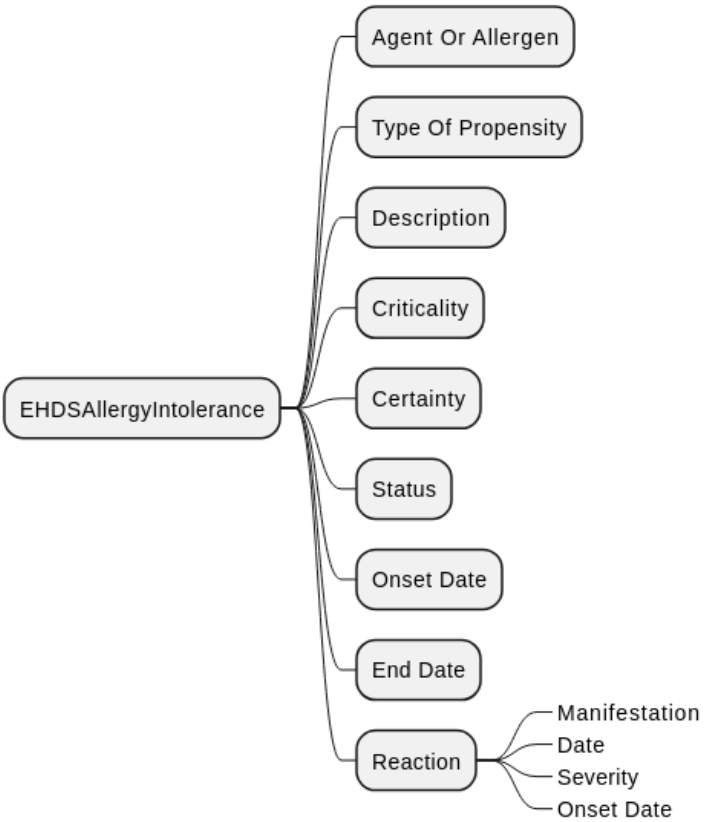
Figure 5 - Alerts

9.3.5.2 Allergy and intolerances

Allergy and Intolerances is suggested as a mandatory section of the PS. The only required element for each listed allergy is specifying the agent or allergen. The Information elements for each allergy are listed in the EHDS-AllergyIntolerance model. If the producing system has no record of allergies to list (e.g. the patient has no allergies, or the system has no allergy information), the system must provide a reason. Receiving systems must be able to handle the data and are encouraged to display the received information to the user, but are not obliged to do so.

The information elements and value sets suggested are taken from the eHN Guideline, MyHealth@EU, ISO IPS and HL7 FHIR IPS.

9.3.5.2.1 Allergy and Intolerances Model



826

827 Figure 6 - Allergy and Intolerance

828

829 *9.3.5.3 Problems*

830 In the PS Guideline, there are two sections containing problems: "Current problems" and "Resolved, closed
831 or inactive problems". In MyHealth@EU specifications and International Patient Summary, "Current
832 problems" is a mandatory section, while "Resolved, closed or inactive problems" is not. However, in
833 clinical practice, the status of a problem is not regularly recorded or updated in this way. Problems are
834 recorded as they are found and treated, but usually not maintained in an always-updated separate list of
835 past and current problems. Having it mandatory to place problems into either of the two categories (past or
836 current), even in cases where this is not explicitly set, could force systems to have to deduce/infer or base
837 on rules based on dates or other available parameters. This could lead to medically incorrect data. Having
838 just one problems section, prevents systems from having to make improper assumptions. Since the
839 European exchange format EEHRxF will support different use cases, we suggest that it is up to the
840 implementers of different use cases (profiles) to decide whether a strict division between past and present
841 problems is achievable and desirable. The proposed model has one section for problems, but each problem
842 listed can have a status that would place it within a specific category (active, inactive).

843 The information elements and value sets suggested are taken from eHN Guideline, MyHealth@EU, ISO IPS
844 specifications and HL7 FHIR IPS (IPS 2.0.0 and Condition (IPS)).

845

9.3.5.3.1 Problem Section

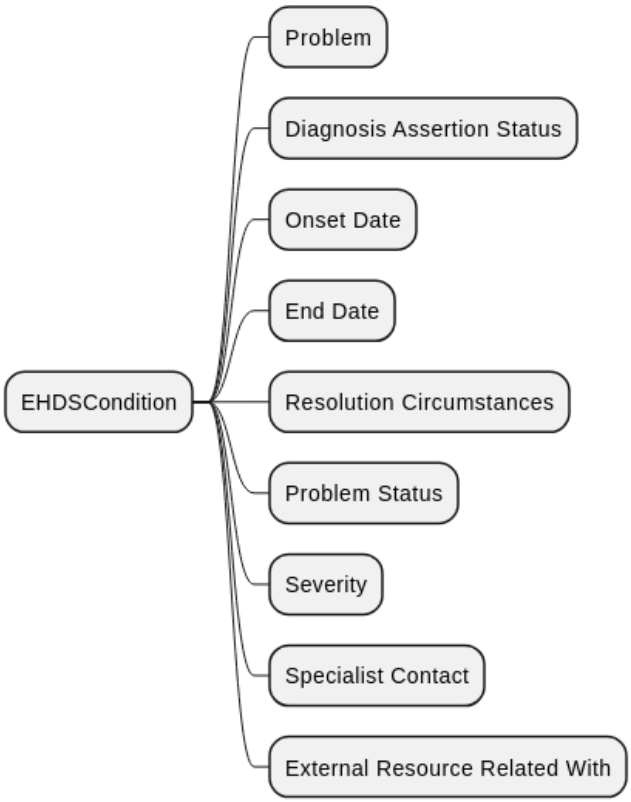


Figure 7 - Problems

9.3.5.4 Medication summary

Medication summary is suggested as a mandatory section of the PS. Implementers should, as a minimum, be able to produce a list of medications. If the producing system has no record of medication to list (e.g., the patient uses no medication, or the system lacks medication information), it must provide a reason. This is similar to the other mandatory sections, and in accordance with the specification in ISO IPS and updates to the HL7 FHIR IPS.

There are several required elements for each listed medication, as both type of medication, its dose and instructions for use, are needed for safe communication. The PS is, however, meant to display a summary, and it is not necessary to include all the same information elements that are needed for ePrescription and eDispensation. This is similar to the other mandatory sections, and in accordance with the specification in ISO IPS and updates to the HL7 FHIR IPS.

Receiving systems must be able to handle the data and are encouraged to display the received information to the user, but are not obliged to do so.

The information elements and value sets suggested are taken from eHN GL, MyHealth@EU, ISO IPS and HL7 FHIR IPS.

9.3.5.4.1 Medication summary section

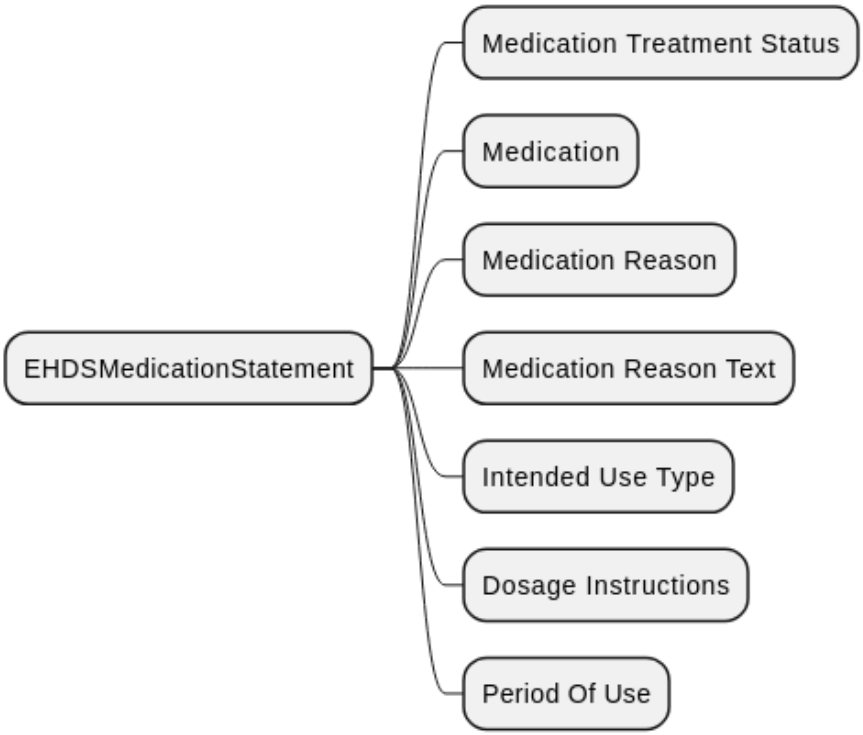


Figure 8 - Medication Summary

9.3.5.5 Medical devices and implants

Medical devices and implants are suggested as a mandatory section of the PS. Implementers should as a minimum be able to produce a list of devices and give an empty list reason if there are no devices. The only required element for each listed device, is specifying the device. The information elements for each device are listed in the EHDS-Device model.

If the producing system has no record of devices to list (e.g. the patient has no devices, or the system has no device information), it must provide a reason for the empty list. This is similar to the other mandatory sections, and in accordance with the specification in ISO IPS.

Receiving systems must be able to handle the data and are encouraged to display the received information to the user but are not obliged to do so.

The information elements and value sets suggested are taken from eHN GL, MyHealth@EU and HL7 FHIR IPS.

9.3.5.5.1 Medical devices and implants section

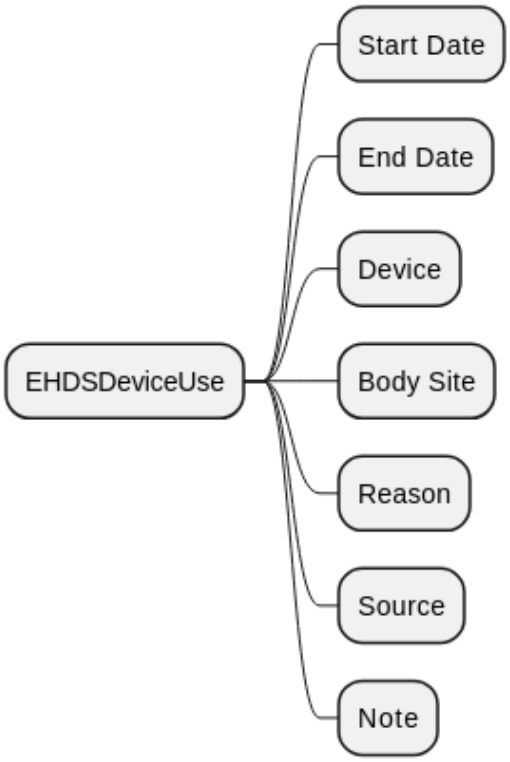


Figure 9 - Medical devices and implants

9.3.5.6 Procedures

The procedures model is suggested as a mandatory section of the PS. Implementers should, as a minimum, be able to produce a list of procedures and give a reason if there are no procedures. The only required element for each listed procedure is specifying the procedure. The information elements for each procedure are listed in the EHDS-Procedure model.

Suppose the producing system has no record of procedures to list (e.g., the patient has no history of procedures, or the system lacks procedure information). In that case, it must provide a reason for the empty list. This is in accordance with the specification in ISO IPS and updates to the HL7 FHIR IPS.

Receiving systems must be able to handle the data and are encouraged to display the received information to the user, but are not obliged to do so. The information elements and value sets suggested are taken from eHN GL, MyHealth@EU and HL7 FHIR IPS.

9.3.5.6.1 Procedure Model

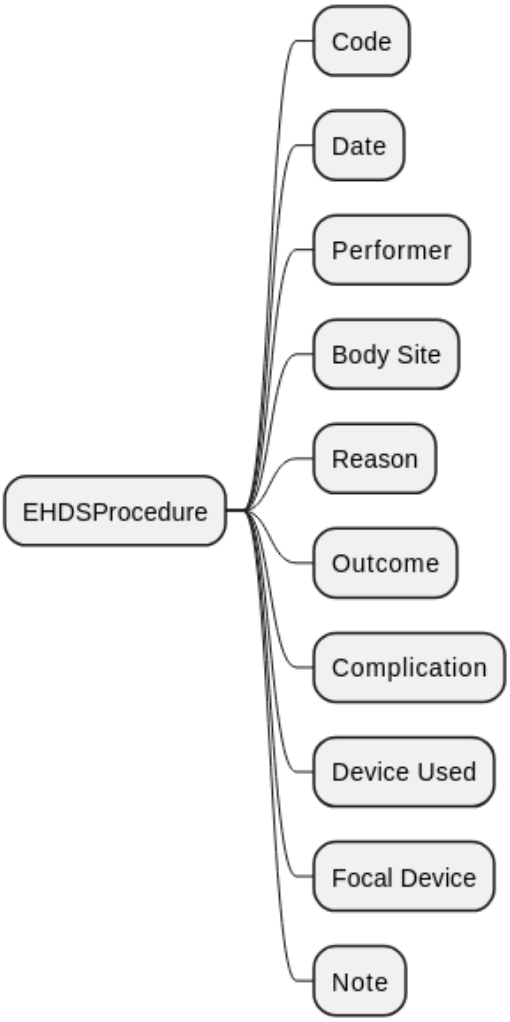


Figure 10 - Procedures

9.3.5.7 *Vaccination/ prophylaxis information*

9.3.5.7.1 Vaccination/ prophylaxis information model

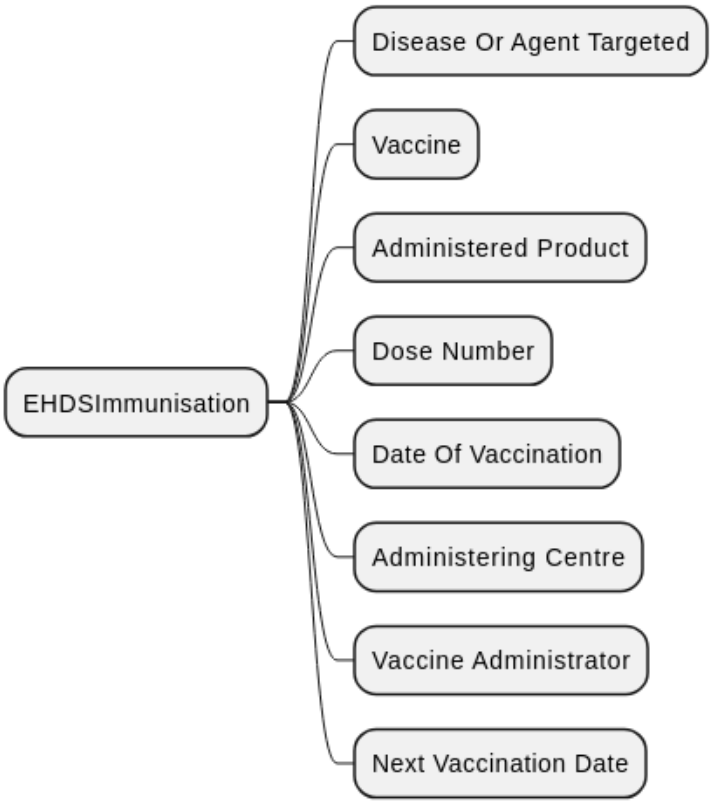


Figure 11 - Vaccination/Prophylaxis information

9.3.5.8 *Functional status*

9.3.5.8.1 Functional status model

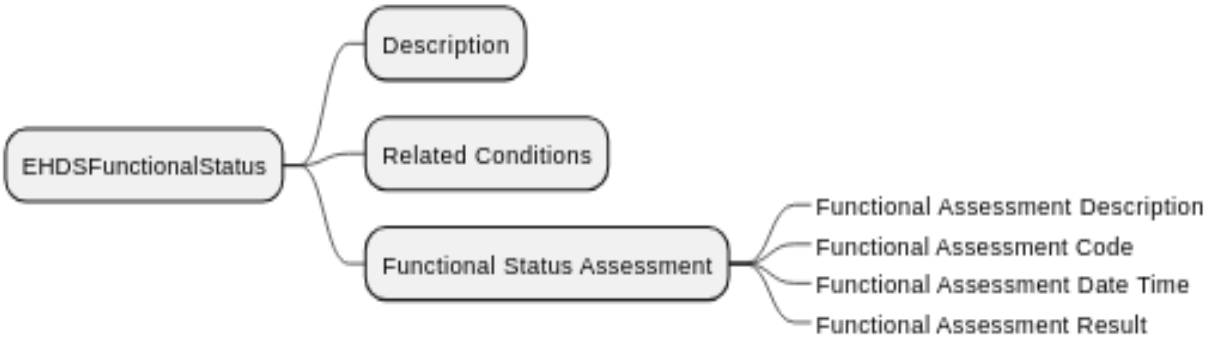


Figure 12 - Functional status

9.3.5.9 Social history

9.3.5.9.1 Social history model

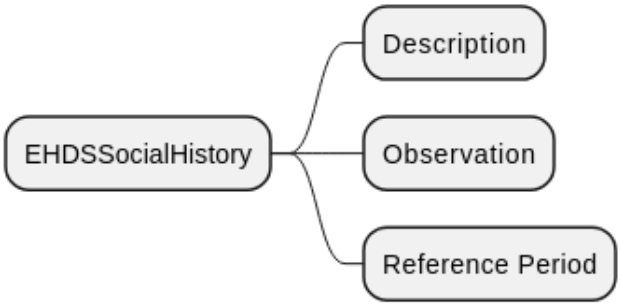


Figure 13 - Social History

9.3.5.10 Pregnancy history

The Pregnancy History section in the eHN Guideline has two subsections: Current Pregnancy Status and History of Previous Pregnancies. A patient can have many previous pregnancies recorded, while the current status should be the most recent status recorded in the system. In the logical model, the History of previous pregnancies is therefore represented as a repeatable model, and information about the current status is a single information element.

9.3.5.10.1 Pregnancy history section

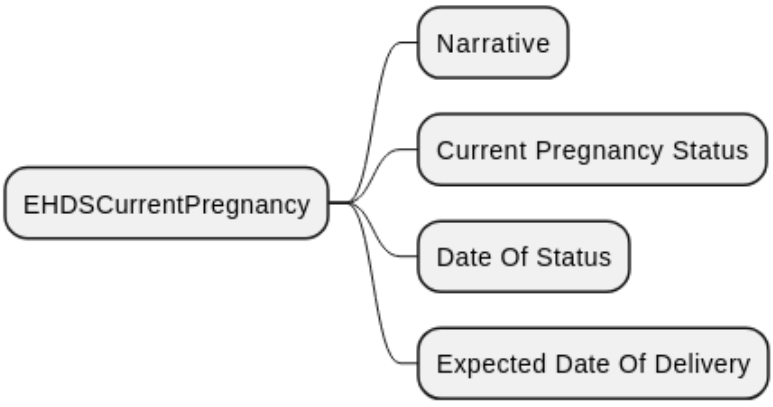


Figure 14 Current pregnancy

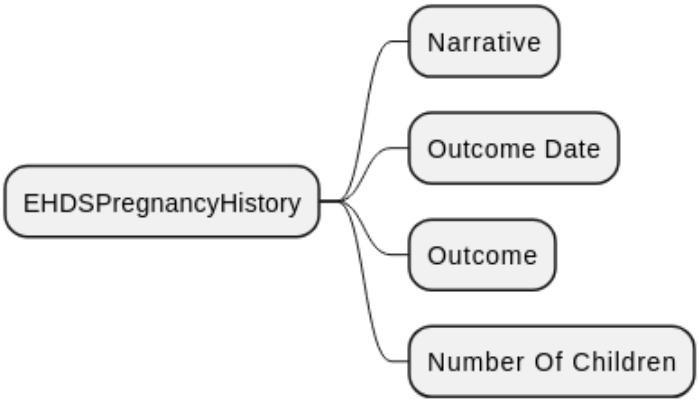


Figure 15 - Pregnancy history

9.3.5.11 Travel History

9.3.5.11.1 Travel History section

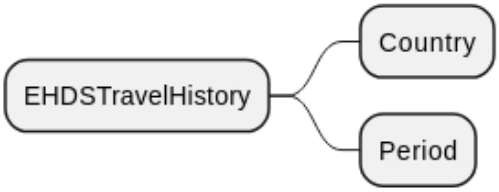


Figure 16 - Travel history

9.3.5.12 Advance Directives

In the eHN guideline, there is only one element: to acknowledge the existence of a living will. In the ISO IPS as well as the discharge report specification, there are structures to list various documents, such as a living will, as well as structured entries of advance directives that include category elements, descriptions, and information about the authorizer of the directive. In this deliverable, we have included a possible model for discussion.

The descriptions of the elements are taken from ISO IPS, and since we have included the actual document references, the element from the eHN, on the existence of a living will document, has been omitted.

9.3.5.12.1 Advance directive model

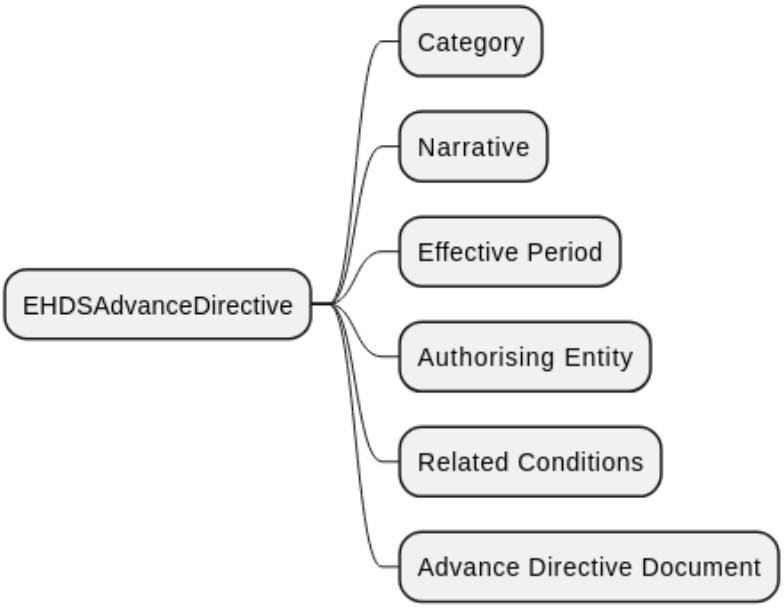


Figure 17 - Advance directive

9.3.5.13 Patient Story

Patient Story is a new concept that is not currently included in the eHN Guideline or MyHealth@EU. However, it has been introduced in the 2025 version of the ISO International Patient Summary (IPS). Given the emphasis on patient inclusion in the EHDS Regulation, the project team concluded that it is highly relevant to incorporate this concept into the current deliverable. The descriptions of the elements are derived from the ISO IPS.

At this stage, the proposed implementation is limited to the inclusion of a narrative text. Further alignment with the ISO standard will be pursued following stakeholder consultation. Patient story isn't its own model but worth addressing as it is visible in the overall figure of the PS, the elements are shown in Annex I.

9.3.5.14 Results

The PS model allows for generic observations to be shared, but also allows for specialised observations such as laboratory or imaging observations to be shared. As seen in Table **1**, both the generic observation model EHDSObservation (see Table 15) and the laboratory observation model EHDSLaboratoryObservation are allowed. However, what would be mandated for producers and consumers of patient summaries is not indicated here. For details on the laboratory observation model, please see Deliverable 7.1 from Xt-EHR.

9.3.5.14.1 Results model

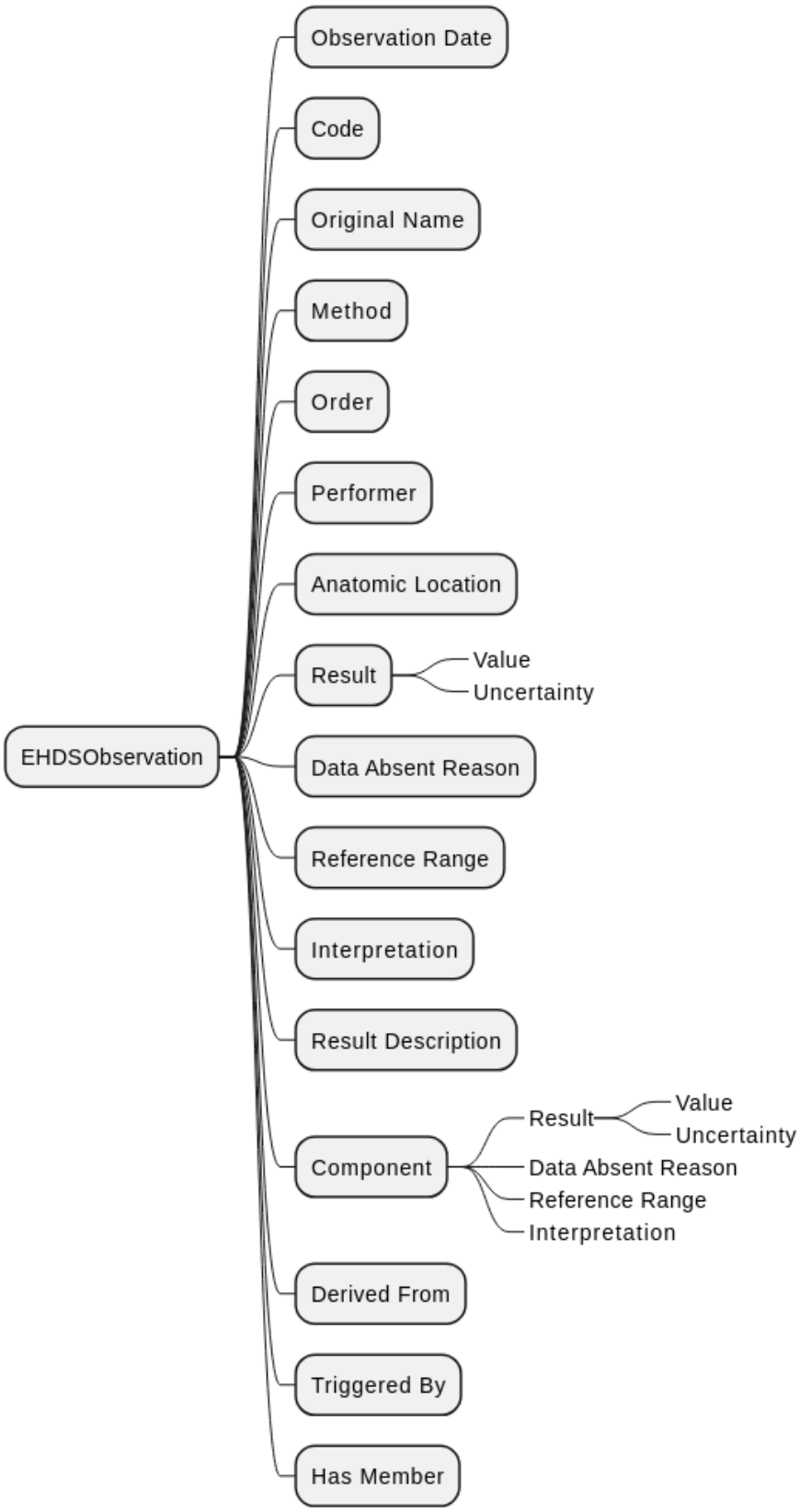


Figure 18 - Results

9.3.5.15 Care plan

The eHealth Network Guideline and MyHealth@EU specifies Plan of Care which when aligning across tasks within Xt-EHR as well as ISO IPS it was agreed to change the model to Care Plan. The data elements included in the sources are much the same and has remained.

9.3.5.15.1 Care plan model

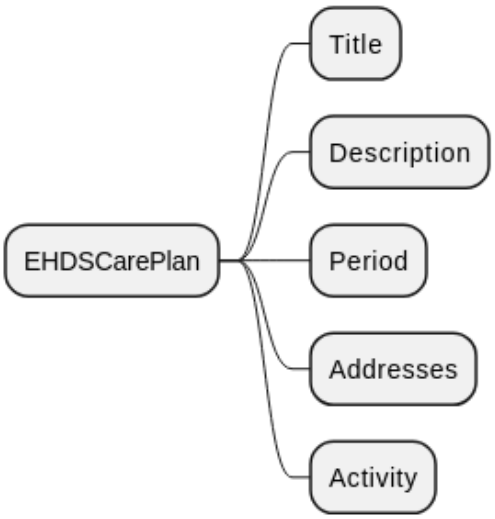


Figure 19 - Care plan

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10 ANNEX

10.1 Annex I Patient summary data sets

10.1.1 Patient summary model

Table 1 Patient summary model

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System/Value set	Requirements
A	EHDSPatientSummary	EHDS Patient Summary	Patient summary model	EHDS refined base model for Patient Summary		0..*		
A.1	.header	Header	Document header elements	Common header for all patient-related data	Base	1..1		
A.1.1	..subject	Subject	Subject	Patient/subject information	EHDSPatient	1..1		
A.1.2	..identifier	Identifier	Document ID	Unique identifier of the document	Identifier	1..*		
A.1.3	..authorship	Authorship	Authorship	Resource authoring details	Base	1..*		
A.1.3.1	…author	Author	Author	Author(s) by whom the resource was/were authored. Multiple authors could be provided.	EHDSHealthProfessional, EHDSOrganisation, EHDSDevice	1..1		
A.1.3.2	…datetime	Datetime	Date and time of authoring/issuing	Date and time of the issuing the document/resource by its author.	dateTime	1..1		
A.1.4	..lastUpdate	Last Update	Date and time of the last update to the resource	Date and time of the last update to the document/information	dateTime	0..1		

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System/Value set	Requirements
A.1.5	..status	Status	Status of the resource	Status of the resource	CodeableConcept	1..1		
A.1.6	..statusReason	Status Reason	Reason for the current status of the resource.	Reason for the current status of the resource.	CodeableConcept, string	0..1		
A.1.7	..language	Language	Language	Language in which the resource is written. Language is expressed by the IETF language tag.	CodeableConcept	0..1	BCP 47	
A.1.8	..version	Version	Version	Business version of the resource.	string	0..1		
A.1.9	..documentType	Document Type	Document type	Identifies the type of document at hand, e.g. Hospital discharge report.	CodeableConcept	1..1	LOINC	
A.1.10	..documentTitle	Document Title	Document title	Document title, such as Hospital Discharge Report, Laboratory Result Report, etc.	string	1..1		
A.1.11	..documentStatus	Document Status	Document status	The status of the Hospital discharge report. E.g., preliminary, final.	CodeableConcept	1..1	hl7:CompositionStatus	
A.1.12	..period	Period	Period	Time of service that is being documented	Period	0..1		
A.1.13	..attestation	Attestation	Attestation	Document attestation details	Base	0..*		

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System/Value set	Requirements
A.1.13.1	…attester	Attester	Attester	Attester who validated the document. Mulitple attesters could be provided.	EHDSHealthProfessional	1..1		
A.1.13.2	…datetime	Datetime	DateTime	Date and time of the approval of the document by Attester.	dateTime	1..1		
A.1.14	..legalAuthentication	Legal Authentication	Legal authentication	Document legal authentication	Base	0..1		
A.1.14.1	…legalAuthenticator	Legal Authenticator	Legal authenticator	The person taking responsibility for the medical content of the document	EHDSHealthProfessional	1..1		
A.1.14.2	…datetime	Datetime	DateTime	Date and time when the document was authorised.	dateTime	1..1		
A.1.15	..eventType	Event Type	Event type	Categorization of the event covered by the document (e.g. laboratory study types, imaging study types including modality, etc.). Selection of such tags or labels depends on the use case and agreement betwen data sharing parties. This meta-data element serves primarily for searching and filtering purpuses.	CodeableConcept	0..*	LOINC, SNOMED CT, dicom-cid-33-Modality	
A.1.16	..authorSpecialty	Author Specialty	Specialty	Additional details about where the content was created (e.g. clinical specialty)	CodeableConcept	0..*	SNOMED CT	

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System/Value set	Requirements
A.1.17	..custodian	Custodian	Document custodian	Organisation that is in charge of maintaining the document/report.	EHDSOrganisation	1..1		
A.1.18	..documentFormat	Document Format	Document format	An identifier of the document constraints, encoding, structure, and template that the document conforms to beyond the base format indicated in the mimeType.	CodeableConcept	0..1	HL7 Document Format Codes	
A.1.19	..confidentiality	Confidentiality	Confidentiality	Level of confidentiality of the document. Implicit value is normal.	CodeableConcept	0..1	hl7:Confidentiality	
A.2	.presentedForm	Presented Form	A narrative easy-to-read representation of the full data set, e.g. PDF-version of a document	A narrative easy-to-read representation of the full data set, e.g. PDF-version of a document	EHDSAttachment	0..*		
A.3	.knowledgeResources	Knowledge Resources	Related documents and information sources	Related documents and information sources	Base	0..*		
A.3.1	..externalReference	External Reference	Reference to external knowledge resource	A reference leading to Clinical Practice Guidelines (CPG), emergency and anesthesia guidelines or other clinical relevant guidelines. This should be used only for	RelatedArtifact	0..*		

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System/Value set	Requirements
				providing specific guidance which may not be readily available to the health professional caring for the patient.				
A.3.2	..relatedTo	Related To	Reference to part of the patient summary	Identify the entry or entries of this Patient Summary for which this additional information relates with, for example a link between a rare disease problem and guidelines for that particular rare disease.		0..*		
A.4	.alerts	Alerts	Section: Alerts.	Information about substantial alerts or warnings that health professionals should be aware of.	Base	1..1		eHN PS Guideline, MyHealth@EU, ISO IPS
A.4.1	..narrative	Narrative	Narrative, potentially formatted, content of the section	Narrative, potentially formatted, content of the section	string	0..1		
A.4.2	..emptyReason	Empty Reason	Reason for absence of data	Reason for absence of data	CodeableConcept	0..1		
A.4.3	..medicalAlert	Medical Alert	Description of medical alerts in textual format: any clinical	Description of medical alerts in textual format: any clinical information that is imperative to know so that the life or	EHDSAlert	0..*		ISO IPS, eHN PS Guideline

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System/Value set	Requirements
			information that is imperative to know so that the life or health of the patient does not come under threat.	health of the patient does not come under threat.				
A.5	.allergiesAndIntolerances	Allergies And Intolerances	Section: Allergies and intolerances	Section: Allergies and intolerances	Base	1..1		eHN PS Guideline, MyHealth@EU, ISO IPS
A.5.1	..narrative	Narrative	Text summary of the content in section	Text summary of the content in section	string	1..1		
A.5.2	..allergyIntolerance	Allergy Intolerance	List of structured allergies and intolerances	List of structured allergies and intolerances	EHDSAllergyIntolerance	0..*		eHN PS Guideline, MyHealth@EU, ISO IPS
A.5.3	..emptyReason	Empty Reason	Use if no Allergies are listed	Reason for absence of data (indicates whether the person is known to have no allergies or the data is considered incomplete)	CodeableConcept	0..1	1.3.6.1.4.1.12559.11.10.1.3.1.42.47eHDSIAbsentOrUnknownAllergy; http://hl7.org/fhir/ValueSet/list-empty-reason	MyHealth@EU , ISO IPS. FHIR IPS IG.
A.6	.problems	Problems	Medical problems.	Conditions that are important to be known for a health	Base	1..1		eHN PS Guideline,

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System/Value set	Requirements
				professional during a health encounter.				MyHealth@EU, ISO IPS.
A.6.1	..narrative	Narrative	Text summary of the content in the section	Text summary of the content in the section	string	0..1		
A.6.2	..emptyReason	Empty Reason	Use if no conditions are listed	Use if no conditions are listed	CodeableConcept	0..1	Coded value Example: 1.3.6.1.4.1.12559.11.10.1.3.1.42.50 eHDSIAbsentOrUnknownProblem (HL7, used in MH@EU) http://hl7.org/fhir/ValueSet/list-empty-reason (HL7, preferred in IPS FHIR IG)	MyHealth@EU , ISO IPS. FHIR IPS IG
A.6.3	..problems	Problems	Health conditions affecting the health of the patient.	Health conditions affecting the health of the patient.	EHDSCondition	0..*		MyHealth@EU , ISO IPS.

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System/Value set	Requirements
A.7	.medicationSummary	Medication Summary	Section: Medication Summary.	Current and relevant past medicine.	Base	1..1		
A.7.1	..narrative	Narrative	Text summary of the content in the section	Text summary of the content in the section	string	0..1		FHIR IPS IG
A.7.2	..emptyReason	Empty Reason	Use if no medicines are listed	Use if no medicines are listed	CodeableConcept	0..1	Coded value Example: 1.3.6.1.4.1.12559.11.10.1.3.1.42.49 eHDSIAbsentOrUnknownMedication (HL7, used in MH@EU) http://hl7.org/fhir/ValueSet/list-empty-reason	MyHealth@EU, ISO IPS
A.7.3	..medicationTreatment	Medication Treatment	Medication treatment/prescription relevant for this patient summary. Typically, medications whose period of	Medication treatment/prescription relevant for this patient summary. Typically, medications whose period of time indicated for the treatment has not yet expired	EHDSMedicationStatement	0..*		

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System/Value set	Requirements
			time indicated for the treatment has not yet expired whether it has been dispensed or not.	whether it has been dispensed or not.				
A.8	.medicalDevicesAndImplants	Medical Devices And Implants	Section: Medical devices and implants	Section: Medical devices and implants	Base	1..1		
A.8.1	..narrative	Narrative	Narrative, potentially formatted, content of the section	Narrative, potentially formatted, content of the section	string	0..1		
A.8.2	..emptyReason	Empty Reason	Reason for absence of data	Reason for absence of data	CodeableConcept	0..1	EMDN, SNOMED CT Coded value Example: ▪ 1.3.6.1.4.1.12559.11.10.1.3.1.42.48 eHDSIAbsentOrUnknownDevice (HL7, used in MH@EU)	MyHealth@Eu, ISO IPS, FHIR IPS IG

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System/Value set	Requirements
							▪ http://hl7.org/fhir/ValueSet/list-empty-reason (HL7, preferred in IPS FHIR IG)	
A.8.3	..medicalDevice	Medical Device	Describes the patient's implanted and external medical devices and equipment that their health status depends on. Includes devices (such as cardiac pacemakers, implantable defibrillator, prothesis, ferromagnetic bone implants etc.) that are	Describes the patient's implanted and external medical devices and equipment that their health status depends on. Includes devices (such as cardiac pacemakers, implantable defibrillator, prothesis, ferromagnetic bone implants etc.) that are important to know by the HP.	EHDSDeviceUse	0..*		eHN PS Guideline, ISO IPS

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System/Value set	Requirements
			important to know by the HP.					
A.9	.procedures	Procedures	Section: Procedures	Section: Procedures	Base	1..1		eHN PS Guideline, ISO IPS
A.9.1	..narrative	Narrative	Narrative, potentially formatted, content of the section	Narrative, potentially formatted, content of the section	string	0..1		
A.9.2	..emptyReason	Empty Reason	Reason for absence of data	Reason for absence of data	CodeableConcept	0..1	Coded value Example: 1.3.6.1.4.1.12559.11.10.1.3.1.42.51 eHDSIAbsentOrUnknownProcedure (HL7, used in MH@EU) http://hl7.org/fhir/ValueSet/list-empty-reason (HL7, preferred in IPS FHIR IG)	

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System/Value set	Requirements
A.9.3	..procedure	Procedure	List of procedures	List of procedures	EHDSProcedure	0..*		eHN PS Guideline, ISO IPS
A.10	.vaccination	Vaccination	Section: Vaccination/prophylaxis.	A patient's immunisation status. The section should include current immunization status and may contain the entire immunization history that is relevant to the period of time being summarised. Adverse reactions against vaccines should be documented in the allergy section.	Base	0..1		eHN PS Guideline
A.10.1	..narrative	Narrative	Narrative, potentially formatted, content of the section	Narrative, potentially formatted, content of the section	string	0..1		
A.10.2	..vaccination	Vaccination	Immunisations given to the patient and their status at the point of care.	Immunisations given to the patient and their status at the point of care.	EHDSImmunisation	0..*		eHN PS Guideline
A.11	.functionalStatus	Functional Status	Section: Functional status	Section: Functional status	Base	0..1		eHN PS Guideline, MyHealth@EU, ISO IPS

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System/Value set	Requirements
A.11.1	..narrative	Narrative	Narrative, potentially formatted, content of the section	Narrative, potentially formatted, content of the section	string	0..1		
A.11.2	..functionalStatusAssessment	Functional Status Assessment	An individual's ability to perform normal daily activities required to meet basic needs, fulfil usual roles and maintain health and well-being	An individual's ability to perform normal daily activities required to meet basic needs, fulfil usual roles and maintain health and well-being	EHDSFunctionalStatus	0..*		eHN PS Guideline
A.12	.socialHistory	Social History	Section: Social history.	Observations on social factors such as alcohol consumption or smoking. From the healthcare perspective, life-style factors relate to well-being but can also provide a source of risk factors.	Base	0..1		eHN PS Guideline, MyHealth@EU, ISO IPS
A.12.1	..narrative	Narrative	Narrative, potentially formatted, content of the section	Narrative, potentially formatted, content of the section	string	0..1		

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System/Value set	Requirements
A.12.2	..socialHistoryObservation	Social History Observation	Social history observations related to health	Health related lifestyle factors or lifestyle observations and social determinants of health. Example: cigarette smoker, alcohol consumption	EHDSSocialHistory	0..*		eHN PS Guideline, MyHealth@EU, ISO IPS
A.13	.pregnancyHistory	Pregnancy History	Section: Pregnancy history	To present the current health state of the patient with respect to pregnancy and to provide chronological and outcome information about past pregnancies.	Base	0..1		eHN PS Guideline, ISO IPS
A.13.1	..generatedNarrative	Generated Narrative	Generated text summary of the content in the section, for human interpretation	Generated text summary of the content in the section, for human interpretation	string	0..1		
A.13.2	..currentPregnancyStatus	Current Pregnancy Status	Current pregnancy status	Current state of the pregnancy at the date the observation was made, e.g. pregnant, not pregnant, unknown.	EHDSCurrentPregnancy	0..1		eHN PS Guideline, ISO IPS
A.13.3	..previousPregnanciesStatus	Previous Pregnancies Status	Overall status of previous pregnancies	Overall status of previous pregnancies, including — Yes, previous pregnancies — No, previous pregnancies — Unknown	CodeableConcept	0..1		eHN PS Guideline, ISO IPS

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System/Value set	Requirements
A.13.4	..previousPregnancies	Previous Pregnancies	History of previous pregnancies	Information about previous pregnancies, including outcomes and number of children/fetuses in each pregnancy.	EHDSPregnancyHistory	0..*		
A.14	.travelHistory	Travel History	Relevant information about the patient's recent travel history	Captures relevant information about the patient's recent travel history that may be of clinical relevance — particularly in relation to exposure to infectious diseases, epidemiological risks, or environmental factors. The intent is to support clinical decision-making and risk assessment, especially in contexts such as outbreaks or endemic disease regions.	Base	0..1		eHN PS Guideline, ISO IPS
A.14.1	..narrative	Narrative	Text summary of the content in the section	Text summary of the content in the section	string	0..1		
A.14.2	..travelHistory	Travel History	Travel history for one country	Travel history for one country	EHDSTravelHistory	0..*		eHN PS Guideline, ISO IPS
A.15	.patientStory	Patient Story	What the patient believes to be important for the attending	A concise narrative from the patient's perspective about their present health state. This is a record of the things that a	Base	0..1		ISO IPS

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System/Value set	Requirements
			clinician to know.	person feels it is important to communicate about their needs, strengths, values, concerns and preferences to others providing support and care.				
A.15.1	..narrative	Narrative	Text summary of the content in the section	Text summary of the content in the section	string	0..1		
A.16	.advanceDirectives	Advance Directives	Section: Advance Directives.	Provision for healthcare decisions if, in the future, a person is unable to make those decisions.	Base	0..1		eHN PS Guideline, MyHealth@EU, ISO IPS.
A.16.1	..narrative	Narrative	Narrative, potentially formatted, content of the section	Narrative, potentially formatted, content of the section	string	0..1		
A.16.2	..advanceDirective	Advance Directive	Provision for healthcare decisions if, in the future, a person is unable to make those decisions	Provision for healthcare decisions if, in the future, a person is unable to make those decisions	EHDSAdvanceDirective	0..*		
A.17	.results	Results	Section: Observation results.	Relevant observation results obtained on the patient. These may be measurements,	Base	0..1		

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System/Value set	Requirements
				laboratory results, anatomic pathology results, radiology results or other imaging or clinical results.				
A.17.1	..narrative	Narrative	Narrative, potentially formatted, content of the section	Narrative, potentially formatted, content of the section	string	0..1		
A.17.2	..resultObservation	Result Observation	Observation results pertaining to the subject of care's health condition and which might have impact on future treatments	Observation results pertaining to the subject of care's health condition and which might have impact on future treatments	EHDSObservation, EHDSLaboratoryObservation	0..*		
A.18	.carePlan	Care Plan	Section: Care plans.	Therapeutic recommendations that do not include pharmacologic treatments, such as diet, physical exercise, planned surgeries	Base	0..1		eHN PS Guideline, MyHealth@EU, ISO IPS.
A.18.1	..narrative	Narrative	Narrative containing the plan including proposals, goals, and order	Narrative containing the plan including proposals, goals, and order requests for monitoring, tracking, or improving the condition of the	string	0..1		

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System/Value set	Requirements
			requests for monitoring, tracking, or improving the condition of the patient. In the future it is expected that this Section could be provided in a structured and coded format.	patient. In the future it is expected that this Section could be provided in a structured and coded format.				
A.18.2	..carePlanEntry	Care Plan Entry	Describes the intention of how one or more practitioners intend to deliver care for a particular patient for a period of time, possibly limited to care for a specific condition or set of conditions.	Describes the intention of how one or more practitioners intend to deliver care for a particular patient for a period of time, possibly limited to care for a specific condition or set of conditions.	EHDSCarePlan	0..*		

10.1.2 Alert model

Table 2 Alert model

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System/Value set	Requirements
A	EHDSAlert	EHDS Alert	Alert flag model	Alert flag		0..*		eHN Guideline
A.1	.header	Header	Common header for all patient-related data	Common header for all patient-related data	Base	1..1		
A.1.1	..subject	Subject	Subject	Patient/subject information	EHDSPatient	1..1		
A.1.2	..identifier	Identifier	Business identifier for the object	Business identifier for the object	Identifier	0..*		
A.1.3	..authorship	Authorship	Authorship	Resource authoring details	Base	1..*		
A.1.3.1	…author	Author	Author	Author(s) by whom the resource was/were authored. Multiple authors could be provided.	EHDSHealthProfessional, EHDSOrganisation, EHDSDevice	1..1		
A.1.3.2	…datetime	Datetime	Date and time of authoring/issuing	Date and time of the issuing the document/resource by its author.	dateTime	1..1		
A.1.4	..lastUpdate	Last Update	Date and time of the last update to the resource	Date and time of the last update to the document/information	dateTime	0..1		
A.1.5	..status	Status	Status of the resource	Status of the resource	CodeableConcept	1..1		

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System/Value set	Requirements
A.1.6	..statusReason	Status Reason	Reason for the current status of the resource.	Reason for the current status of the resource.	CodeableConcept, string	0..1		
A.1.7	..language	Language	Language	Language in which the resource is written. Language is expressed by the IETF language tag.	CodeableConcept	0..1	BCP 47	
A.1.8	..version	Version	Version	Business version of the resource.	string	0..1		
A.2	.presentedForm	Presented Form	A narrative easy-to-read representation of the full data set, e.g. PDF-version of a document	A narrative easy-to-read representation of the full data set, e.g. PDF-version of a document	EHDSAttachment	0..*		
A.3	.text	Text	Text	A human-readable narrative that contains a summary of the flag and can be used to represent the content of the resource to a human. The narrative need not encode all the structured data, but is required to contain sufficient detail to make it "clinically safe" for a human to just read the narrative.Example 1:	string	0..1		

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System/Value set	Requirements
				intolerance to aspirin due to gastrointestinal bleeding.Example 2: intolerance to captopril because of cough (the patient is not allergic but can't tolerate it because of persistent cough)Example 3: the patient has a rare disease that requires special treatmentExample 4: Airway Alert / Difficult IntubationExample 5: Diagnoses such as malignant hyperthermia, porphyria, and bleeding disorders; special treatments like anticoagulants or immunosuppressants; implanted devices.Example 6: transplanted organs illustrate other information that has to be taken into account in a healthcare contact.Example 7: participation in a clinical trial that has to be taken into account in a healthcare contact.				

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System/Value set	Requirements
A.4	.priority	Priority	Priority	A code that identifies the priority of the alert.	CodeableConcept	0..*	hl7:Flag-priority-code	
A.5	.status	Status	Status	Current status of the flag, Indicates whether this flag is active and needs to be displayed to a user, or whether it is no longer needed or was entered in error.	CodeableConcept	0..1	hl7:Flag-status	
A.6	.code	Code	Code	A coded or textual representation of the flag.	CodeableConcept	1..1	SNOMED CT	
A.7	.period	Period	Period	Time period when flag is active. The period of time from the activation of the flag to inactivation of the flag. If the flag is active, the end of the period should be unspecified.	Period	0..1		

10.1.3 Allergy intolerance model

Table 3 Allergy intolerance model

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System	Requirements
A	EHDSAllergyIntolerance	EHDS Allergy Intolerance	Allergy intolerance model	EHDS refined base model for		0..*		

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System	Requirements
				allergy/intolerance				
A.1	.header	Header	Common header for all patient-related data	Common header for all patient-related data	Base	1..1		
A.1.1	..subject	Subject	Subject	Patient/subject information	EHDSPatient	1..1		
A.1.2	..identifier	Identifier	Business identifier for the object	Business identifier for the object	Identifier	0..*		
A.1.3	..authorship	Authorship	Authorship	Resource authoring details	Base	1..*		
A.1.3.1	…author	Author	Author	Author(s) by whom the resource was/were authored. Multiple authors could be provided.	EHDSHealthProfessional, EHDSOrganisation, EHDSDevice	1..1		
A.1.3.2	…datetime	Datetime	Date and time of authoring/issuing	Date and time of the issuing the document/resource by its author.	dateTime	1..1		
A.1.4	..lastUpdate	Last Update	Date and time of the last	Date and time of the last update to the	dateTime	0..1		

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System	Requirements
			update to the resource	document/information				
A.1.5	..status	Status	Status of the resource	Status of the resource	CodeableConcept	1..1		
A.1.6	..statusReason	Status Reason	Reason for the current status of the resource.	Reason for the current status of the resource.	CodeableConcept, string	0..1		
A.1.7	..language	Language	Language	Language in which the resource is written. Language is expressed by the IETF language tag.	CodeableConcept	0..1	BCP 47	
A.1.8	..version	Version	Version	Business version of the resource.	string	0..1		
A.2	.presentedForm	Presented Form	A narrative easy-to-read representation of the full data set, e.g. PDF-version of a document	A narrative easy-to-read representation of the full data set, e.g. PDF-version of a document	EHDSAttachment	0..*		
A.3	.agentOrAllergen	Agent Or Allergen	A specific allergen or other agent/substan	A specific allergen or other agent/substance (drug, food,	CodeableConcept	1..1	1.3.6.1.4.1.12559.11.10.1.3.1.42.24 **eHDSIActiveIngredient** (ATC, used in MH@EU); 1.3.6.1.4.1.12559.11.10.1.3.1.42.61	eHN PS Guideline, MyHealth@EU, ISO IPS

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System	Requirements
			ce (drug, food, chemical agent, etc.) to which the patient has an adverse reaction propensity.	chemical agent, etc.) to which the patient has an adverse reaction propensity.			eHDSISubstance (EMA SMS, used in MH@EU); 1.3.6.1.4.1.12559.11.10.1.3.1.42.19 eHDSIAllergenNoDrug (SCT, used in MH@EU); ICD-11 Allergens	
A.4	.typeOfPropensity	Type Of Propensity	This element describes whether this condition refers to an allergy, non-allergy intolerance, or unknown class of intolerance (not known to be allergy or intolerance)	This element describes whether this condition refers to an allergy, non-allergy intolerance, or unknown class of intolerance (not known to be allergy or intolerance)	CodeableConcept	0..1	1.3.6.1.4.1.12559.11.10.1.3.1.42.18 eHDSIAdverseEventType (SCT, used in MH@EU); http://hl7.org/fhir/ValueSet/allergy-intolerance-type (HL7, required in HL7 FHIR)	eHN PS Guideline, MyHealth@EU
A.5	.description	Description	Textual description of the allergy or intolerance	Textual description of the allergy or intolerance	string	0..1		eHN PS Guideline, ISO IPS
A.6	.criticality	Criticality	Estimate of the potential	Estimate of the potential clinical	CodeableConcept	0..1	1.3.6.1.4.1.12559.11.10.1.3.1.42.57 eHDSICriticality (HL7, used in	eHN PS Guideline,

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System	Requirements
			clinical harm, or seriousness, of a reaction to an identified substance.	harm, or seriousness, of a reaction to an identified substance.			MH@EU); http://hl7.org/fhir/ValueSet/allergy-intolerance-criticality (HL7, required in HL7 FHIR)	MyHealth@EU, ISO IPS
A.7	.certainty	Certainty	Assertion about the certainty associated with a propensity, or potential risk, of a reaction to the identified substance. Diagnostic and /or clinical evidence of condition	Assertion about the certainty associated with a propensity, or potential risk, of a reaction to the identified substance. Diagnostic and /or clinical evidence of condition	CodeableConcept	0..1	1.3.6.1.4.1.12559.11.10.1.3.1.42.58 eHDSIAllergyCertainty (HL7, used in MH@EU) ; http://hl7.org/fhir/ValueSet/allergyintolerance-verification (HL7, required in HL7 FHIR)	eHN PS Guideline, MyHealth@EU, ISO IPS
A.8	.status	Status	Current status of the allergy or intolerance, for example, whether it is active, in remission, resolved, etc.	Current status of the allergy or intolerance, for example, whether it is active, in remission, resolved, etc.	CodeableConcept	0..1	1.3.6.1.4.1.12559.11.10.1.3.1.42.59 eHDSIAllergyStatus (HL7, used in MH@EU); http://hl7.org/fhir/ValueSet/allergyintolerance-clinical (HL7, required in HL7 FHIR)	eHN PS Guideline, MyHealth@EU, ISO IPS

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System	Requirements
A.9	.onsetDate	Onset Date	When allergy or intolerance was identified	When allergy or intolerance was identified	dateTime	0..1		MyHealth@EU, ISO IPS
A.10	.endDate	End Date	Date of resolution of the allergy (e.g. when the clinician deemed there is no longer any need to track the underlying condition)	Date of resolution of the allergy (e.g. when the clinician deemed there is no longer any need to track the underlying condition)	dateTime	0..1		eHN PS Guideline, MyHealth@EU, ISO IPS
A.11	.reaction	Reaction	Adverse Reaction Events linked to exposure to substance..	Adverse Reaction Events linked to exposure to substance..	Base	0..*		ISO IPS (explicit), implicitly in eHN PS Guideline, MH@EU
A.11.1	..manifestation	Manifestation	Description of the clinical manifestation of the allergic reaction. Example: anaphylactic shock,	Description of the clinical manifestation of the allergic reaction. Example: anaphylactic shock, angioedema. (the	CodeableConcept	0..*	1.3.6.1.4.1.12559.11.10.1.3.1.42.5 eHDSIIllnessandDisorder (ICD-10, alternative in MH@EU); 1.3.6.1.4.1.12559.11.10.1.3.1.42.11 eHDSIReactionAllergy (SCT, alternative in MH@EU); ICD-11 MMS	The element is present in eHN PS GL, MyHealth@EU specifications and ISO IPS. Element

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System	Requirements
			angioedema. (the clinical manifestation also gives information about the severity of the observed reaction).	clinical manifestation also gives information about the severity of the observed reaction).				name and description is taken from eHNPS GL. Cardinality in MyHealth@EU for this element, used here, is one manifestation per severity and onset, while the cardinality in FHIR IPS IG allows multiple manifestations per severity and onset.
A.11.2	..date	Date	Date and time of allergy manifestation	Date and time of allergy manifestation	dateTime	0..1		

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System	Requirements
A.11.3	..severity	Severity	Severity of the clinical manifestation of the allergic reaction.	Severity of the clinical manifestation of the allergic reaction.	CodeableConcept	0..1	1.3.6.1.4.1.12559.11.10.1.3.1.42.13 eHDSISeverity (SCT, used in MH@EU); http://hl7.org/fhir/ValueSet/reaction-event-severity (HL7, Required in HL7 FHIR)	The element is present in eHN PS GL, MyHealth@EU specifications and ISO IPS. Element name and description is taken from eHN PS GL.
A.11.4	..onsetDate	Onset Date	Date of the observation of the reaction	Date of the observation of the reaction	dateTime	0..1		The element is present in eHN PS GL. Element name and description is taken from eHN PS GL.

1010

10.1.4 Condition model

Table 4 Condition model

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System/Value set	Requirements
A	EHDSCondition	EHDS Condition	Condition model	Health conditions affecting the health of the patient and are important to be known for a health professional during a health encounter.		0..*		eHN PS Guideline, MyHealth@EU, ISO IPS
A.1	.header	Header	Common header for all patient-related data	Common header for all patient-related data	Base	1..1		
A.1.1	..subject	Subject	Subject	Patient/subject information	EHDSPatient	1..1		
A.1.2	..identifier	Identifier	Business identifier for the object	Business identifier for the object	Identifier	0..*		
A.1.3	..authorship	Authorship	Authorship	Resource authoring details	Base	1..*		
A.1.3.1	…author	Author	Author	Author(s) by whom the resource was/were	EHDSHealthProfessional, EHDSOrganisation, EHDSDevice	1..1		

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System/Value set	Requirements
				authored. Multiple authors could be provided.				
A.1.3.2	…datetime	Datetime	Date and time of authoring/issuing	Date and time of the issuing the document/resource by its author.	dateTime	1..1		
A.1.4	..lastUpdate	Last Update	Date and time of the last update to the resource	Date and time of the last update to the document/information	dateTime	0..1		
A.1.5	..status	Status	Status of the resource	Status of the resource	CodeableConcept	1..1		
A.1.6	..statusReason	Status Reason	Reason for the current status of the resource.	Reason for the current status of the resource.	CodeableConcept, string	0..1		
A.1.7	..language	Language	Language	Language in which the resource is written. Language is expressed by the IETF language tag.	CodeableConcept	0..1	BCP 47	

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System/Value set	Requirements
A.1.8	..version	Version	Version	Business version of the resource.	string	0..1		
A.2	.presentedForm	Presented Form	A narrative easy-to-read representation of the full data set, e.g. PDF-version of a document	A narrative easy-to-read representation of the full data set, e.g. PDF-version of a document	EHDSAttachment	0..*		
A.3	.problem	Problem	Identification of the condition, problem or diagnosis. Coded values are preferable, but text should be accepted.	Identification of the condition, problem or diagnosis. Coded values are preferable, but text should be accepted.	CodeableConcept	1..1	1.3.6.1.4.1.12559.11.10.1.3.1.42.5 eHDSIIllnessandDisorder (ICD-10, used in MH@EU); 1.3.6.1.4.1.12559.11.10.1.3.1.42.63 eHDSIRareDisease (OrphaCodes, used in MH@EU); ICD-11; SNOMED CT	eHN PS Guideline, ISO IPS
A.4	.diagnosisAssertionStatus	Diagnosis Assertion Status	Assertion about the certainty associated with a diagnosis. Diagnostic and/or clinical	Assertion about the certainty associated with a diagnosis. Diagnostic and/or clinical evidence of condition.	CodeableConcept	0..1	1.3.6.1.4.1.12559.11.10.1.3.1.42.64 eHDSICertainty (HL7, used in MH@EU); http://hl7.org/fhir/ValueSet/condition-ver-status (HL7, required in HL7 FHIR)	eHN PS Guideline

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System/Value set	Requirements
			evidence of condition.					
A.5	.onsetDate	Onset Date	Date of problem onset	Onset date of a problem/condition	dateTime	0..1		eHN PS Guideline, ISO IPS
A.6	.endDate	End Date	Problem resolution date	The date (or estimated date) that the condition resolved or went into remission.	dateTime	0..1		eHN PS Guideline, ISO IPS
A.7	.resolutionCircumstances	Resolution Circumstances	Describes the reason for which the status of the problem changed from current to inactive (e.g. surgical procedure, medical treatment, etc.).	This field includes free text if the resolution circumstances are not already included in other fields such as surgical procedure, medical device, etc., e.g. hepatic cystectomy (this will be the resolution circumstances for the problem 'hepatic cyst' and will be included in	string	0..1		eHN PS Guideline

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System/Value set	Requirements
				surgical procedures).				
A.8	.problemStatus	Problem Status	The clinical status of the condition	The clinical status of the condition	CodeableConcept	0..1	1.3.6.1.4.1.12559.11.10.1.3.1.42.15 eHDSIStatusCode (SCT, used in MH@EU); http://hl7.org/fhir/ValueSet/condition-clinical (HL7, required in HL7 FHIR)	ISO IPS, MyHealth@EU, eHN PS GUideline
A.9	.severity	Severity	Subjective assessment of the severity of the condition.	Subjective assessment of the severity of the condition.	CodeableConcept	0..1	1.3.6.1.4.1.12559.11.10.1.3.1.42.13 eHDSISeverity (SCT, used in MH@EU); http://hl7.org/fhir/ValueSet/condition-severity (SCT, Preferred in HL7 FHIR); Basic 3-Value Severity Scale Value: Mild-Moderate-Severe http://id.who.int/icd/entity/681697550 (ICD-11)	ISO IPS, MyHealth@EU
A.10	.specialistContact	Specialist Contact	Health Professional who may be specifically related to the problem, as a preferred contact.	Health Professional who may be specifically related to the problem, as a preferred contact.	EHDSHealthProfessional	0..*		ISO IPS, MyHealth@EU
A.11	.externalResourceRelatedWith	External Resource	External Resource	External Resource which may be	uri	0..*		MyHealth@EU

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System/Value set	Requirements
		Related With	which may be specifically related to the problem, for example a link between a rare disease problem and the corresponding guidelines.	specifically related to the problem, for example a link between a rare disease problem and the corresponding guidelines.				

1013

1014 ### 10.1.5 Medication statement model

1015 Table 5 Medication statement model

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System/Value set	Requirements
A	EHDSMedicationStatement	EHDS Medication Statement	Medication Statement	Statement about a single medication as part of a medication summary.		0..*		MyHealth@EU
A.1	.header	Header	Common header for all patient-related data	Common header for all patient-related data	Base	1..1		
A.1.1	..subject	Subject	Subject	Patient/subject information	EHDSPatient	1..1		

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System/Value set	Requirements
A.1.2	..identifier	Identifier	Business identifier for the object	Business identifier for the object	Identifier	0..*		
A.1.3	..authorship	Authorship	Authorship	Resource authoring details	Base	1..*		
A.1.3.1	…author	Author	Author	Author(s) by whom the resource was/were authored. Multiple authors could be provided.	EHDSHealthProfessional, EHDSOrganisation, EHDSDevice	1..1		
A.1.3.2	…datetime	Datetime	Date and time of authoring/issuing	Date and time of the issuing the document/resource by its author.	dateTime	1..1		
A.1.4	..lastUpdate	Last Update	Date and time of the last update to the resource	Date and time of the last update to the document/information	dateTime	0..1		
A.1.5	..status	Status	Status of the resource	Status of the resource	CodeableConcept	1..1		
A.1.6	..statusReason	Status Reason	Reason for the current status of the resource.	Reason for the current status of the resource.	CodeableConcept, string	0..1		
A.1.7	..language	Language	Language	Language in which the resource is written. Language is	CodeableConcept	0..1	BCP 47	

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System/Value set	Requirements
				expressed by the IETF language tag.				
A.1.8	..version	Version	Version	Business version of the resource.	string	0..1		
A.2	.presentedForm	Presented Form	A narrative easy-to-read representation of the full data set, e.g. PDF-version of a document	A narrative easy-to-read representation of the full data set, e.g. PDF-version of a document	EHDSAttachment	0..*		
A.3	.medicationTreatmentStatus	Medication Treatment Status	The current status of the taking of medicine	The current status of the taking of medicine	CodeableConcept	0..1		MyHealth@EU
A.4	.medication	Medication	Describes the medicinal product.	Describes the medicinal product.	EHDSMedication	1..1		eHN PS Guideline, ISO IPS, MyHealth@EU
A.5	.medicationReason	Medication Reason	Coded reason for the use of the medication (typically diagnosis, or a procedure)	Coded reason for the use of the medication (typically diagnosis, or a procedure)	CodeableConcept	0..*		eHN PS Guideline, ISO IPS, MyHealth@EU

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System/Value set	Requirements
A.6	.medicationReasonText	Medication Reason Text	Reason for the use of the medication (typically diagnosis, or a procedure) in free text.	Reason for the use of the medication (typically diagnosis, or a procedure) in free text.	string	0..1		eHN PS Guideline, ISO IPS, MyHealth@ EU
A.7	.intendedUseType	Intended Use Type	The type of intended use of the medication, e.g. prophylactic, therapeutic, diagnostic, anesthesia, etc.	The type of intended use of the medication, e.g. prophylactic, therapeutic, diagnostic, anesthesia, etc.	CodeableConcept	0..1		eHN PS Guideline, MyHealth@ EU
A.8	.dosageInstructions	Dosage Instructions	Details of how medication is/was taken or should be taken	Details of how medication is/was taken or should be taken. This includes the number of units per intake and frequency of intake over a specified duration of time. Example: 1 tablet every 24h, for 10 days.	EHDSDosaging	1..*		eHN PS Guideline, ISO IPS, MyHealth@ EU
A.9	.periodOfUse	Period Of Use	Period when patient took, is	Period when patient took, is taking or is	Period	0..1		eHN PS Guideline,

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System/Value set	Requirements
			taking or is expected to take the medication	expected to take the medication. This information may be expressed using start and end date times OR indicating the duration. The first is used to indicate a specified interval (e.g., from March 15th, 2017); the latter for indicating a 'floating' period (e.g., 2 weeks). In case of unbounded period (continuous therapy), the end element will be valued with an exceptional value.				ISO IPS, MyHealth@EU

1016

10.1.6 Medical devices and implants model

Table 6 Medical devices and implants model

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System/Value set	Requirements
A	EHDSDeviceUse	EHDS Device Use	Device use model	EHDS refined base model for device use information		0..*		eHN PS Guideline
A.1	.header	Header	Common header for all patient-related data	Common header for all patient-related data	Base	1..1		
A.1.1	..subject	Subject	Subject	Patient/subject information	EHDSPatient	1..1		
A.1.2	..identifier	Identifier	Business identifier for the object	Business identifier for the object	Identifier	0..*		
A.1.3	..authorship	Authorship	Authorship	Resource authoring details	Base	1..*		
A.1.3.1	…author	Author	Author	Author(s) by whom the resource was/were authored. Multiple authors could be provided.	EHDSHealthProfessional, EHDSOrganisation, EHDSDevice	1..1		
A.1.3.2	…datetime	Datetime	Date and time of authoring/issuing	Date and time of the issuing the document/resource by its author.	dateTime	1..1		
A.1.4	..lastUpdate	Last Update	Date and time of the last update to the resource	Date and time of the last update to the document/information	dateTime	0..1		

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System/Value set	Requirements
A.1.5	..status	Status	Current status of the device usage.	Status of the resource	CodeableConcept	1..1	HL7 device-statement-status	
A.1.6	..statusReason	Status Reason	Reason for the current status of the resource.	Reason for the current status of the resource.	CodeableConcept, string	0..1		
A.1.7	..language	Language	Language	Language in which the resource is written. Language is expressed by the IETF language tag.	CodeableConcept	0..1	BCP 47	
A.1.8	..version	Version	Version	Business version of the resource.	string	0..1		
A.2	.presentedForm	Presented Form	A narrative easy-to-read representation of the full data set, e.g. PDF-version of a document	A narrative easy-to-read representation of the full data set, e.g. PDF-version of a document	EHDSAttachment	0..*		
A.3	.startDate	Start Date	Date when the device was implantable to the patient or the external device was first in use.	Date when the device was implantable to the patient or the external device was first in use.	dateTime	0..1		eHN PS Guideline, ISO IPS.
A.4	.endDate	End Date	Date when the device was explanted from the patient or the	Date when the device was explanted from the patient	dateTime	0..1		eHN PS Guideline, ISO IPS.

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System/Value set	Requirements
			external device was no longer in use.	or the external device was no longer in use.				
A.5	.device	Device	The details of the device used.	The details of the device used.	CodeableConcept, EHDSDevice	1..1		eHN PS Guideline, ISO IPS.
A.6	.bodySite	Body Site	Anatomical location of the device. May include laterality.	Anatomical location of the device. May include laterality.	EHDSBodyStructure	0..1		eHN PS Guideline, ISO IPS.
A.7	.reason	Reason	Reason or justification for the use of the device.	Reason or justification for the use of the device.	CodeableConcept, EHDSCondition, EHDSObservation, EHDSProcedure	0..*		eHN PS Guideline, ISO IPS.
A.8	.source	Source	Who reported the device was being used by the patient.	Who reported the device was being used by the patient.	EHDSPatient, EHDSHealthProfessional, EHDSRelatedPerson	0..1		
A.9	.note	Note	Note about the device statement that were not represented at all or sufficiently in one of the attributes provided in a class. These may include for example a comment, an instruction, or a note	Note about the device statement that were not represented at all or sufficiently in one of the attributes provided in a class. These may include for example a comment, an instruction, or a note associated with the statement.	string	0..*		

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System/Value set	Requirements
			associated with the statement.					

1019

1020 ### 10.1.7 Procedure model

1021 Table 7 Procedure model

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System/Value set	Requirements
A	EHDSProcedure	EHDS Procedure	Procedure model	EHDS refined base model for an action that is or was performed on or for a patient		0..*		eHN PS Guideline, ISO IPS.
A.1	.header	Header	Common header for all patient-related data	Common header for all patient-related data	Base	1..1		
A.1.1	..subject	Subject	Subject	Patient/subject information	EHDSPatient	1..1		
A.1.2	..identifier	Identifier	Business identifier for the object	Business identifier for the object	Identifier	0..*		
A.1.3	..authorship	Authorship	Authorship	Resource authoring details	Base	1..*		

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System/Value set	Requirements
A.1.3.1	…author	Author	Author	Author(s) by whom the resource was/were authored. Multiple authors could be provided.	EHDSHealthProfessional, EHDSOrganisation, EHDSDevice	1..1		
A.1.3.2	…datetime	Datetime	Date and time of authoring/issuing	Date and time of the issuing the document/resource by its author.	dateTime	1..1		
A.1.4	..lastUpdate	Last Update	Date and time of the last update to the resource	Date and time of the last update to the document/information	dateTime	0..1		
A.1.5	..status	Status	Status of the resource	Status of the resource	CodeableConcept	1..1		
A.1.6	..statusReason	Status Reason	Reason for the current status of the resource.	Reason for the current status of the resource.	CodeableConcept, string	0..1		
A.1.7	..language	Language	Language	Language in which the resource is written. Language is expressed by the IETF language tag.	CodeableConcept	0..1	BCP 47	
A.1.8	..version	Version	Version	Business version of the resource.	string	0..1		

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System/Value set	Requirements
A.2	.presentedForm	Presented Form	A narrative easy-to-read representation of the full data set, e.g. PDF-version of a document	A narrative easy-to-read representation of the full data set, e.g. PDF-version of a document	EHDSAttachment	0..*		
A.3	.code	Code	Code identifying the procedure	Code identifying the procedure	CodeableConcept	0..1	SNOMED CT	
A.4	.date	Date	Date and time of the procedure or interval of its performance	Date and time of the procedure or interval of its performance	dateTime, Period	0..1		
A.5	.performer	Performer	An actor who performed the procedure	An actor who performed the procedure	EHDSHealthProfessional	0..*		
A.6	.bodySite	Body Site	Procedure target body site. Details of where the procedure was performed. Laterality may be included as qualifier of the body site.	Procedure target body site. Details of where the procedure was performed. Laterality may be included as qualifier of the body site.	EHDSBodyStructure	0..*	1.3.6.1.4.1.12559.11.10.1.3.1.42.65 eHDSIBodySite	eHN PS Guideline, ISO IPS.

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System/Value set	Requirements
A.7	.reason	Reason	The reason why the procedure was performed. This may be a concept from a terminology or a reference to a specific instance that describes the reason.	The reason why the procedure was performed. This may be a concept from a terminology or a reference to a specific instance that describes the reason.	CodeableConcept, EHDSCondition, EHDSObservation, EHDSProcedure	0..*	SNOMED CT, ICD-10, Orphacode if rare disease is diagnosed	eHN PS Guideline, ISO IPS.
A.8	.outcome	Outcome	The outcome of the procedure - did it resolve the reasons for the procedure being performed?	The outcome of the procedure - did it resolve the reasons for the procedure being performed?	CodeableConcept	0..1	SNOMED CT	eHN PS Guideline, ISO IPS.
A.9	.complication	Complication	Any complications that occurred during the procedure, or in the immediate post-performance period. These are generally tracked separately from	Any complications that occurred during the procedure, or in the immediate post-performance period. These are generally tracked separately from the procedure description, which will typically describe the procedure itself	CodeableConcept	0..*	ICD-10, SNOMED CT, Orphacode if rare disease is diagnosed	eHN PS Guideline, ISO IPS.

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System/Value set	Requirements
			the procedure description, which will typically describe the procedure itself rather than any 'post procedure' issues.	rather than any 'post procedure' issues.				
A.10	.deviceUsed	Device Used	Device used to perform the procedure	Device used to perform the procedure	EHDSDevice	0..*		
A.11	.focalDevice	Focal Device	Device(s) that is/are implanted, removed, or otherwise manipulated (calibration, battery replacement, fitting a prosthesis, attaching a wound-vac, etc.) as a focal portion of the Procedure.	Device(s) that is/are implanted, removed, or otherwise manipulated (calibration, battery replacement, fitting a prosthesis, attaching a wound-vac, etc.) as a focal portion of the Procedure.	EHDSDevice	0..*		

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System/Value set	Requirements
A.12	.note	Note	Additional information about the procedure	Additional information about the procedure	string	0..1		

1022

1023 ### 10.1.8 Vaccination/prophylaxis model

1024 Table 8 Vaccination/prophylaxis model

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System/Value set	Requirements
A	EHDSImmunisation	EHDS Immunisation	Immunisation model	EHDS refined base model for Immunisation		0..*		eHN PS Guideline, ISO IPS
A.1	.header	Header	Common header for all patient-related data	Common header for all patient-related data	Base	1..1		
A.1.1	..subject	Subject	Subject	Patient/subject information	EHDSPatient	1..1		
A.1.2	..identifier	Identifier	Business identifier for the object	Business identifier for the object	Identifier	0..*		
A.1.3	..authorship	Authorship	Authorship	Resource authoring details	Base	1..*		

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System/Value set	Requirements
A.1.3.1	…author	Author	Author	Author(s) by whom the resource was/were authored. Multiple authors could be provided.	EHDSHealthProfessional, EHDSOrganisation, EHDSDevice	1..1		
A.1.3.2	…datetime	Datetime	Date and time of authoring/issuing	Date and time of the issuing the document/resource by its author.	dateTime	1..1		
A.1.4	..lastUpdate	Last Update	Date and time of the last update to the resource	Date and time of the last update to the document/information	dateTime	0..1		
A.1.5	..status	Status	Status of the resource	Indicates the current status of the immunisation event (completed, not-done).	CodeableConcept	1..1		
A.1.6	..statusReason	Status Reason	Reason for the current status of the resource.	Reason for the current status of the resource.	CodeableConcept, string	0..1		
A.1.7	..language	Language	Language	Language in which the resource is written. Language is expressed	CodeableConcept	0..1	BCP 47	

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System/Value set	Requirements
				by the IETF language tag.				
A.1.8	..version	Version	Version	Business version of the resource.	string	0..1		
A.2	.presentedForm	Presented Form	A narrative easy-to-read representation of the full data set, e.g. PDF-version of a document	A narrative easy-to-read representation of the full data set, e.g. PDF-version of a document	EHDSAttachment	0..*		
A.3	.diseaseOrAgentTargeted	Disease Or Agent Targeted	Disease or agent targeted	Disease or agent that the vaccination provides protection against.	CodeableConcept	0..*	ICD-10, SNOMED CT	
A.4	.vaccine	Vaccine	Type of vaccine	Generic description of the vaccine/prophylaxis or its component(s).	CodeableConcept	1..1	SNOMED CT, ATC	
A.5	.administeredProduct	Administered Product	Administered product	Medicinal product administered.	EHDSMedication	0..1		
A.6	.doseNumber	Dose Number	Number in a series of vaccinations / doses	Order in the vaccination course.	integer	0..1		

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System/Value set	Requirements
A.7	.dateOfVaccination	Date Of Vaccination	Date of vaccination	The date and time when the vaccination was administered	date	1..1		
A.8	.administeringCentre	Administering Centre	Administering centre	Name/code of administering centre or a health authority responsible for the vaccination event	EHDSOrganisation	0..*		
A.9	.vaccineAdministrator	Vaccine Administrator	Administrator of vaccine	Health professional responsible for administering the vaccine or prophylaxis	EHDSHealthProfessional	0..*		
A.10	.nextVaccinationDate	Next Vaccination Date	Next vaccination date	The date when the vaccination is planned to be given/repeated (e.g. next dose)	date	0..1		

1025

10.1.9 Functional status model

Table 9 Functional status model

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System/Value set	Requirements
A	EHDSFunctionalStatus	EHDS Functional Status	Functional status	EHDS refined base model for Functional status		0..*		eHN PS Guideline, ISO IPS.
A.1	.header	Header	Common header for all patient-related data	Common header for all patient-related data	Base	1..1		
A.1.1	..subject	Subject	Subject	Patient/subject information	EHDSPatient	1..1		
A.1.2	..identifier	Identifier	Business identifier for the object	Business identifier for the object	Identifier	0..*		
A.1.3	..authorship	Authorship	Authorship	Resource authoring details	Base	1..*		
A.1.3.1	…author	Author	Author	Author(s) by whom the resource was/were authored. Multiple authors could be provided.	EHDSHealthProfessional, EHDSOrganisation, EHDSDevice	1..1		
A.1.3.2	…datetime	Datetime	Date and time of authoring/issuing	Date and time of the issuing the document/resource by its author.	dateTime	1..1		

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System/Value set	Requirements
A.1.4	..lastUpdate	Last Update	Date and time of the last update to the resource	Date and time of the last update to the document/information	dateTime	0..1		
A.1.5	..status	Status	Status of the resource	Status of the resource	CodeableConcept	1..1		
A.1.6	..statusReason	Status Reason	Reason for the current status of the resource.	Reason for the current status of the resource.	CodeableConcept, string	0..1		
A.1.7	..language	Language	Language	Language in which the resource is written. Language is expressed by the IETF language tag.	CodeableConcept	0..1	BCP 47	
A.1.8	..version	Version	Version	Business version of the resource.	string	0..1		
A.2	.presentedForm	Presented Form	A narrative easy-to-read representation of the full data set, e.g. PDF-version of a document	A narrative easy-to-read representation of the full data set, e.g. PDF-version of a document	EHDSAttachment	0..*		
A.3	.description	Description	Narrative description of	Narrative description of the need for the	string	0..1		eHN HDR Guideline,

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System/Value set	Requirements
			the functional status	patient to be continuously assessed by third parties; functional status may influence decisions about how to plan and administer treatments.				MyHealth@EU, ISO IPS
A.4	.relatedConditions	Related Conditions	Conditions related to the functional status	Conditions related to the functional status	EHDSCondition	0..*		eHN HDR Guideline, ISO IPS
A.5	.functionalStatusAssessment	Functional Status Assessment	Functional assessment of the patient	Functional status assessment of the patient according to a specific assessment scheme.	Base	0..*		eHN HDR Guideline, ISO IPS
A.5.1	..functionalAssessmentDescription	Functional Assessment Description	Description of the functional assessment	Description of the functional assessment	string	0..1		eHN HDR Guideline, ISO IPS
A.5.2	..functionalAssessmentCode	Functional Assessment Code	Standardised code corresponding	Standardised code corresponding to the Functional assessment	CodeableConcept	0..1	ICF, SNOMED CT	eHN HDR Guideline, ISO IPS

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System/Value set	Requirements
			to the Functional assessment					
A.5.3	..functionalAssessmentDateTime	Functional Assessment Date Time	Date and time of the functional assessment	Date and time of the functional assessment	dateTime	0..1		eHN HDR Guideline, ISO IPS
A.5.4	..functionalAssessmentResult	Functional Assessment Result	Functional assessment result value	Functional assessment result value	string, Quantity, CodeableConcept	0..1	ICF, SNOMED CT	eHN HDR Guideline, ISO IPS

1028

1029 ### 10.1.10 Social history model

1030 **Table 10 Social history model**

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System/Value set	Requirements
A	EHDSSocialHistory	EHDS Social History	Social history model	EHDS model for social history observations		0..*		eHN PS Guideline, ISO IPS
A.1	.header	Header	Common header for all patient-related data	Common header for all patient-related data	Base	1..1		
A.1.1	..subject	Subject	Subject	Patient/subject information	EHDSPatient	1..1		

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System/Value set	Requirements
A.1.2	..identifier	Identifier	Business identifier for the object	Business identifier for the object	Identifier	0..*		
A.1.3	..authorship	Authorship	Authorship	Resource authoring details	Base	1..*		
A.1.3.1	…author	Author	Author	Author(s) by whom the resource was/were authored. Multiple authors could be provided.	EHDSHealthProfessional, EHDSOrganisation, EHDSDevice	1..1		
A.1.3.2	…datetime	Datetime	Date and time of authoring/issuing	Date and time of the issuing the document/resource by its author.	dateTime	1..1		
A.1.4	..lastUpdate	Last Update	Date and time of the last update to the resource	Date and time of the last update to the document/information	dateTime	0..1		
A.1.5	..status	Status	Status of the resource	Status of the resource	CodeableConcept	1..1		
A.1.6	..statusReason	Status Reason	Reason for the current status of the resource.	Reason for the current status of the resource.	CodeableConcept, string	0..1		
A.1.7	..language	Language	Language	Language in which the resource is written. Language is expressed	CodeableConcept	0..1	BCP 47	

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System/Value set	Requirements
				by the IETF language tag.				
A.1.8	..version	Version	Version	Business version of the resource.	string	0..1		
A.2	.presentedForm	Presented Form	A narrative easy-to-read representation of the full data set, e.g. PDF-version of a document	A narrative easy-to-read representation of the full data set, e.g. PDF-version of a document	EHDSAttachment	0..*		
A.3	.description	Description	Textual description of the social history.	Textual description of the social history.	string	0..1		eHN PS Guideline, MyHealth@EU, ISO IPS
A.4	.observation	Observation	Social history observations related to health	Health related lifestyle factors or lifestyle observations and social determinants of health. Example: cigarette smoker, alcohol consumption	EHDSObservation	0..1		MyHealth@EU,
A.5	.referencePeriod	Reference Period	Reference date range	Example: from 1974 to 2004	Period	0..1		eHN PS Guideline, MyHealth@EU, ISO IPS

10.1.11 Current pregnancy model

Table 11 Current pregnancy model

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System/Value set	Requirements
A	EHDSCurrentPregnancy	EHDS Current Pregnancy	Current pregnancy status model	Current pregnancy status		0..*		eHN PS Guideline, ISO IPS.
A.1	.header	Header	Common header for all patient-related data	Common header for all patient-related data	Base	1..1		
A.1.1	..subject	Subject	Subject	Patient/subject information	EHDSPatient	1..1		
A.1.2	..identifier	Identifier	Business identifier for the object	Business identifier for the object	Identifier	0..*		
A.1.3	..authorship	Authorship	Authorship	Resource authoring details	Base	1..*		
A.1.3.1	…author	Author	Author	Author(s) by whom the resource was/were authored. Multiple authors could be provided.	EHDSHealthProfessional, EHDSOrganisation, EHDSDevice	1..1		
A.1.3.2	…datetime	Datetime	Date and time of authoring/issuing	Date and time of the issuing the document/resource by its author.	dateTime	1..1		

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System/Value set	Requirements
A.1.4	..lastUpdate	Last Update	Date and time of the last update to the resource	Date and time of the last update to the document/information	dateTime	0..1		
A.1.5	..status	Status	Status of the resource	Status of the resource	CodeableConcept	1..1		
A.1.6	..statusReason	Status Reason	Reason for the current status of the resource.	Reason for the current status of the resource.	CodeableConcept, string	0..1		
A.1.7	..language	Language	Language	Language in which the resource is written. Language is expressed by the IETF language tag.	CodeableConcept	0..1	BCP 47	
A.1.8	..version	Version	Version	Business version of the resource.	string	0..1		
A.2	.presentedForm	Presented Form	A narrative easy-to-read representation of the full data set, e.g. PDF-version of a document	A narrative easy-to-read representation of the full data set, e.g. PDF-version of a document	EHDSAttachment	0..*		
A.3	.narrative	Narrative	Textual description of current	Narrative description describing the status of the current pregnancy.	string	0..1		eHN PS Guideline, ISO IPS

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System/Value set	Requirements
			pregnancy status					
A.4	.currentPregnancyStatus	Current Pregnancy Status	Current pregnancy status	Current state of the pregnancy at the date the observation was made, e.g. pregnant, not pregnant, unknown.	CodeableConcept	1..1	1.3.6.1.4.1.12559.11.10.1.3.1.42.60 eHDSICurrentPregnancyStatus (SNOMED CT, used in MH@EU); 1.3.6.1.4.1.12559.11.10.1.3.1.42.63 eHDSIRareDisease (OrphaCodes, used in MH@EU); ICD-11; SNOMED CT	eHN PS Guideline, ISO IPS
A.5	.dateOfStatus	Date Of Status	Date of status	Effective date of the current pregnancy status.	dateTime	0..1		eHN PS Guideline, ISO IPS
A.6	.expectedDateOfDelivery	Expected Date Of Delivery	Expected date of delivery	Date in which the woman is due to give birth. Year, day and month are required.	date	0..1		eHN PS Guideline, ISO IPS

1034

10.1.12 Pregnancy history model

Table 12 Pregnancy history model

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System/Value set	Requirements
A	EHDSPregnancyHistory	EHDS Pregnancy History	Pregnancy history model	Pregnancy history for one pregnancy		0..*		eHN PS Guideline, ISO IPS.
A.1	.header	Header	Common header for all patient-related data	Common header for all patient-related data	Base	1..1		
A.1.1	..subject	Subject	Subject	Patient/subject information	EHDSPatient	1..1		
A.1.2	..identifier	Identifier	Business identifier for the object	Business identifier for the object	Identifier	0..*		
A.1.3	..authorship	Authorship	Authorship	Resource authoring details	Base	1..*		
A.1.3.1	…author	Author	Author	Author(s) by whom the resource was/were authored. Multiple authors could be provided.	EHDSHealthProfessional, EHDSOrganisation, EHDSDevice	1..1		
A.1.3.2	…datetime	Datetime	Date and time of authoring/issuing	Date and time of the issuing the document/resource by its author.	dateTime	1..1		

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System/Value set	Requirements
A.1.4	..lastUpdate	Last Update	Date and time of the last update to the resource	Date and time of the last update to the document/information	dateTime	0..1		
A.1.5	..status	Status	Status of the resource	Status of the resource	CodeableConcept	1..1		
A.1.6	..statusReason	Status Reason	Reason for the current status of the resource.	Reason for the current status of the resource.	CodeableConcept, string	0..1		
A.1.7	..language	Language	Language	Language in which the resource is written. Language is expressed by the IETF language tag.	CodeableConcept	0..1	BCP 47	
A.1.8	..version	Version	Version	Business version of the resource.	string	0..1		
A.2	.presentedForm	Presented Form	A narrative easy-to-read representation of the full data set, e.g. PDF-version of a document	A narrative easy-to-read representation of the full data set, e.g. PDF-version of a document	EHDSAttachment	0..*		
A.3	.narrative	Narrative	Narrative, potentially formatted,	Narrative description describing the outcome of any	string	0..1		eHN PS Guideline, ISO IPS

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System/Value set	Requirements
			content of the section	previous pregnancies.				
A.4	.outcomeDate	Outcome Date	Outcome date	Date referred to the previous pregnancies outcome.	dateTime	0..1		eHN PS Guideline, ISO IPS
A.5	.outcome	Outcome	Outcome	Outcome of the previous pregnancy.	CodeableConcept	0..1	1.3.6.1.4.1.12559.11.10.1.3.1.42.62 eHDSIOutcomeOfPregnancy (SNOMED CT, used in MH@EU); 1.3.6.1.4.1.12559.11.10.1.3.1.42.63 eHDSIRareDisease (OrphaCodes, used in MH@EU); ICD-11; SNOMED CT	eHN PS Guideline, ISO IPS
A.6	.numberOfChildren	Number Of Children	Number of children/fetuses in this specific pregnancy	Number of children/fetuses in this specific pregnancy	integer	0..1		eHN PS Guideline, ISO IPS

1037

10.1.13 Travel history model

Table 13 Travel history model

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System/Value set	Requirements
A	EHDSTravelHistory	EHDS Travel History	Travel history model	Relevant information about the patient's recent travel history, for one visit		0..*		eHN PS Guideline, ISO IPS.
A.1	.header	Header	Common header for all patient-related data	Common header for all patient-related data	Base	1..1		
A.1.1	..subject	Subject	Subject	Patient/subject information	EHDSPatient	1..1		
A.1.2	..identifier	Identifier	Business identifier for the object	Business identifier for the object	Identifier	0..*		
A.1.3	..authorship	Authorship	Authorship	Resource authoring details	Base	1..*		
A.1.3.1	…author	Author	Author	Author(s) by whom the resource was/were authored. Multiple authors could be provided.	EHDSHealthProfessional, EHDSOrganisation, EHDSDevice	1..1		
A.1.3.2	…datetime	Datetime	Date and time of authoring/issuing	Date and time of the issuing the document/resource by its author.	dateTime	1..1		

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System/Value set	Requirements
A.1.4	..lastUpdate	Last Update	Date and time of the last update to the resource	Date and time of the last update to the document/information	dateTime	0..1		
A.1.5	..status	Status	Status of the resource	Status of the resource	CodeableConcept	1..1		
A.1.6	..statusReason	Status Reason	Reason for the current status of the resource.	Reason for the current status of the resource.	CodeableConcept, string	0..1		
A.1.7	..language	Language	Language	Language in which the resource is written. Language is expressed by the IETF language tag.	CodeableConcept	0..1	BCP 47	
A.1.8	..version	Version	Version	Business version of the resource.	string	0..1		
A.2	.presentedForm	Presented Form	A narrative easy-to-read representation of the full data set, e.g. PDF-version of a document	A narrative easy-to-read representation of the full data set, e.g. PDF-version of a document	EHDSAttachment	0..*		
A.3	.country	Country	Country visited	Country visited	CodeableConcept	1..1	ISO 3166	eHN PS Guideline
A.4	.period	Period	Date of entry and departure	The period during which the patient visited the country	Period	0..1		eHN PS Guideline

10.1.14 Advance directive model

Table 14 Advance directive model

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System/Value set	Requirements
A	EHDSAdvanceDirective	EHDS Advance Directive	Advance directive model	Healthcare directives concerning life or after life wishes of the patient		0..*		eHN PS Guideline, ISO IPS, MyHealth@EU
A.1	.header	Header	Common header for all patient-related data	Common header for all patient-related data	Base	1..1		
A.1.1	..subject	Subject	Subject	Patient/subject information	EHDSPatient	1..1		
A.1.2	..identifier	Identifier	Business identifier for the object	Business identifier for the object	Identifier	0..*		
A.1.3	..authorship	Authorship	Authorship	Resource authoring details	Base	1..*		
A.1.3.1	…author	Author	Author	Author(s) by whom the resource was/were authored. Multiple authors could be provided.	EHDSHealthProfessional, EHDSOrganisation, EHDSDevice	1..1		
A.1.3.2	…datetime	Datetime	Date and time of authoring/issuing	Date and time of the issuing the document/resource by its author.	dateTime	1..1		

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System/Value set	Requirements
A.1.4	..lastUpdate	Last Update	Date and time of the last update to the resource	Date and time of the last update to the document/information	dateTime	0..1		
A.1.5	..status	Status	Status of the resource	Status of the resource	CodeableConcept	1..1		
A.1.6	..statusReason	Status Reason	Reason for the current status of the resource.	Reason for the current status of the resource.	CodeableConcept, string	0..1		
A.1.7	..language	Language	Language	Language in which the resource is written. Language is expressed by the IETF language tag.	CodeableConcept	0..1	BCP 47	
A.1.8	..version	Version	Version	Business version of the resource.	string	0..1		
A.2	.presentedForm	Presented Form	A narrative easy-to-read representation of the full data set, e.g. PDF-version of a document	A narrative easy-to-read representation of the full data set, e.g. PDF-version of a document	EHDSAttachment	0..*		
A.3	.category	Category	Categories of Directives related to	Categories of Directives related to decisions prior and after death	CodeableConcept	0..*	SNOMED CT	ISO IPS

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System/Value set	Requirements
			decisions prior and after death					
A.4	.narrative	Narrative	Textual description of the directive	Textual description of the directive	string	0..1		eHN PS and HDR Guidelines, MyHealth@EU, ISO IPS
A.5	.effectivePeriod	Effective Period	Time period during which the directive is effective	Time period during which the directive is effective	Period	0..1		eHN HDR Guideline, ISO IPS
A.6	.authorisingEntity	Authorising Entity	Person or organisation that authorises the directive	Person or organisation that authorises the directive	EHDSPatient, EHDSHealthProfessional, EHDSRelatedPerson, EHDSOrganisation	0..1		ISO IPS
A.7	.relatedConditions	Related Conditions	The problem or disorder to which the living will applies. Multiple fields could be provided.	The problem or disorder to which the living will applies. Multiple fields could be provided.	CodeableConcept	0..*	ICD-10, SNOMED CT, Orphacode	ISO IPS
A.8	.advanceDirectiveDocument	Advance Directive Document	Scanned source document with the living will and the patient's	Scanned source document with the living will and the	EHDSAttachment	0..1		eHN HDR Guideline, ISO IPS

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System/Value set	Requirements
			signature, such as a PDF.	patient's signature, such as a PDF.				

1043

1044 ### 10.1.15 Results model

1045 **Table 15 Results model**

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System	Requirements
A	EHDSObservation	EHDS Observation	Observation model	EHDS refined base model for Observation information		0..*		
A.1	.header	Header	Common header for all patient-related data	Common header for all patient-related data	Base	1..1		
A.1.1	..subject	Subject	Subject	Patient/subject information	EHDSPatient	1..1		
A.1.2	..identifier	Identifier	Business identifier for the object	Business identifier for the object	Identifier	0..*		
A.1.3	..authorship	Authorship	Authorship	Resource authoring details	Base	1..*		
A.1.3.1	…author	Author	Author	Author(s) by whom the resource was/were authored.	EHDSHealthProfessional, EHDSOrganisation, EHDSDevice	1..1		

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System	Requirements
				Multiple authors could be provided.				
A.1.3.2	…datetime	Datetime	Date and time of authoring/issuing	Date and time of the issuing the document/resource by its author.	dateTime	1..1		
A.1.4	..lastUpdate	Last Update	Date and time of the last update to the resource	Date and time of the last update to the document/information	dateTime	0..1		
A.1.5	..status	Status	Status of the resource	Status of the resource	CodeableConcept	1..1	HL7 Observation status	
A.1.6	..statusReason	Status Reason	Reason for the current status of the resource.	Reason for the current status of the resource.	CodeableConcept, string	0..1		
A.1.7	..language	Language	Language	Language in which the resource is written. Language is expressed by the IETF language tag.	CodeableConcept	0..1	BCP 47	
A.1.8	..version	Version	Version	Business version of the resource.	string	0..1		
A.2	.presentedForm	Presented Form	A narrative easy-to-read representation of the full data set,	A narrative easy-to-read representation of the full data set, e.g. PDF-version of a document	EHDSAttachment	0..*		

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System	Requirements
			e.g. PDF-version of a document					
A.3	.observationDate	Observation Date	Clinically relevant time or time period for the observation	Clinically relevant time or time period for the observation	dateTime, Period	1..1		
A.4	.code	Code	Observation code	Code representing the observation using the agreed code systems.	CodeableConcept	1..1	LOINC, NPU, SNOMED CT	
A.5	.originalName	Original Name	Original (conventional) name of the observation	Original (conventional) name of the observation	string	0..1		
A.6	.method	Method	Observation method	Observation method (measurement principle) to obtain the result.	CodeableConcept	0..1	SNOMED CT	
A.7	.order	Order	Identifies order and order placer this observation belongs to	Identifies order and order placer this observation belongs to	EHDSServiceRequest	0..1		
A.8	.performer	Performer	Performer	Performer	EHDSHealthProfessional	0..1		
A.9	.anatomicLocation	Anatomic Location	Anatomic location and laterality where the observation was performed.	Anatomic location and laterality where the observation was performed.	EHDSBodyStructure	0..1		

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System	Requirements
A.10	.result	Result	Result of the observation including text, numeric and coded results of the measurement and measurement uncertainty. Content of the observation result will vary according to the type of the observation.	Result of the observation including text, numeric and coded results of the measurement and measurement uncertainty. Content of the observation result will vary according to the type of the observation.	Base	0..1		
A.10.1	..value	Value	Observation result value according to the type of observation	Observation result value according to the type of observation	string, Quantity, Range, CodeableConcept	1..1	UCUM for units, SNOMED CT for coded results	
A.10.2	..uncertainty	Uncertainty	Measurement uncertainty type and interval if needed.	Measurement uncertainty type and interval if needed.	Base [Not modelled]	0..1		
A.11	.dataAbsentReason	Data Absent Reason	Provides a reason why the expected value in the element Observation.value[x] is missing.	Provides a reason why the expected value in the element Observation.value[x] is missing.	CodeableConcept	0..1	HL7 Data absent reason	

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System	Requirements
A.12	.referenceRange	Reference Range	Reference range, multiple reference ranges of different types culd by provided. Provides guide for interpretation of result.	Reference range, multiple reference ranges of different types culd by provided. Provides guide for interpretation of result.	Base [Not modelled]	0..*		
A.13	.interpretation	Interpretation	Information about reference intervals and result interpretation.	Information about reference intervals and result interpretation.	CodeableConcept	0..*	SNOMED CT, HL7 ObservationInterpretation	
A.14	.resultDescription	Result Description	Comments and narrative representation of the observation result and findings.	Comments and narrative representation of the observation result and findings.	string	0..1		
A.15	.component	Component	Component in case the observation consists of multiple sub-observations (e.g. blood pressure).	Component in case the observation consists of multiple sub-observations (e.g. blood pressure).	Base	0..*		
A.15.1	..result	Result	Result of the observation including text,	Result of the observation including text,	Base	0..1		

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System	Requirements
			numeric and coded results of the measurement and measurement uncertainty. Content of the observation result will vary according to the type of the observation.	numeric and coded results of the measurement and measurement uncertainty. Content of the observation result will vary according to the type of the observation.				
A.15.1.1	…value	Value	Observation result value according to the type of observation	Observation result value according to the type of observation	string, Quantity, Range, CodeableConcept	1..1		
A.15.1.2	…uncertainty	Uncertainty	Measurement uncertainty type and interval if needed.	Measurement uncertainty type and interval if needed.	Base [Not modelled]	0..1		
A.15.2	..dataAbsentReason	Data Absent Reason	Provides a reason why the expected value in the element Observation.value[x] is missing.	Provides a reason why the expected value in the element Observation.value[x] is missing.	CodeableConcept	0..1	HL7 Data absent reason	
A.15.3	..referenceRange	Reference Range	Reference range, multiple reference ranges of different	Reference range, multiple reference ranges of different	Base [Not modelled]	0..*		

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System	Requirements
			types culd by provided. Provides guide for interpretation of result.	types culd by provided. Provides guide for interpretation of result.				
A.15.4	..interpretation	Interpretation	Information about reference intervals and result interpretation.	Information about reference intervals and result interpretation.	CodeableConcept	0..*	SNOMED CT, HL7 ObservationInterpretation	
A.16	.derivedFrom	Derived From	Reference to the related resource from which the observation has been made. For example, a calculated anion gap or a fetal measurement based on an ultrasound image.	Reference to the related resource from which the observation has been made. For example, a calculated anion gap or a fetal measurement based on an ultrasound image.	EHDSObservation, EHDSLaboratoryObservation, EHDSImagingStudy	0..*		
A.17	.triggeredBy	Triggered By	References to the observation(s) that triggered the performance of this observation.	References to the observation(s) that triggered the performance of this observation.	EHDSLaboratoryObservation, EHDSObservation	0..*		
A.18	.hasMember	Has Member	This observation is a group observation (e.g. a	This observation is a group observation (e.g. a battery, a	EHDSLaboratoryObservation, EHDSObservation	0..*		

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System	Requirements
			battery, a panel of tests, a set of vital sign measurements) that includes the target as a member of the group.	panel of tests, a set of vital sign measurements) that includes the target as a member of the group.				

1046

1047 ### 10.1.16 Care plan model

1048 **Table 16 Care plan model**

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System/Value set	Requirements
A	EHDSCarePlan	EHDS Care Plan	Care plan model	EHDS simplified model for care plan. The model includes very minimal information and is not designed to cover the full functionality of care plans.		0..*		eHN Guideline, ISO IPS, MyHealth@EU
A.1	.header	Header	Common header for all patient-related data	Common header for all patient-related data	Base	1..1		
A.1.1	..subject	Subject	The patient whose intended care is described by the plan.	Patient/subject information	EHDSPatient	1..1		
A.1.2	..identifier	Identifier	Identifier for the care plan	Business identifier for the object	Identifier	0..*		

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System/Value set	Requirements
A.1.3	..authorship	Authorship	Authorship	Resource authoring details	Base	1..*		
A.1.3.1	…author	Author	Author	Author(s) by whom the resource was/were authored. Multiple authors could be provided.	EHDSHealthProfessional, EHDSOrganisation, EHDSDevice	1..1		
A.1.3.2	…datetime	Datetime	Date and time of authoring/issuing	Date and time of the issuing the document/resource by its author.	dateTime	1..1		
A.1.4	..lastUpdate	Last Update	Date and time of the last update to the resource	Date and time of the last update to the document/information	dateTime	0..1		
A.1.5	..status	Status	Indicates whether the plan is currently being acted upon, represents future intentions or is now a historical record.	Status of the resource	CodeableConcept	1..1	HL7 Request status	
A.1.6	..statusReason	Status Reason	Reason for the current status of the resource.	Reason for the current status of the resource.	CodeableConcept, string	0..1		
A.1.7	..language	Language	Language	Language in which the resource is written. Language is expressed by the IETF language tag.	CodeableConcept	0..1	BCP 47	
A.1.8	..version	Version	Version	Business version of the resource.	string	0..1		
A.2	.presentedForm	Presented Form	A narrative easy-to-read representation of the full data set, e.g. PDF-version of a document	A narrative easy-to-read representation of the full data set, e.g. PDF-version of a document	EHDSAttachment	0..*		

Code	Path	Element	Short	Definition	Datatype	Cardinality	Preferred Code System/Value set	Requirements
A.3	.title	Title	Human-friendly name for the care plan	Human-friendly name for the care plan	string	0..1		
A.4	.description	Description	A description of the scope and nature of the plan.	A description of the scope and nature of the plan.	string	0..1		
A.5	.period	Period	Indicates when the plan did (or is intended to) come into effect and end.	Indicates when the plan did (or is intended to) come into effect and end.	Period	0..1		
A.6	.addresses	Addresses	Conditions/problems/concerns/diagnoses/etc. whose management and/or mitigation are handled by this plan.	Conditions/problems/concerns/diagnoses/etc. whose management and/or mitigation are handled by this plan.	CodeableConcept	0..*	ICD-10, SNOMED CT, Orphacode	eHN Guideline
A.7	.activity	Activity	The details of the proposed activity represented in a specific resource.	The details of the proposed activity represented in a specific resource.	string	0..1		

10.2 Annex II Patient summary conformance questionnaire results

The Patient Summary Questionnaire follows the same structure in which the Patient Summary contents are presented. The information in the Patient Summary is grouped into three hierarchical levels, starting from the wider: Conceptual Grouping, Sections and Data Elements, in a way that a single Conceptual Grouping collects different Sections, and each Section collects different Data Elements.

Concerning the Patient Clinical Data section of the Patient Summary, the Conceptual Grouping and the respective Sections are as shown below.

Conceptual groupings and Sections of Patient Clinical Data (part of Patient Summary)

CONCEPTUAL GROUPING	SECTION
ALERTS	Allergies and intolerances
ALERTS	Medical alert information
MEDICAL HISTORY	Vaccinations
MEDICAL HISTORY	List of Resolved, Closed or Inactive problems
MEDICAL HISTORY	Medical History
MEDICAL PROBLEMS	List of current problems/diagnosis
MEDICAL PROBLEMS	Medical devices
MEDICAL PROBLEMS	Procedures
MEDICAL PROBLEMS	Functional status
MEDICATION SUMMARY	Current and relevant past medicines
SOCIAL HISTORY	Social History Observations
PREGNANCY HISTORY	Current pregnancy status
PREGNANCY HISTORY	History of previous pregnancies
PATIENT PROVIDED DATA	Travel history
PATIENT PROVIDED DATA	Advance Directive
RESULTS	Result observations
PLAN OF CARE	Therapeutic recommendations

Sections of the Patient Summary are classified into two different optionality categories of the information that the Country of Affiliation must necessarily make available to the Country of Treatment.

For this analysis, NCPeHs are considered EHR systems. From another perspective, the "NCPeH of Country of affiliation" is a producer, and the "NCPeH of Country of treatment" is a consumer.

The NCPeH of the Country of Affiliation must make available to the NCPeH of the Country of Treatment at least the basic (or essential) information needed by the health professional (HP) of the Country of Treatment to provide safe healthcare.

The Patient Clinical Data has five Basic Sections that are mandatory for a Patient Summary clinical document to include. The Basic Sections are the following:

- Allergies and intolerances: provides clinical information about the patient's allergic reactions and intolerances (other medical alert information not included in allergies).

- List of current problems/diagnosis: provides clinical information about the chronic diseases, persistent conditions or repeated medication that the patient is receiving at the moment of treatment.
- Medical devices: provides clinical information about the implanted and external medical devices and equipment of which the HP needs to be aware.
- Significant procedures: provide clinical information about the important procedures, surgical and non-surgical, that the patient had. Procedures that are deemed not to be useful in the care of the patient shall be excluded to avoid distracting the end user by recording any procedures performed in a clinical record or in the provision of health care in general.
- List of current medicines (Medication Summary): provides clinical information about all prescribed medicines for which the period of time indicated for the treatment has not yet expired, whether it has been dispensed or not. Therefore, it is not necessarily related to the prescription/dispensation process.

Sections that are not classified as basic can be completely omitted and are labelled as Extended. Data elements are subject to a similar classification: data elements classified as mandatory must be provided (when the respective section is provided), data elements classified as required must be provided (when the respective section is provided), although exceptional justifications can be provided, and data elements classified as optional can be omitted.

NCPeH of Country of Affiliation must provide information about the reason of the missing data for the basic sections of the Patient Summary clinical document sent to the NCPeH of the Country of Treatment.

Within the Patient Summary Questionnaire, the MS are asked to provide an explanatory response to each section and each of the relevant data elements. The responses that the MS should provide are categorised as conformant or non-conformant, with the latter attributable to five different non-conformance reasons. The responses classification is described below:

Conformance (C): If a MS provides this response, it means that the "source information is structured, coded and compatible with eHDSI CDA Implementation Guides."

On the other hand, if a MS results non-conformant to a PS Questionnaire item, the MyHealth@EU Requirements Catalogue indicates that one out of the following five non-conformance reasons should be specified by the respondent:

(1) Source of information is not available (this covers the case when the information is optional in the source, and therefore not provided). For example, the data element "Allergy description" is optional in the national infrastructure/systems and is not filled by the users, which means it cannot be provided.

(2) Source of information is non-structured (i.e. free text) – structure and coding issues. For example: the data element "Agent (Agent description)" is captured as free text in the national infrastructure/system of 22 MS.

(3) Source of information is structured but not coded – coding issue. For example: the "Medical devices and implants" section is structured differently than in the eHDSI CDA Implementation Guides.

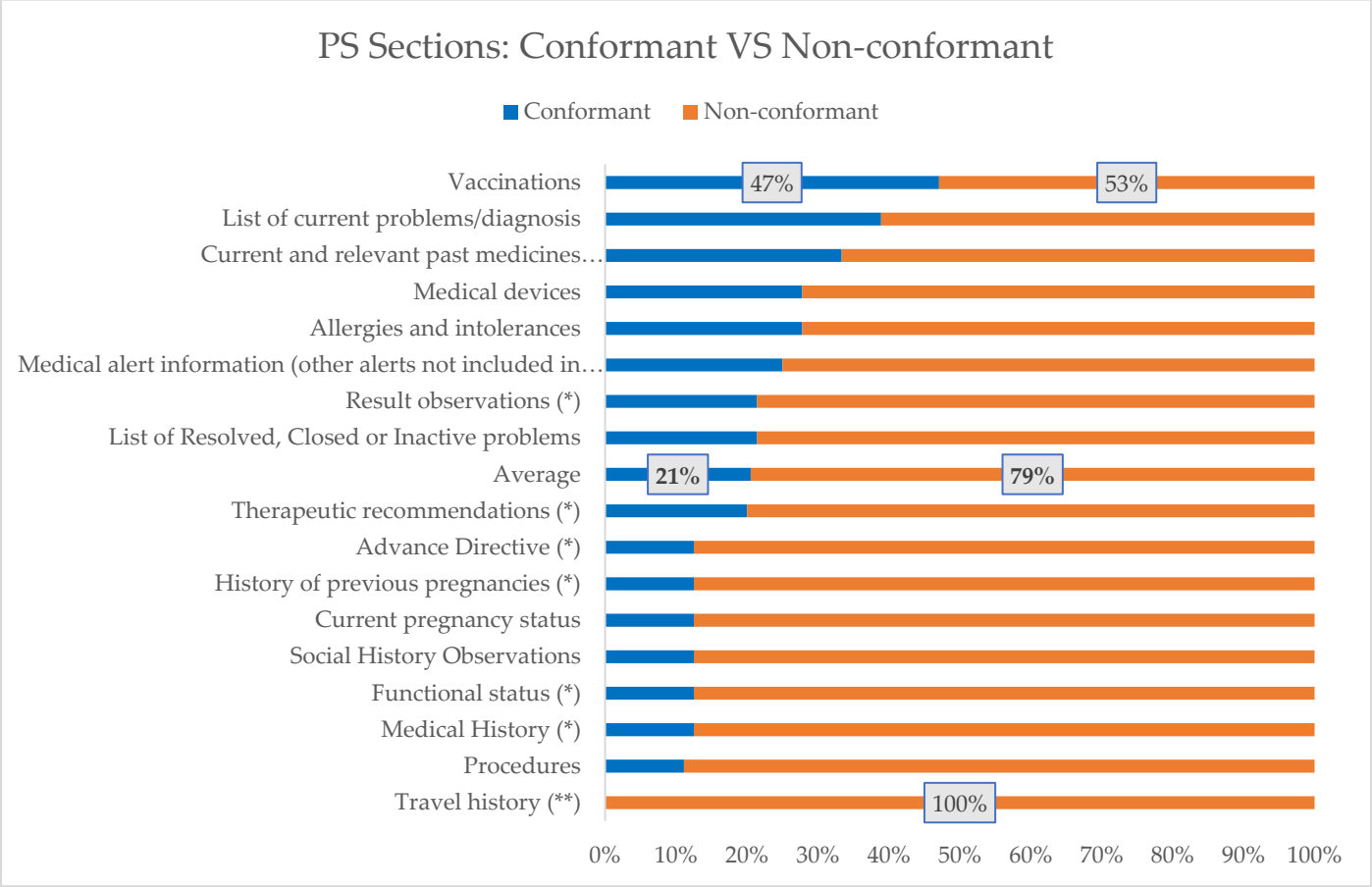
(4) Source of information is structured, but structure is not compatible with eHDSI CDA Implementation Guides – structure issue. For example: the "Medical Devices and Implants" section is structured differently than the eHDSI CDA Implementation Guides.

(5) Source of information is coded with national code system, but mapping to MVC cannot be performed or will result in a clinically relevant loss of information – transcoding issue. This is also the situation when the data was mapped to the closest MVC value.

10.2.1.1 PS Questionnaire results

Of the 22 MS that took part in the survey 18 MS provided a response at Section level. Considering all 18 Sections of the Patient Summary "Patient clinical data" part, on average 21% of the MS resulted to be conformant, with a conformance rate ranging from a bottom of 0% for the section "Travel history" and a peak of 47% for the section "Vaccination". The overall conformance of the various sections, ranking from high to low, is represented in the following graphic:

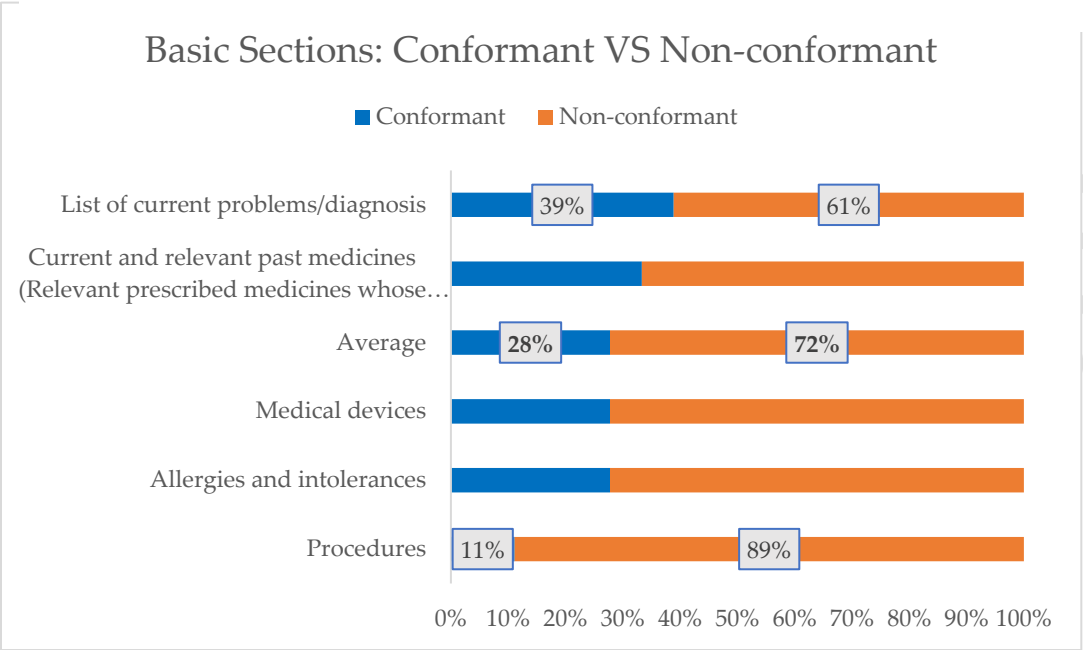
PS Sections: Conformant VS Non-conformant



10.2.1.2 PS Questionnaire Basic Sections analysis: Section level

To highlight the importance of the Basic Sections of the Patient Summary as described in the paragraph above, this document reports the analysis of the MS compliance grade to the Basic Sections in a dedicated paragraph, followed by the analysis conducted on the MS compliance grade to Data Elements associated to the Basic Sections. The same format is applied to the Extended Sections.

The average conformance rate for the Basic sections is 28%, ranging from 11% for the section



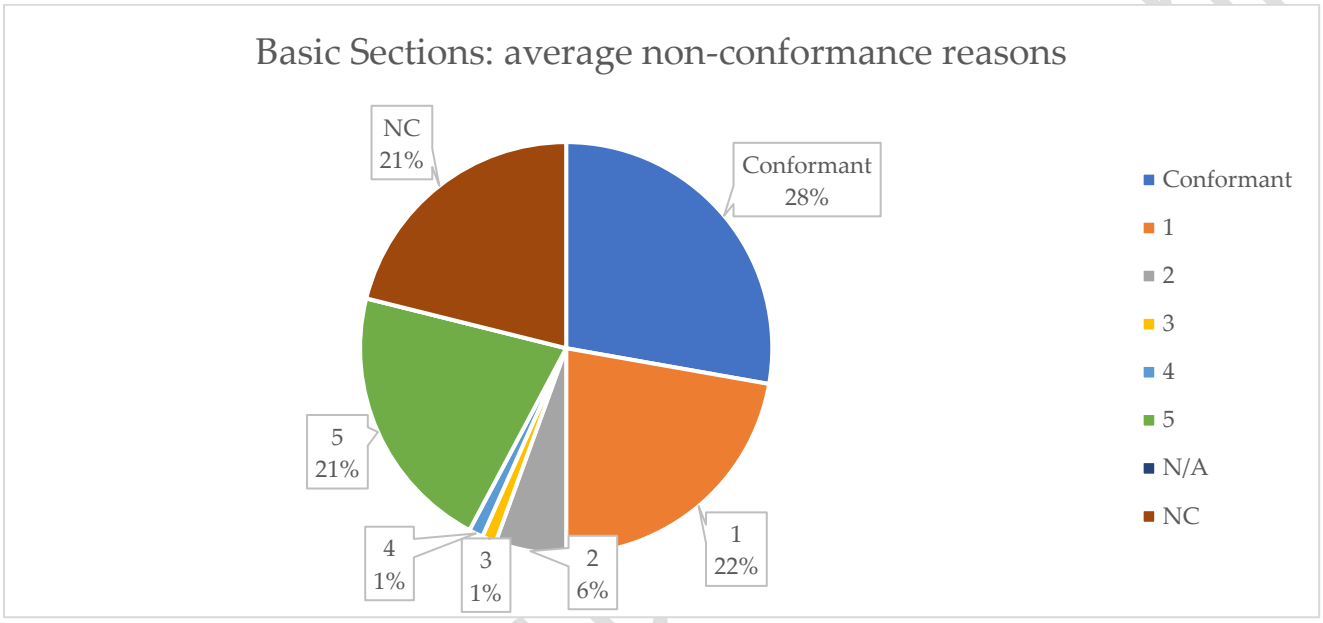
"Procedures" to 39% for the section "List of current problem/diagnosis". The following graphic shows the results for all the Basic Sections.

To investigate the roots of non-conformance, a deep analysis on the non-conformance reasons as classified in the MyHealth@EU Requirements Catalogue was conducted on each Basic Section.

The first evidence that emerged from this analysis was a relevant data quality issue due to ambiguous responses provided by the MS. For example, some MS provided multiple non-conformance reasons for the same Basic Section (e.g. "1/2" or "2/3/4/5", etc.) or answered "non-conformant" without specifying any non-conformance reason. The same data quality issue affected the Extended Sections. This criticality led the authors of the analysis to associate some MS responses to a non-specific non-conformance category labelled as "Non-conformant (NC)".

The most relevant specific non-conformance reason on average for the Basic Sections resulted to be reason n. 1 "Source of information is not available" (22%), followed by reason n. 5 "Source of information is coded with national cod system, but mapping to MVC cannot be performed or will result in a clinically relevant loss of information - transcoding issue" (21%) and by the generic category "Non-conformant (NC)" (21%) that represents the ambiguous responses provided by some MS. The following graphic shows the overall distribution.

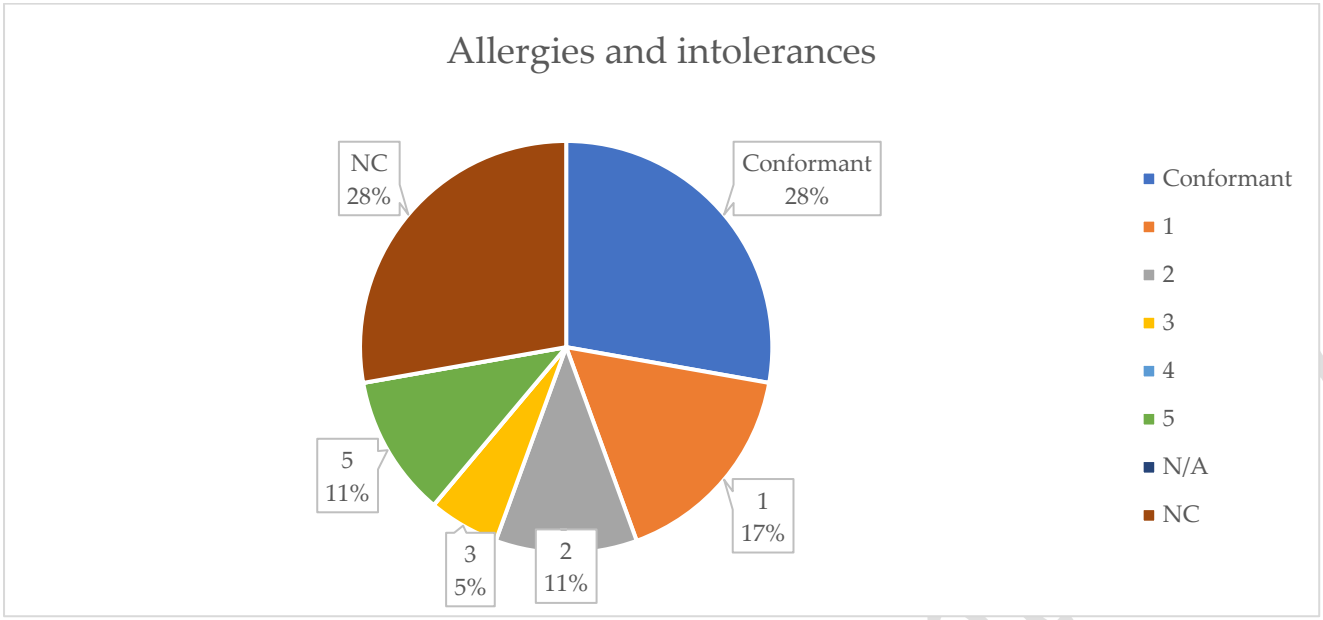
Basic Sections: average non-conformance reasons



The state of the art of non-conformance reasons for each specific Basic Section is reported in annex I.

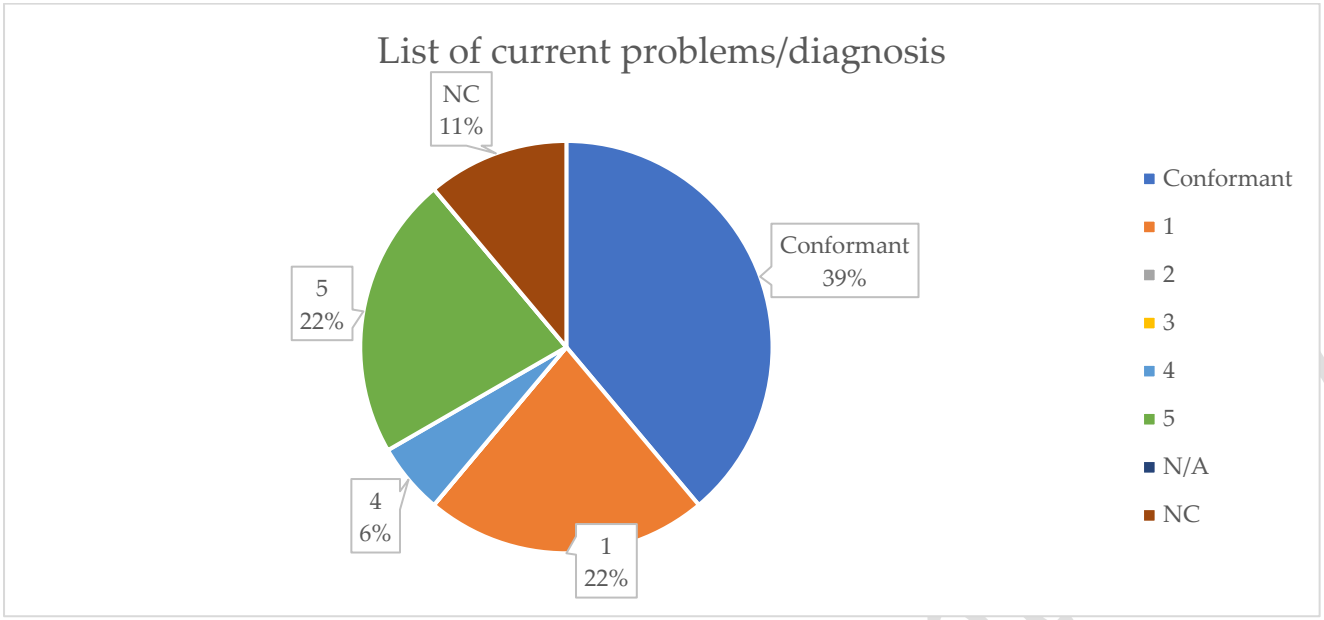
The section "Allergies and intolerances" is associated with a conformance rate of 28% and with a non-conformance rate of 72%. Considering the five non-conformance reasons, the non-conformance rate of 72% is composed by reason n. 1 for 17%, reason n. 2 for 11%, reason n. 3 for 6% and reason n. 5 for 11%. The remaining 28% of non-conformance was classified as generic Non-conformant (NC).

Allergies and intolerances



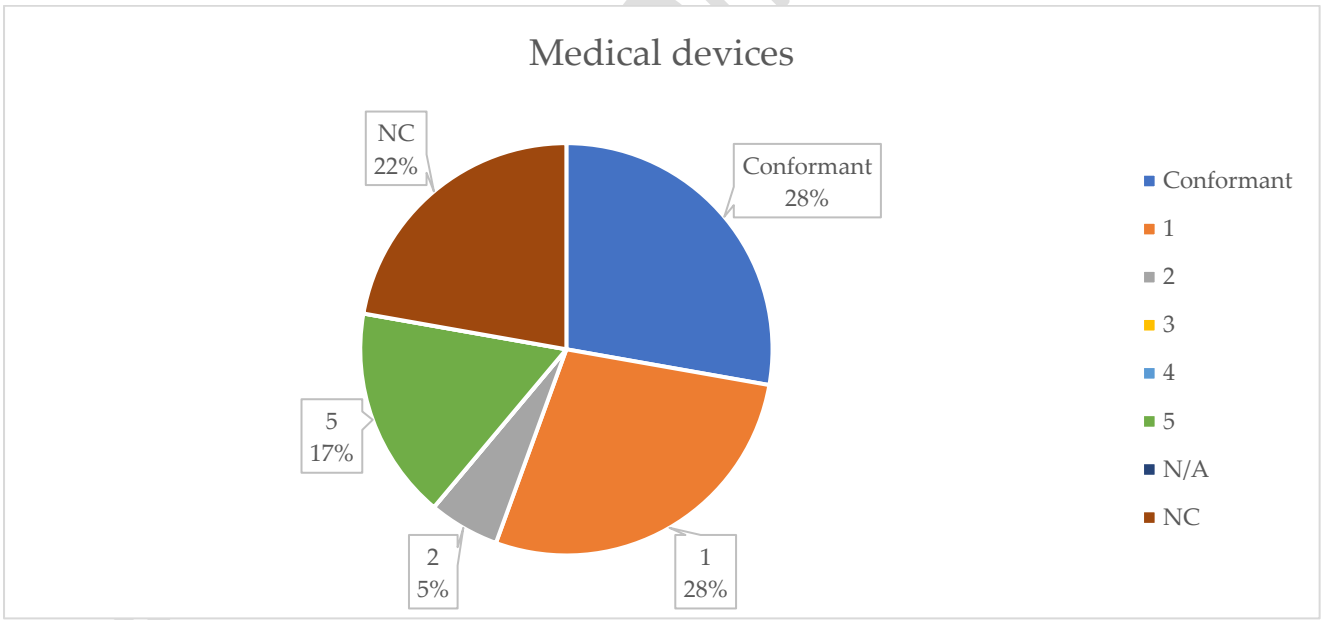
The section "List of current problems/diagnosis" is associated with a conformance rate of 39% and with a non-conformance rate of 61%. Considering the five non-conformance reasons, the non-conformance rate of 61% is composed by reason n. 1 and reason n. 5 for 22% both, followed by reason n. 4 for 6%. The remaining 11% of non-conformance was classified as generic Non-conformant (NC).

List of current problems/diagnosis



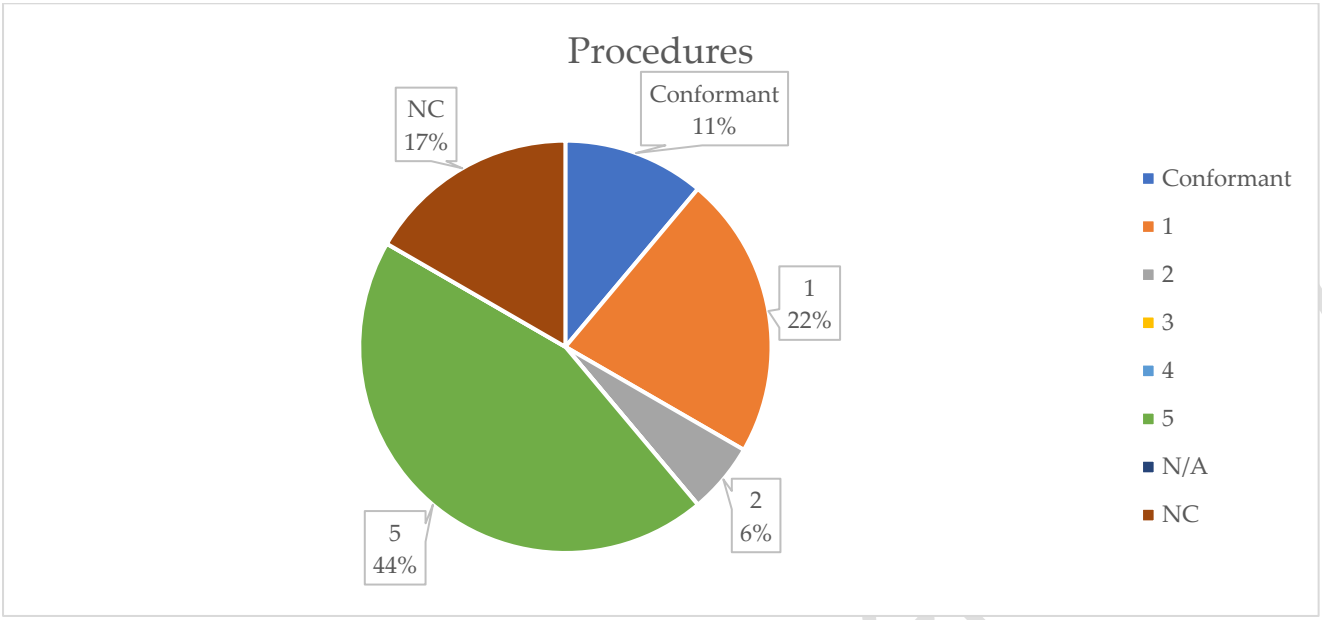
The section "Medical devices" is associated with a conformance rate of 28% and with a non-conformance rate of 72%. Considering the five non-conformance reasons, the non-conformance rate of 72% is composed by reason n. 1 for 28%, reason n. 5 for 17% and reason n. 2 for 5. The remaining 22% of non-conformance was classified as generic Non-conformant (NC).

Medical devices



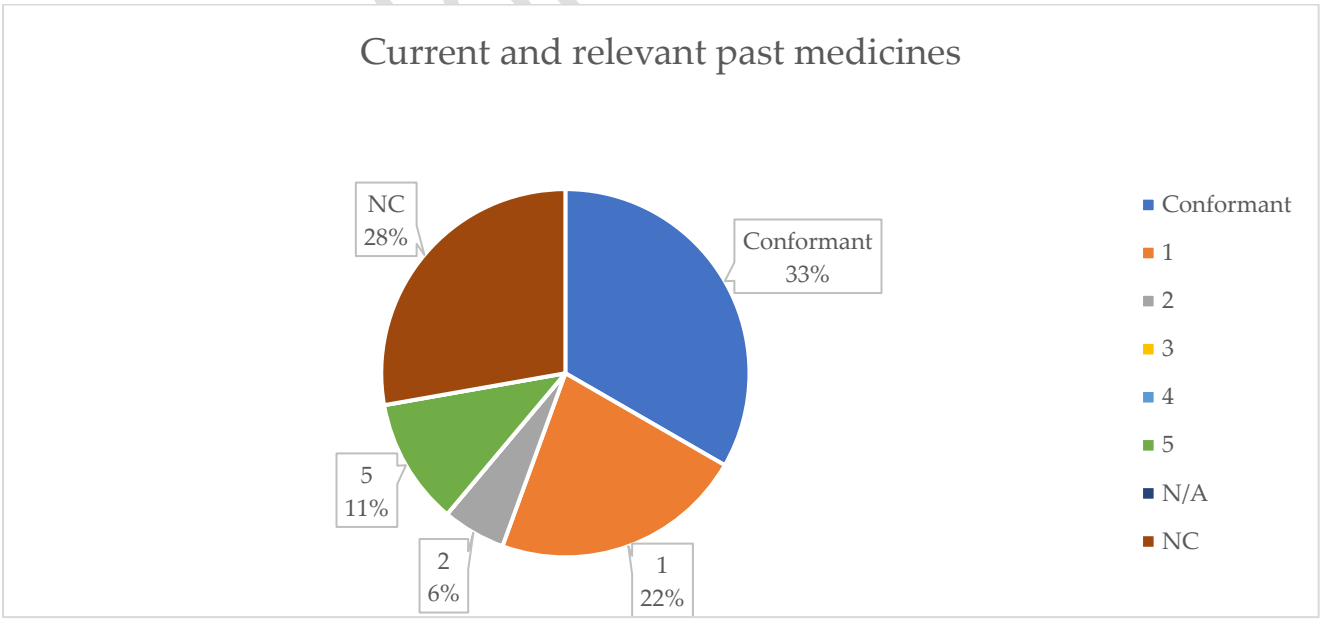
The section "Procedures" is associated with a conformance rate of 11% and with a non-conformance rate of 89%. Considering the five non-conformance reasons, the non-conformance rate of 89% is composed by reason n. 5 for 44%, reason n. 1 for 22%, reason n. 2 for 6%. The remaining 17% of non-conformance was classified as generic Non-conformant (NC).

Procedures



The section "Current and relevant past medicines (relevant prescribed medicines whose period of time indicated for the treatment has not yet expired whether it has been dispensed or not, or medicines that influence current health status or are relevant to a clinical decision)" is represented by a conformance rate of 33% and with a non-conformance rate of 67%. Considering the five non-conformance reasons, the non-conformance rate of 67% is composed of reason n. 1 for 22%, reason n. 5 for 11% and reason n. 2 for 6% and reason n. 5 for 11%. The remaining 28% of non-conformance was classified as generic Non-conformant (NC).

Current and relevant past medicines

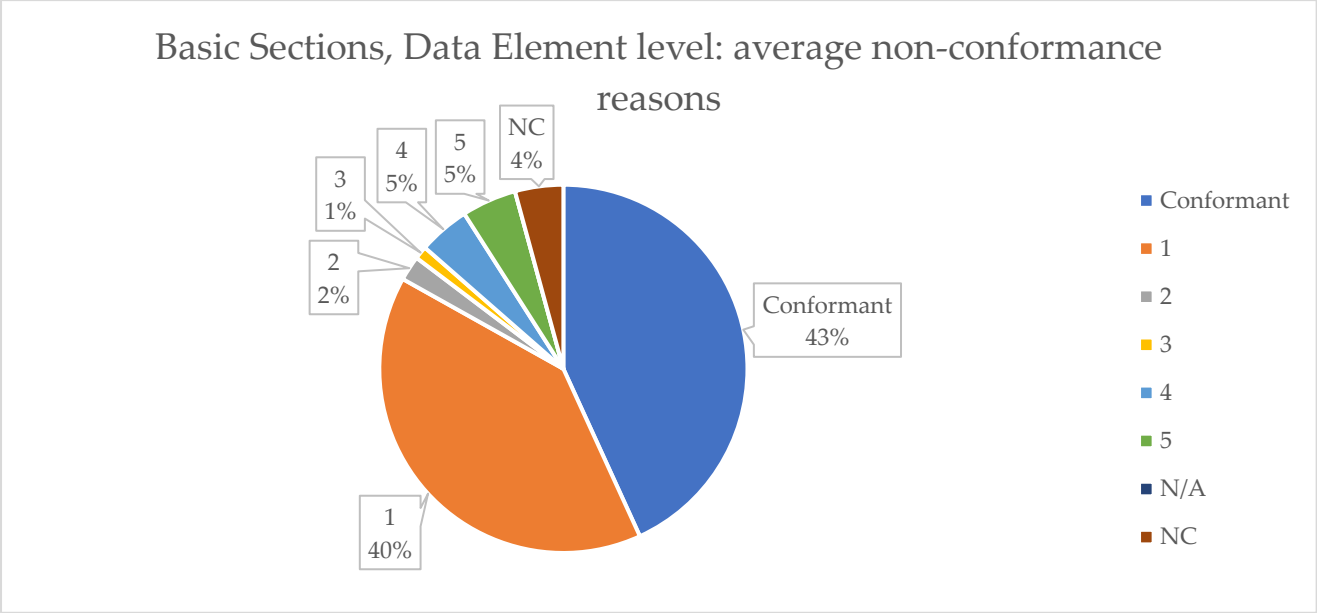


10.2.1.3 PS Questionnaire Basic Sections analysis: Data Element level

The investigation carried out to deepen the roots of non-conformance reasons at section level was put in place also at Data Element level. Basic Sections count 36 Data Element in total, distributed among the 5 Basic Sections.

The overall state of the art at Data Element level brings out an average conformance rate of 43% and a non-conformance rate of 57%. The prevalent non-conformance reason is n. 1 "Source of data is not available" which represents 40% of the cases, followed by reasons n. 4 and n. 5 accounting for 5% both, reason n. 2 (2%) and reason n. 3 (1%). The non-specific response "Non-conformant (NC)" was associated with 4% of MS responses on average.

Basic Sections, Data Element level: average non-conformance reasons

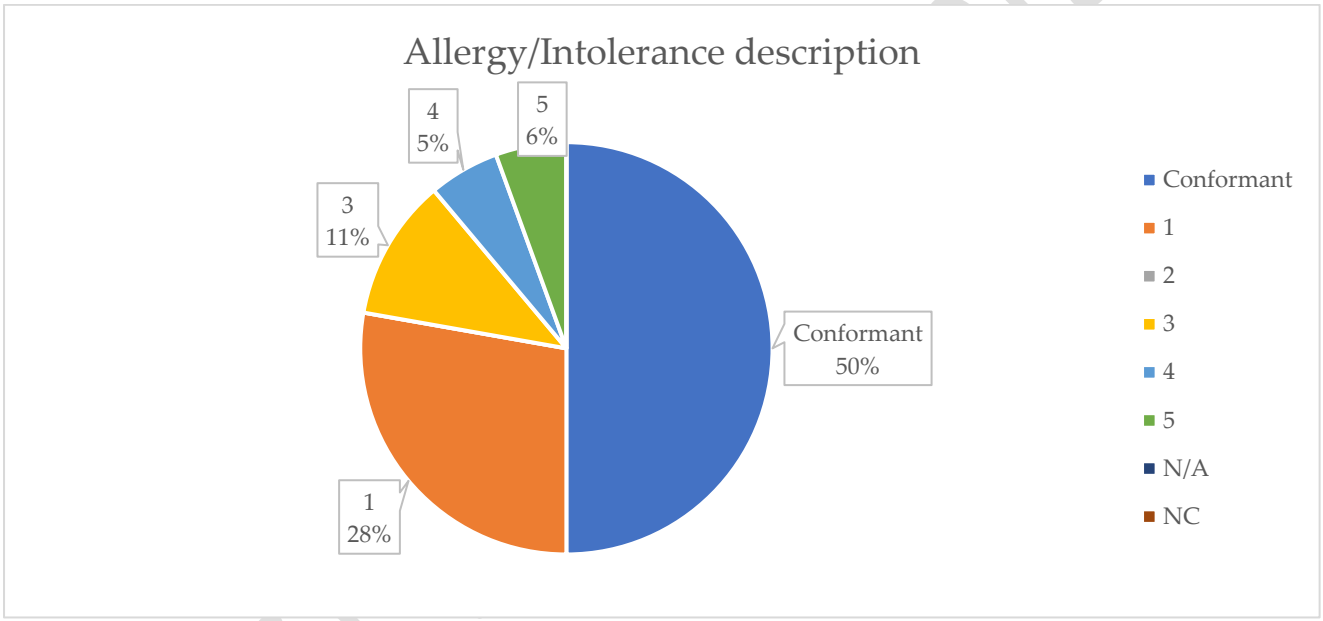


In the following pages the situation of the non-conformance reasons for each Data Element is reported.

The Data Elements "Allergy/Intolerance description", "Type of propensity", "Allergy manifestation", "Onset date", "End Date", "Severity", "Criticality", "Status", "Certainty", "Allergen description", "Allergen code" are part of the Basic Section "Allergies and intolerances".

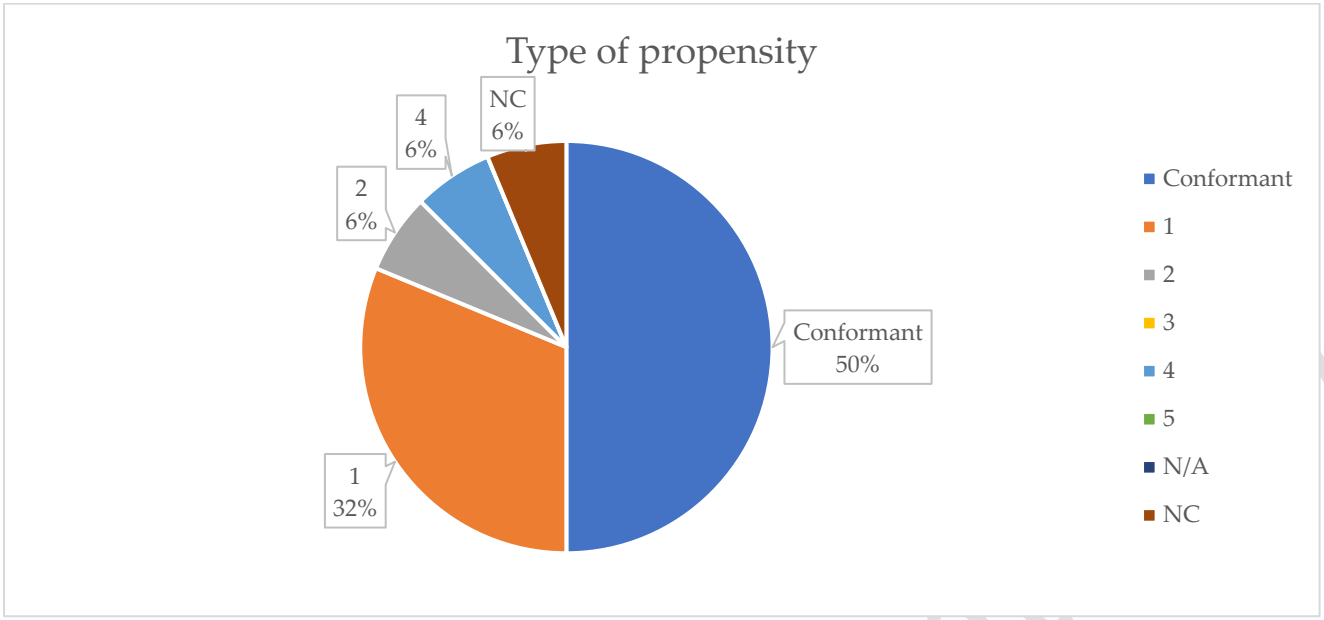
"Allergy/Intolerance description" has a conformance rate of 50%. The non-conformance rate of 50% is represented by reason n. 1 (28%), reason n. 3 (11%), reasons n. 4 and n. 5 for 6% both.

Allergy/Intolerance description



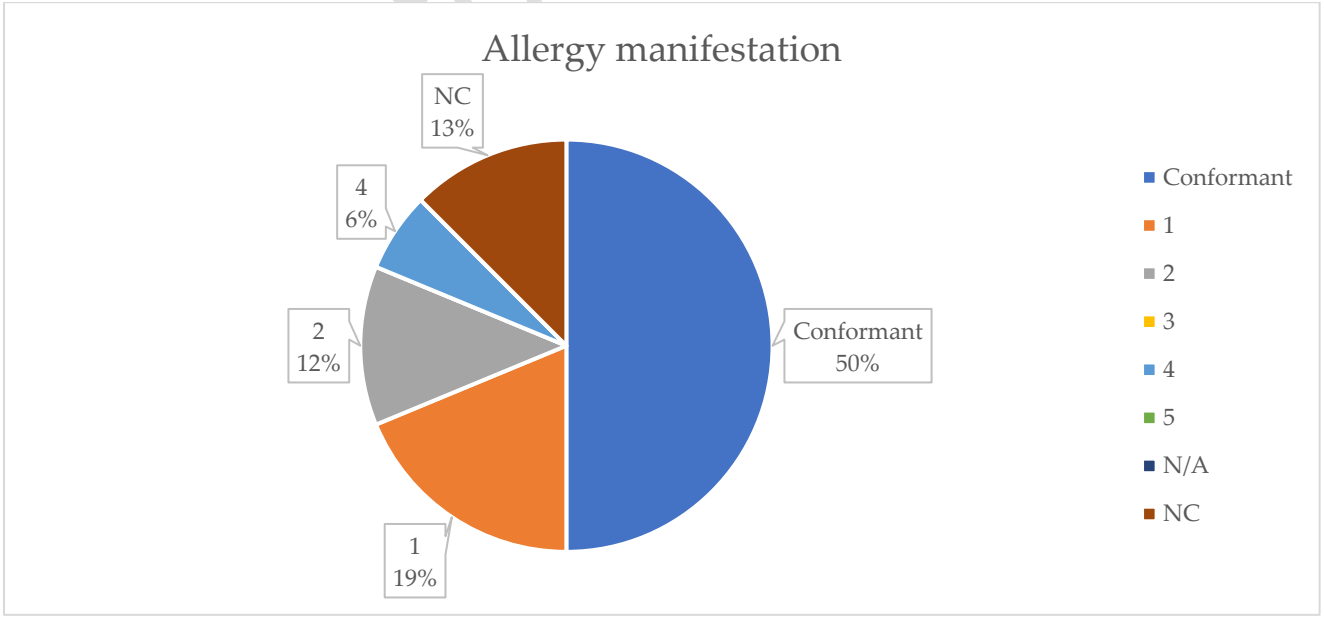
"Type of propensity" has a conformance rate of 50%. The non-conformance rate of 50% is represented by reason n. 1 (32%), while reasons n. 4, n. 5 and non-specific reason NC account for 6% each one.

Type of propensity



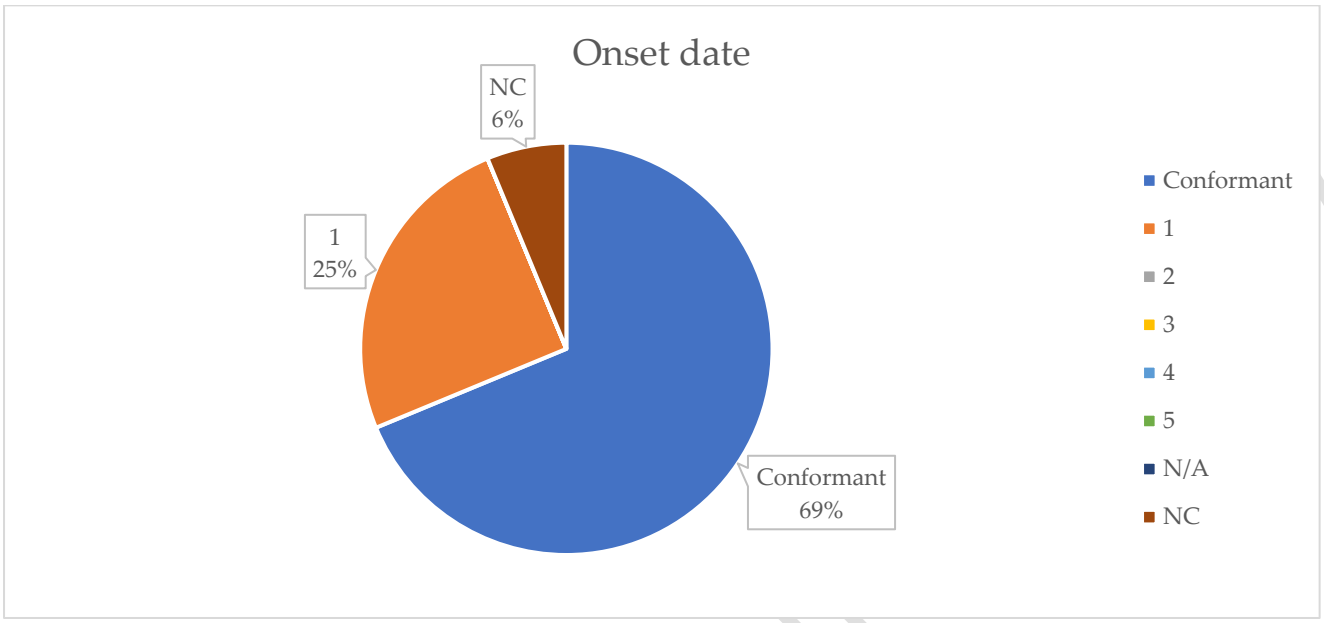
"Allergy manifestation" has a conformance rate of 50%. The non-conformance rate of 50% is represented by reason n. 1 (19%), reason n. 2 (12%) and reasons n. 4 (6%). NC represent the 13% of the MS responses.

Allergy manifestation



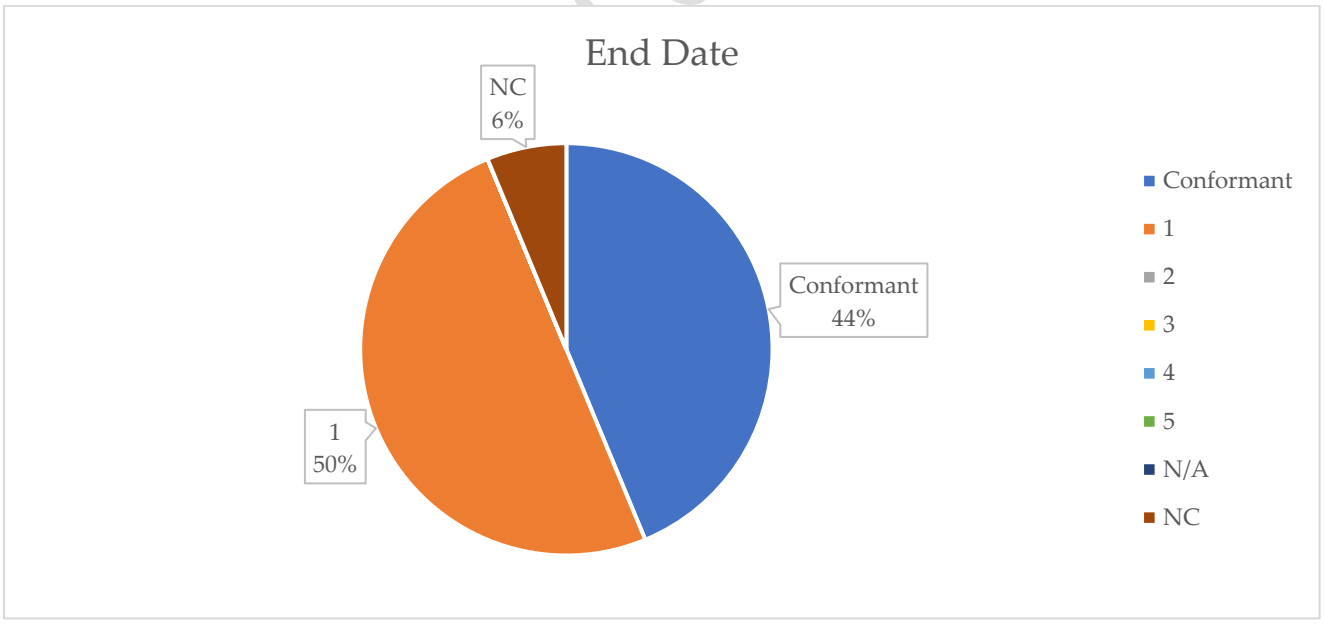
"Onset date" has a conformance rate of 69%. The non-conformance rate of 31% is represented by reason n. 1 25%), while the remaining 6% non-conformance responses are classified as NC.

Onset date



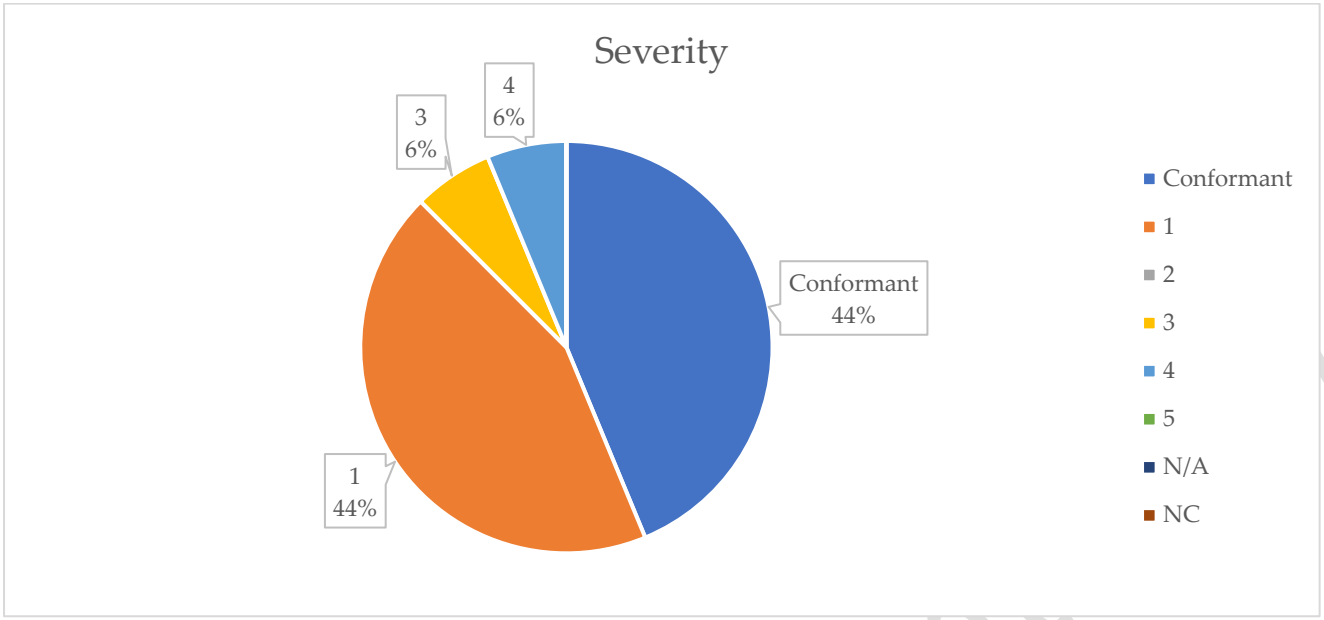
"End Date" has a conformance rate of 44%. The non-conformance rate of 56% is represented by reason n. 1 50%), while the remaining 6% non-conformance responses are classified as NC.

End date



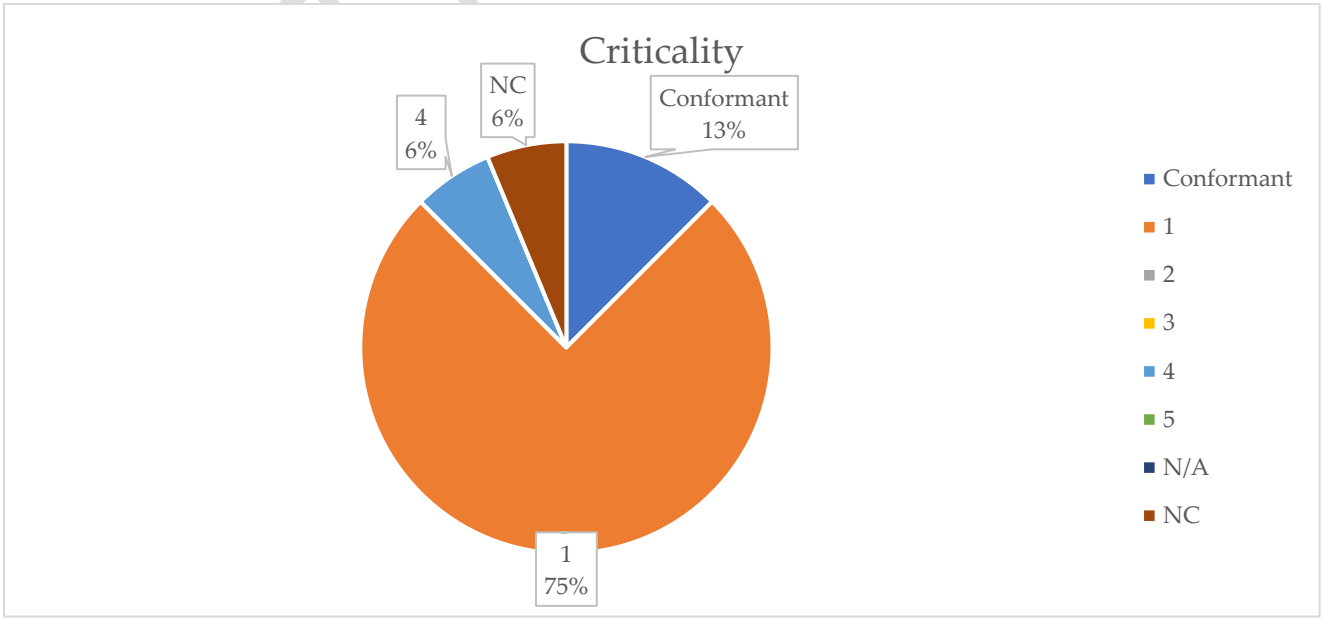
"Severity" has a conformance rate of 44%. The non-conformance rate of 56% is represented by reason n. 1 (44%), reasons n. 3 and n. 4 for 6% both.

Severity



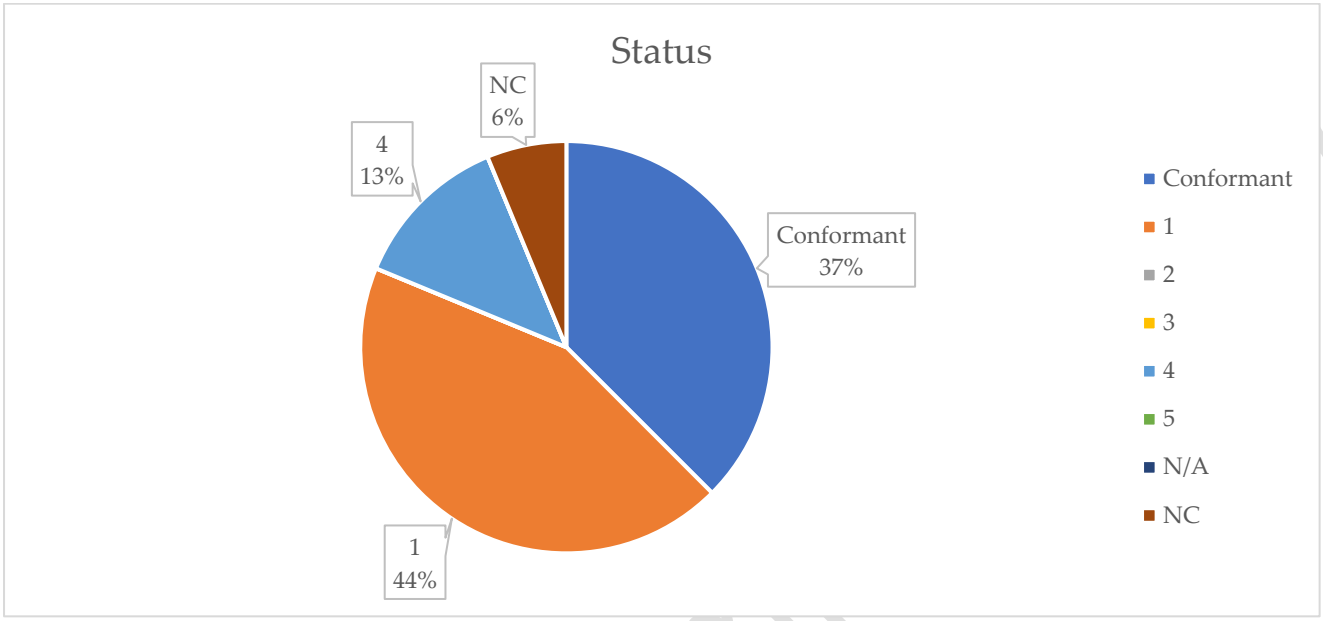
"Criticality" has a conformance rate of 13%. The non-conformance rate of 87% is represented by reason n. 1 (75%), reason n. 4 (6%) while the remaining 6% non-conformance responses are classified as NC.

Criticality



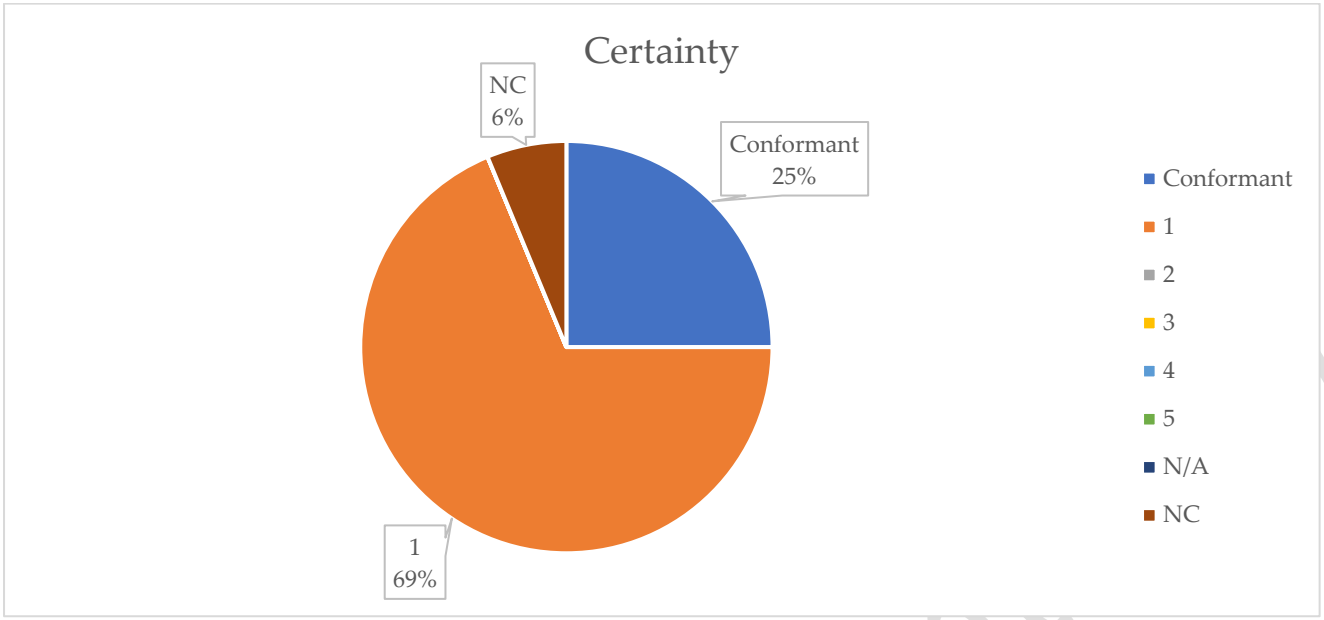
"Status" has a conformance rate of 37%. The non-conformance rate of 63% is represented by reason n. 1 (44%), reason n. 4 (13%) while the remaining 6% non-conformance responses are classified as NC.

Status



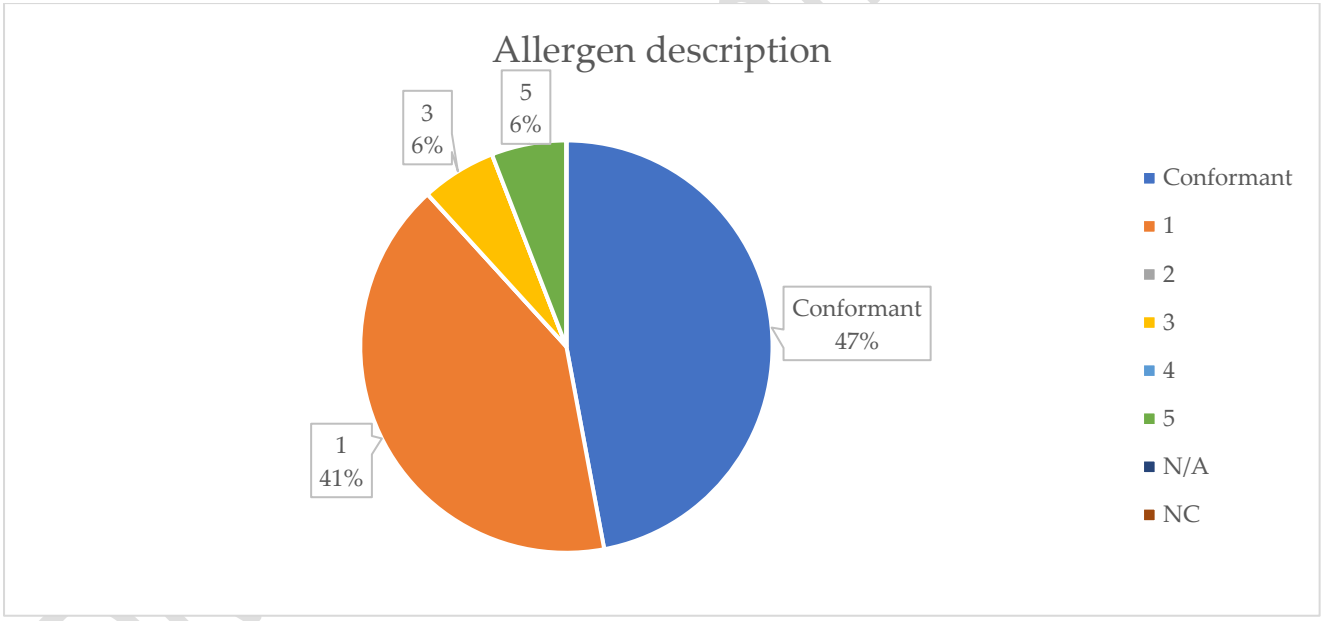
"Certainty" has a conformance rate of 25%. The non-conformance rate of 75% is represented by reason n. 1 (69%), while the remaining 6% non-conformance responses are classified as NC.

Certainty



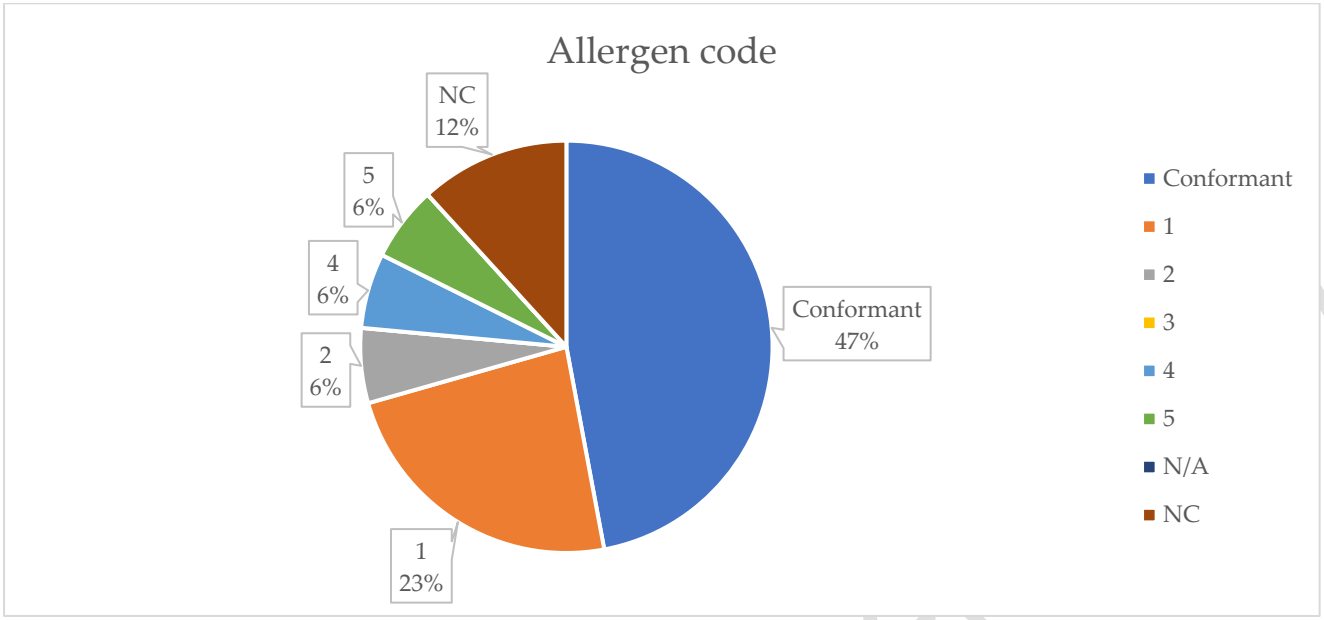
"Allergen description" has a conformance rate of 47%. The non-conformance rate of 53% is represented by reason n. 1 (41%), while reasons n. 3 and n. 5 account for 6% both.

Allergen description



"Allergen code" has a conformance rate of 47%. The non-conformance rate of 53% is represented by reason n. 1 (23%), reasons n. 2, n. 4 and n. 5 accounts for 6% each one. The remaining 12% non-conformance responses are classified as NC.

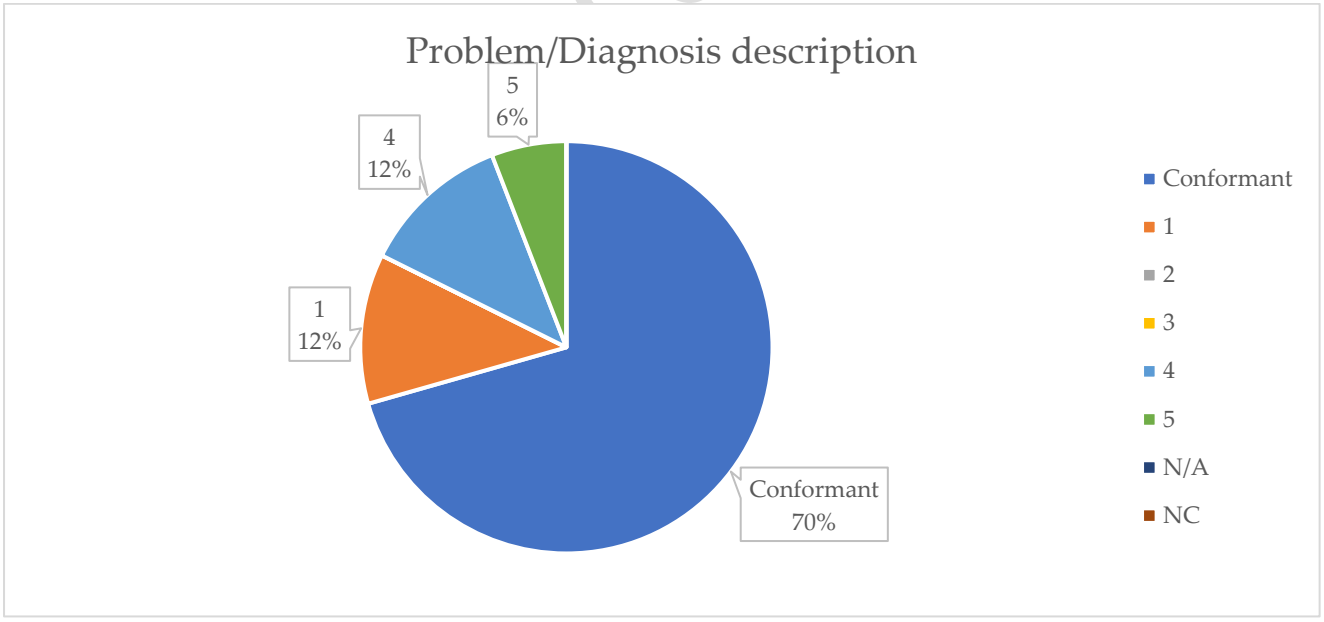
Allergen code



Data Elements: "Problem/Diagnosis description", "Problem code", "Onset date", "Diagnosis assertion status" are associated with Basic Section "List of current problems/diagnosis".

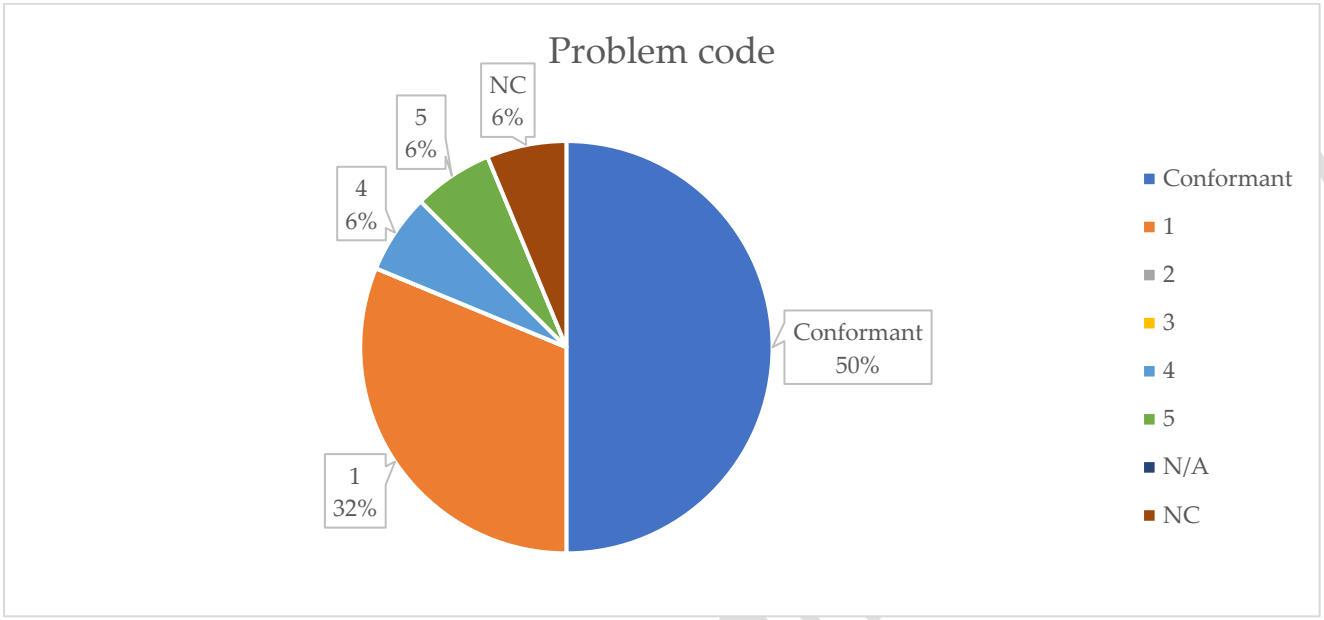
"Problem/Diagnosis description" is associated with a conformance rate of 70%. Non-conformance reasons resulted to be as follows: reason n. 1 (12%), reason n. 4 (12%), reason n. 5 (6%).

Problem/Diagnosis description



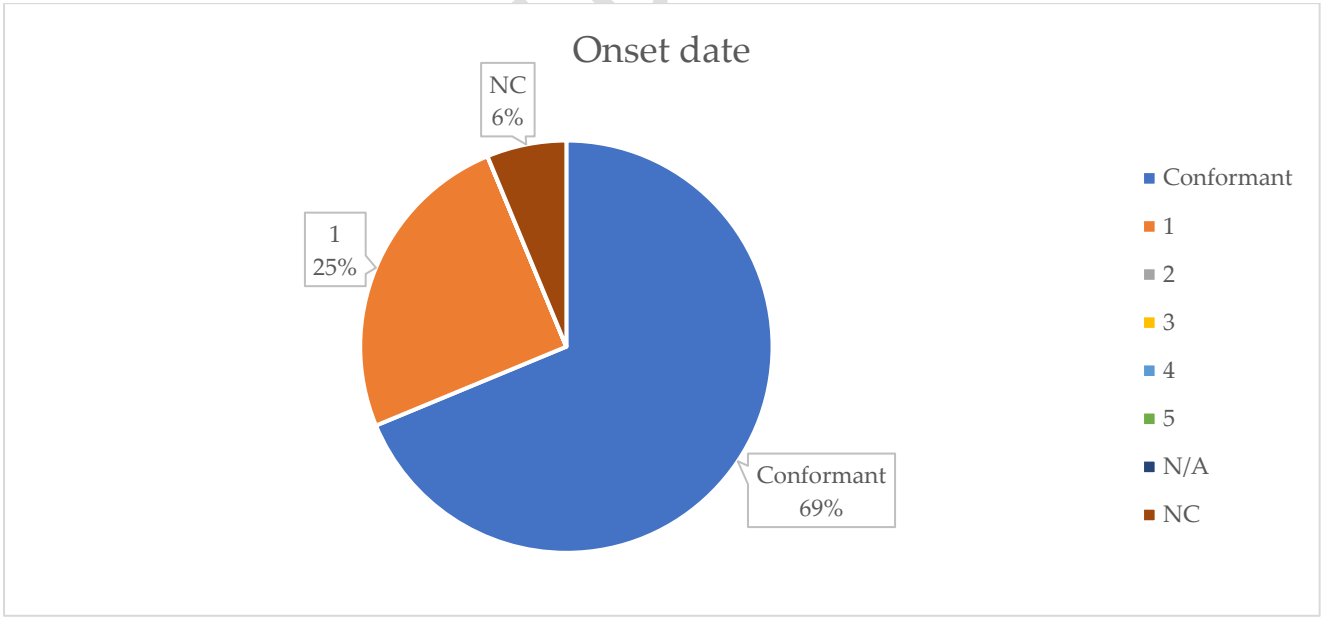
"Problem code" is associated with a conformance rate of 50%. Non-conformance reasons resulted to be as follows: reason n. 1 (32%), reason n. 4 (6%), reason n. 5 (6%), non-specific reason "Non-conformant (NC)" (6%).

Problem code



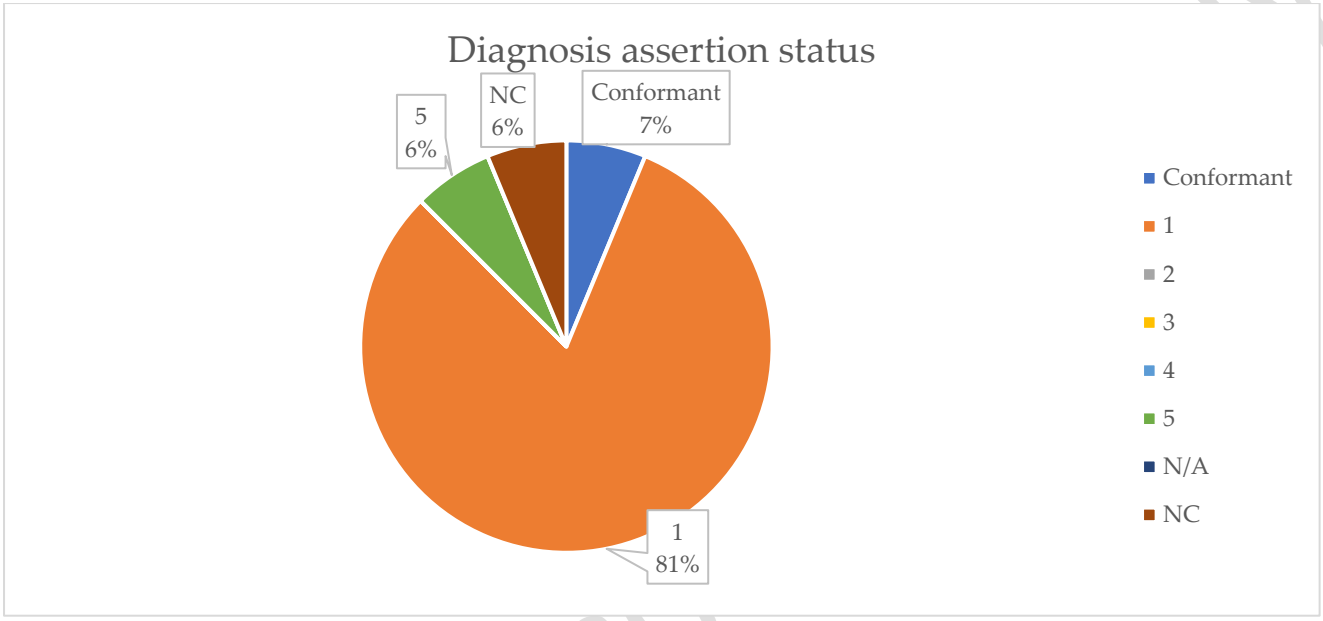
"Onset date" is associated with a conformance rate of 69%. Non-conformance reasons resulted to be as follows: reason n. 1 (25%), non-specific reason "Non-conformant (NC)" (6%).

Onset date



"Diagnosis assertion status" is associated with a conformance rate of 7%. Non-conformance reasons resulted to be as follows: reason n. 1 (81%), reason n. 5 (6%), non-specific reason "Non-conformant (NC)" (6%).

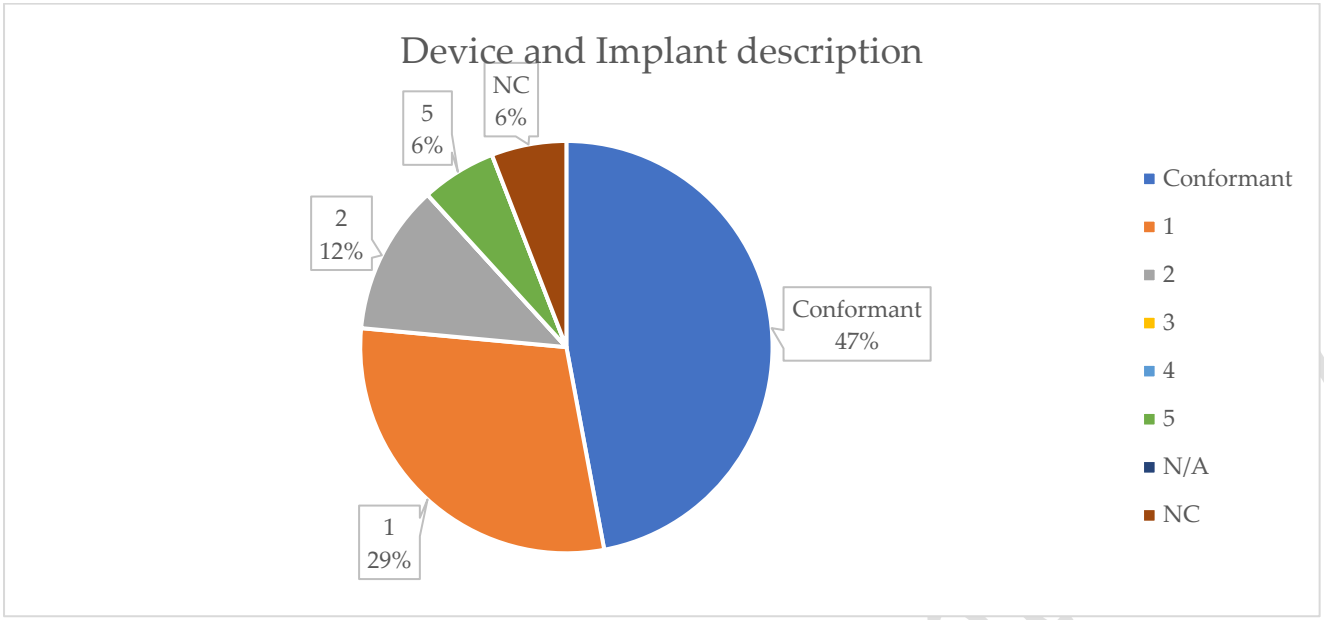
Diagnosis assertion status



The Data Elements: “Device and Implant description”, “Device unique identifier”, “Implant date”, “End date” are are part of the Basic Section “Medical devices”.

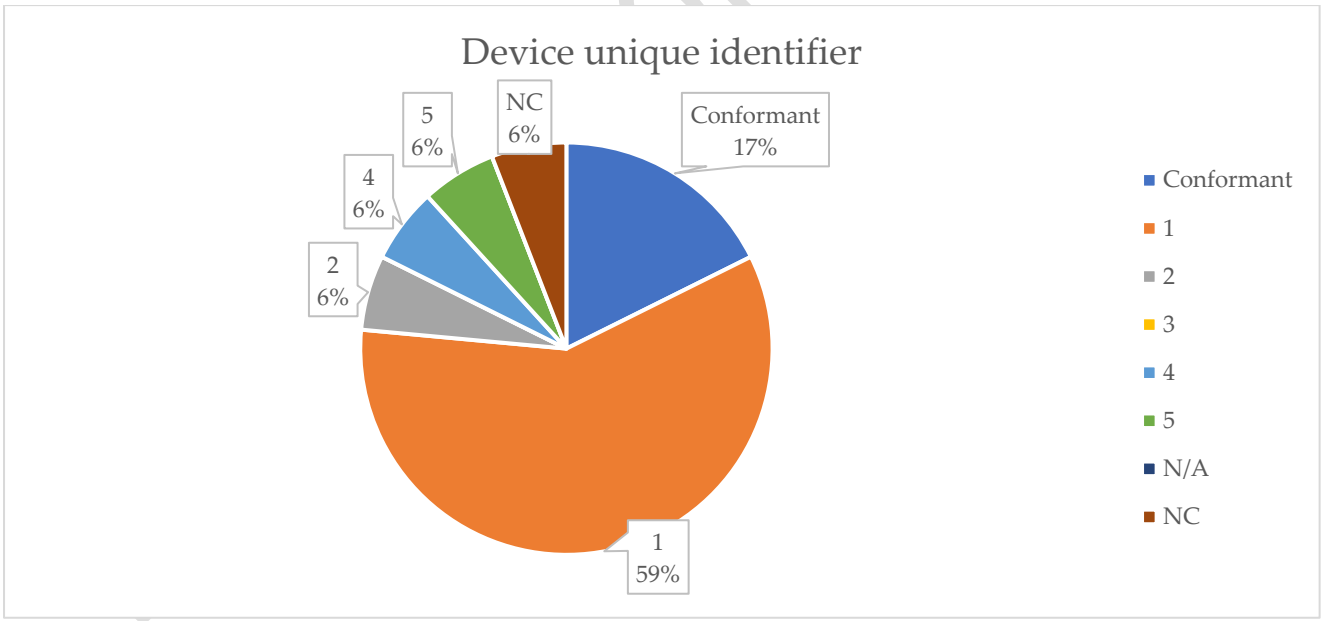
“Device and Implant description” is associated with a conformance rate of 47%. Non-conformance reasons resulted to be as follows: reason n. 1 (29%), reason n. 2 (12%), reason n. 5 (6%), non-specific reason “Non-conformant (NC)” (6%).

Device and Implant description



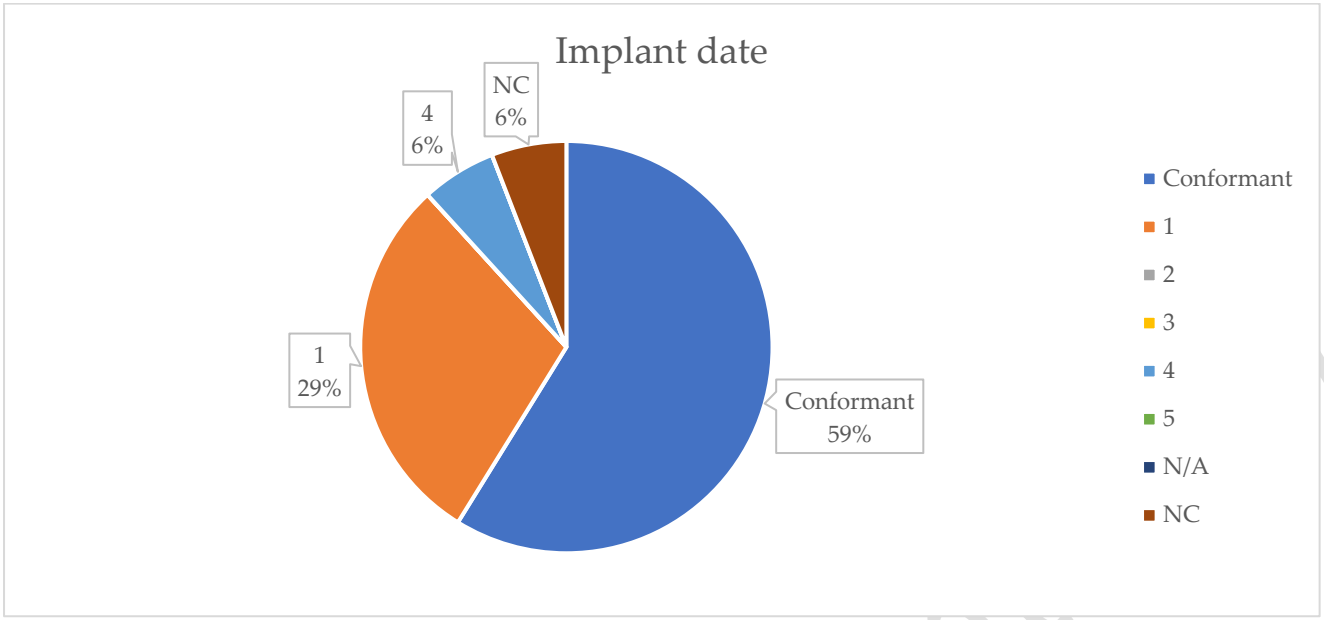
"Device unique identifier" is associated with a conformance rate of 17%. Non-conformance reasons resulted to be as follows: reason n. 1 (59%), reason n. 2 (6%), reason n. 4 (6%), reason n. 5 (6%), non-specific reason "Non-conformant (NC)" (6%).

Device unique identifier



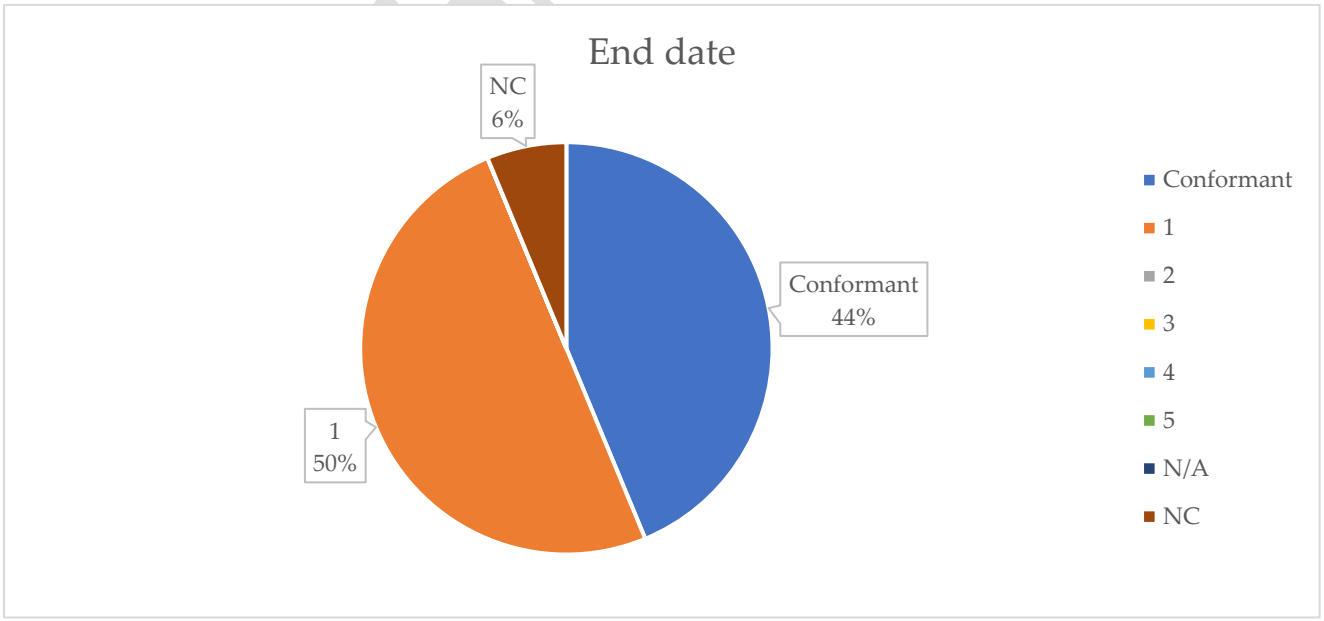
"Implant date" is associated with a conformance rate of 59%. Non-conformance reasons resulted to be as follows: reason n. 1 (29%), reason n. 4 (6%), non-specific reason "Non-conformant (NC)" (6%).

Implant date



"End date" is associated with a conformance rate of 44%. Non-conformance reasons resulted to be as follows: reason n. 1 (50%), non-specific reason "Non-conformant (NC)" (6%).

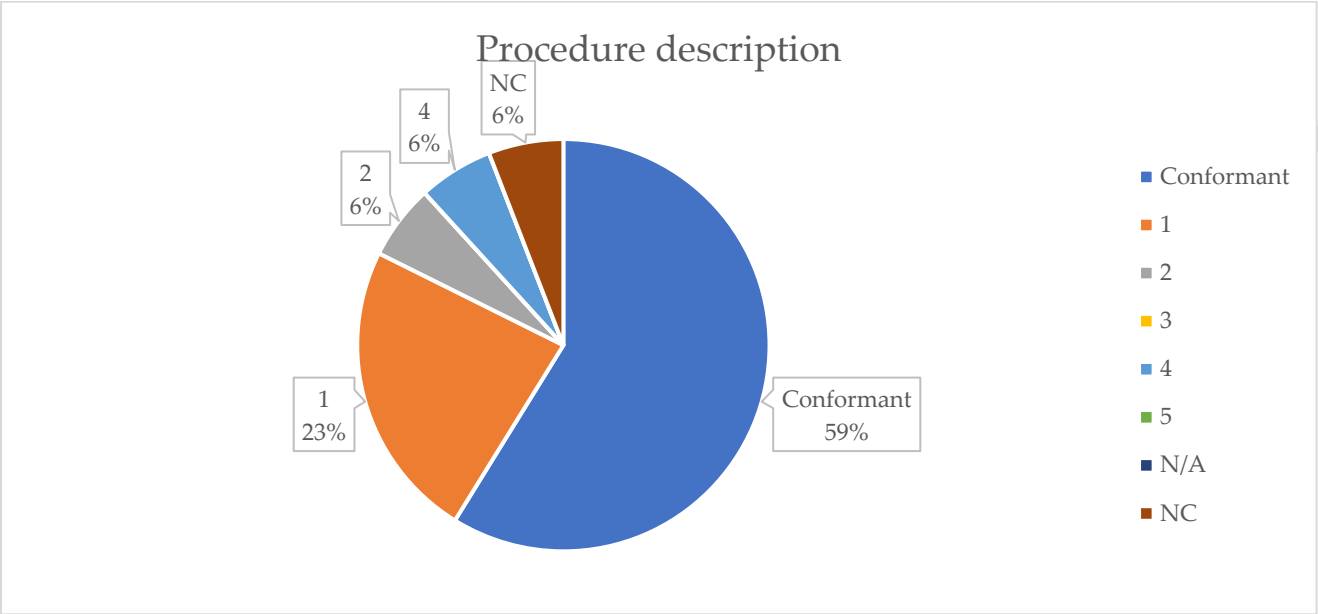
End date



The Data Elements "Procedure description", "Procedure code", "Body site", "Procedure date" are part of the Basic Section "Procedures".

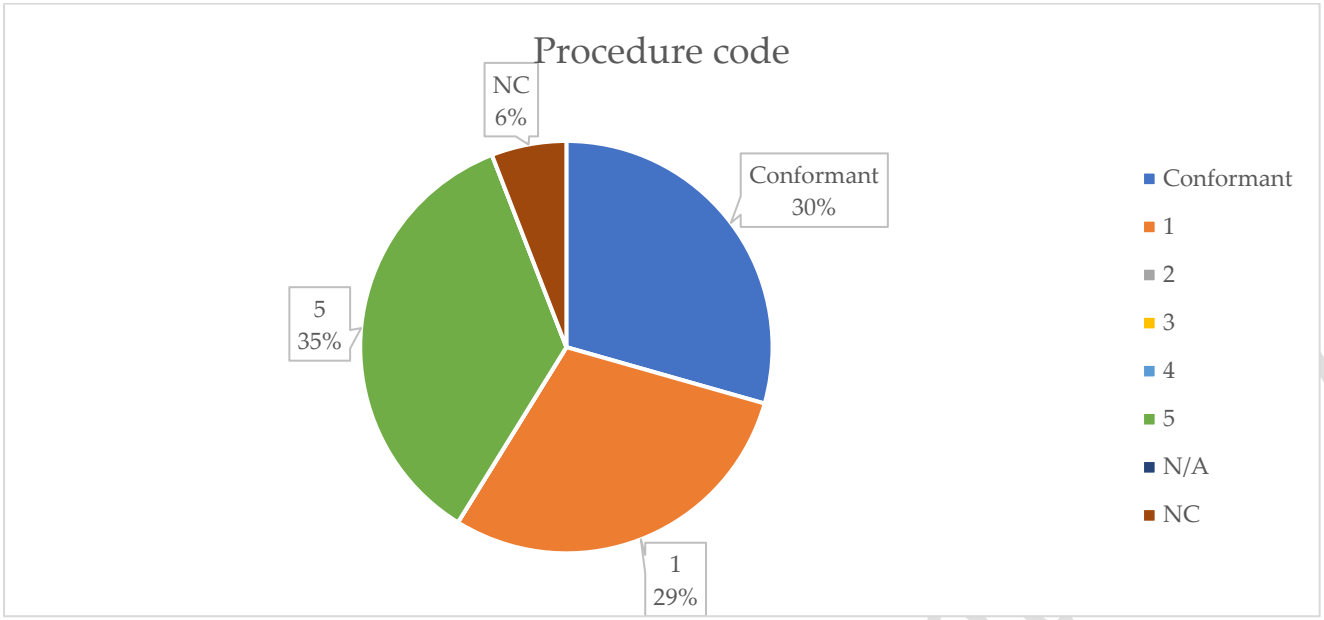
"Procedure description" is associated with a conformance rate of 59%. Non-conformance reasons resulted to be as follows: reason n. 1 (23%), reason n. 2 (6%), reason n. 4 (6%) and non-specific reason "Non-conformant (NC)" (6%).

Procedure description



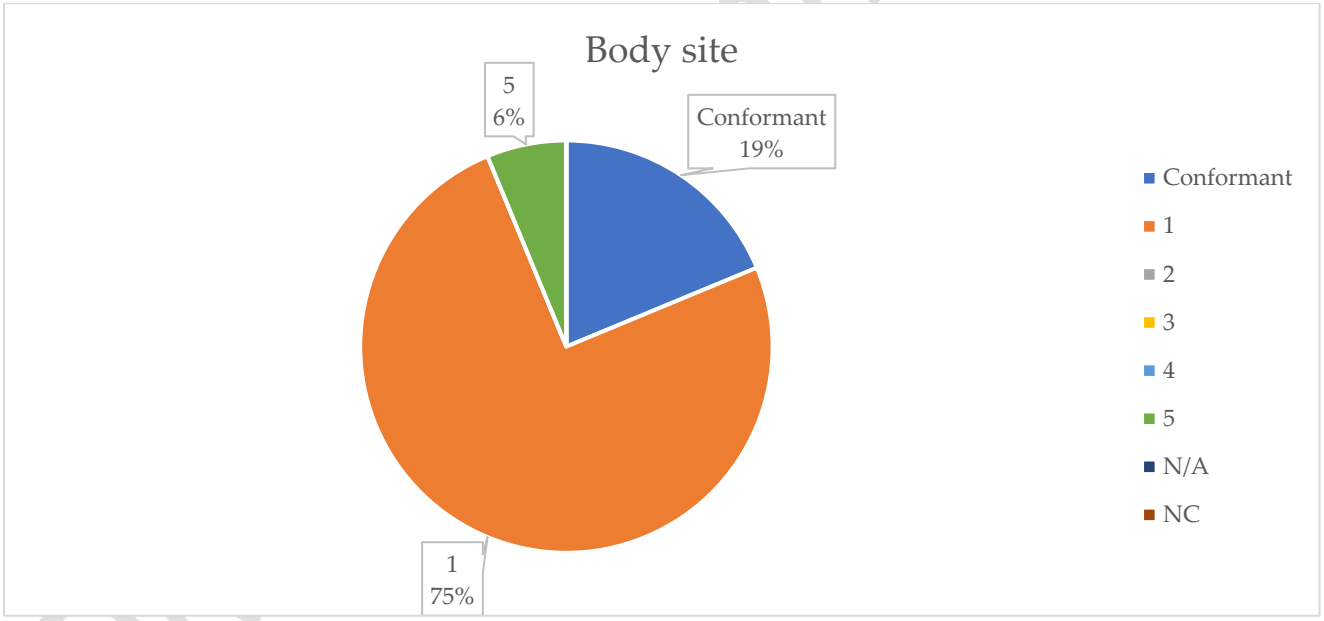
"Procedure code" is associated with a conformance rate of 30%. Non-conformance reasons resulted to be as follows: reason n. 1 (29%), reason n. 5 (35%), non-specific reason "Non-conformant (NC)" (6%).

Procedure code



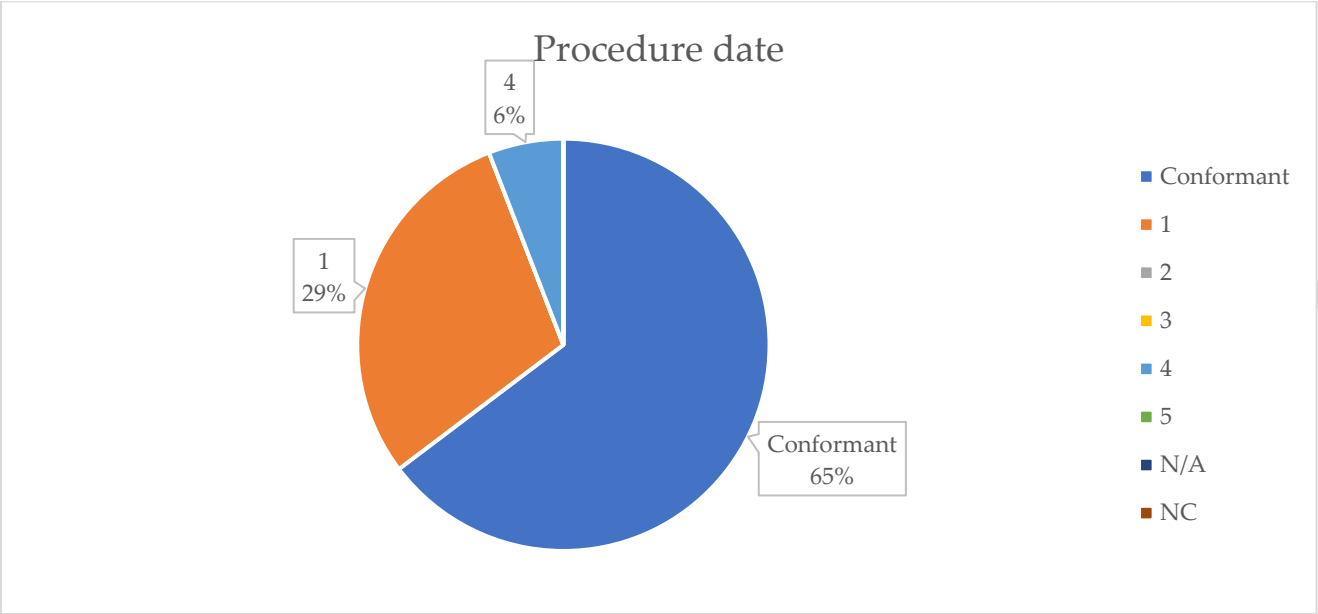
"Body site" is associated with a conformance rate of 19%. Non-conformance reasons resulted to be as follows: reason n. 1 (75%), reason n. 5 (6%).

Body site



"Procedure date" is associated with a conformance rate of 65%. Non-conformance reasons resulted to be as follows: reason n. 1 (29%), reason n. 4 (6%).

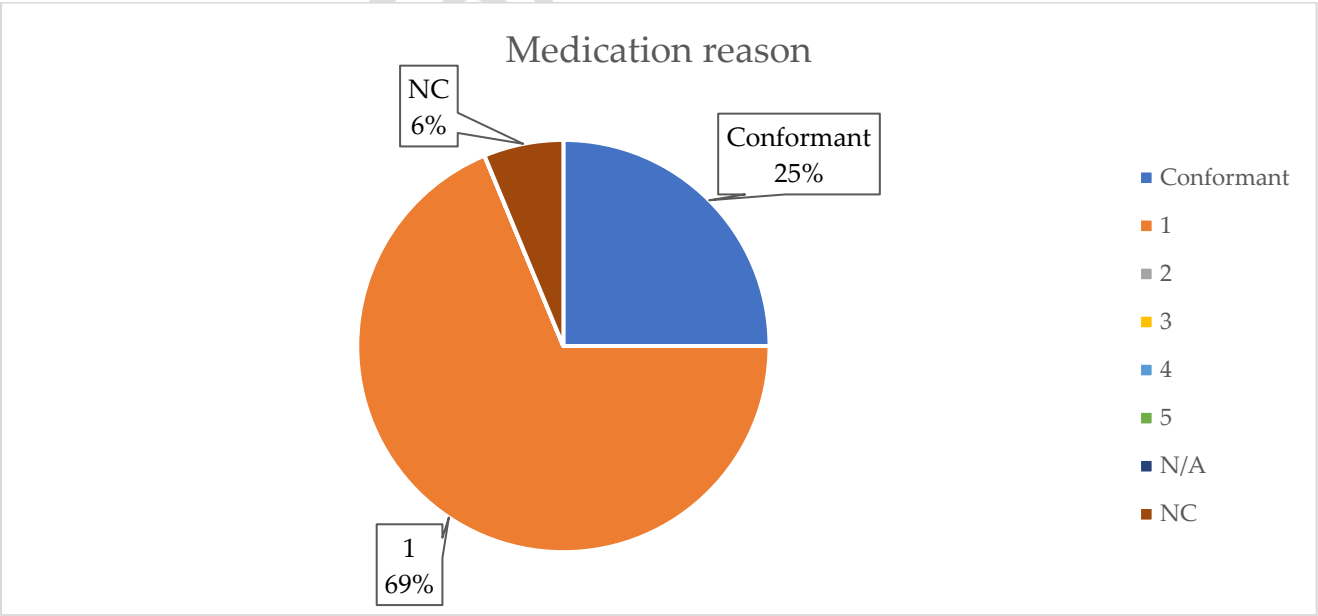
Procedure date



The Data Elements “Medication reason”, “Intended use”, “Brand name”, “Active ingredient(s)”, “Strength(s)”, “Pharmaceutical dose form”, “Dosage Regimen”, “Frequency of intakes”, “Timing of intakes”, “Duration of treatment”, “Date of onset of treatment”, “Medicine status”, “Route of administration” are part of the Basic Section "Current and relevant past medicines”.

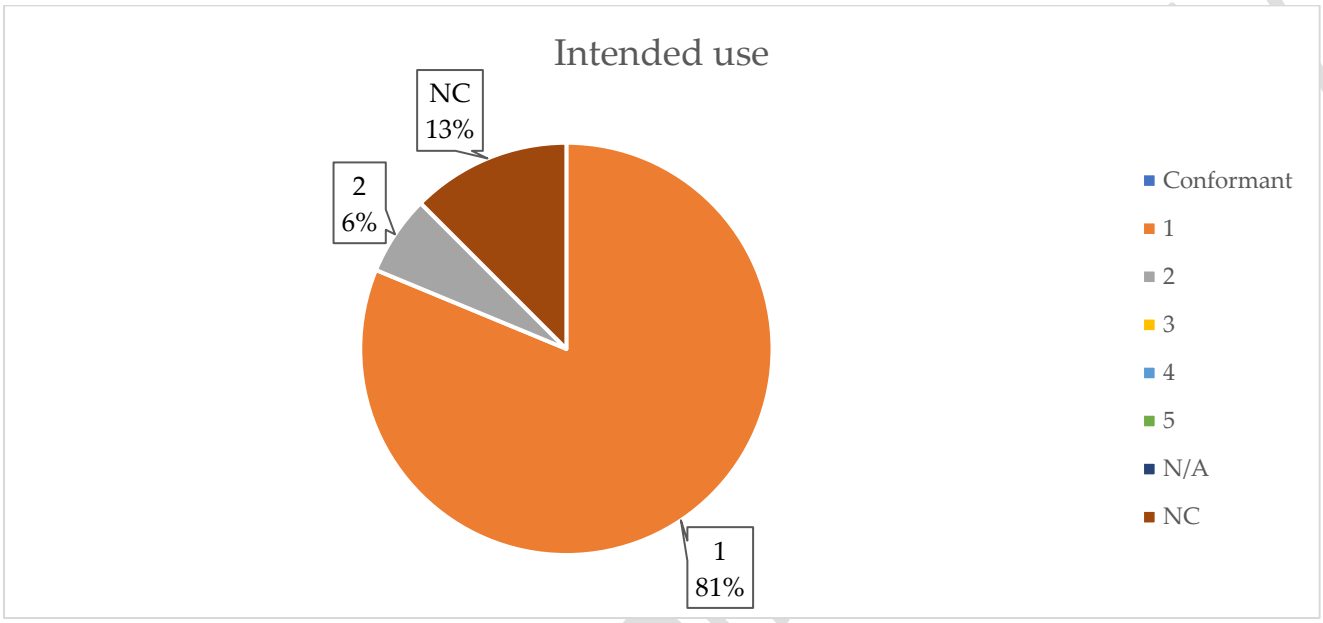
“Medication reason” is associated with a conformance rate of 25%. Non-conformance reasons resulted to be as follows: reason n. 1 (69%) and non-specific reason “Non-conformant (NC)” (6%).

Medication reason



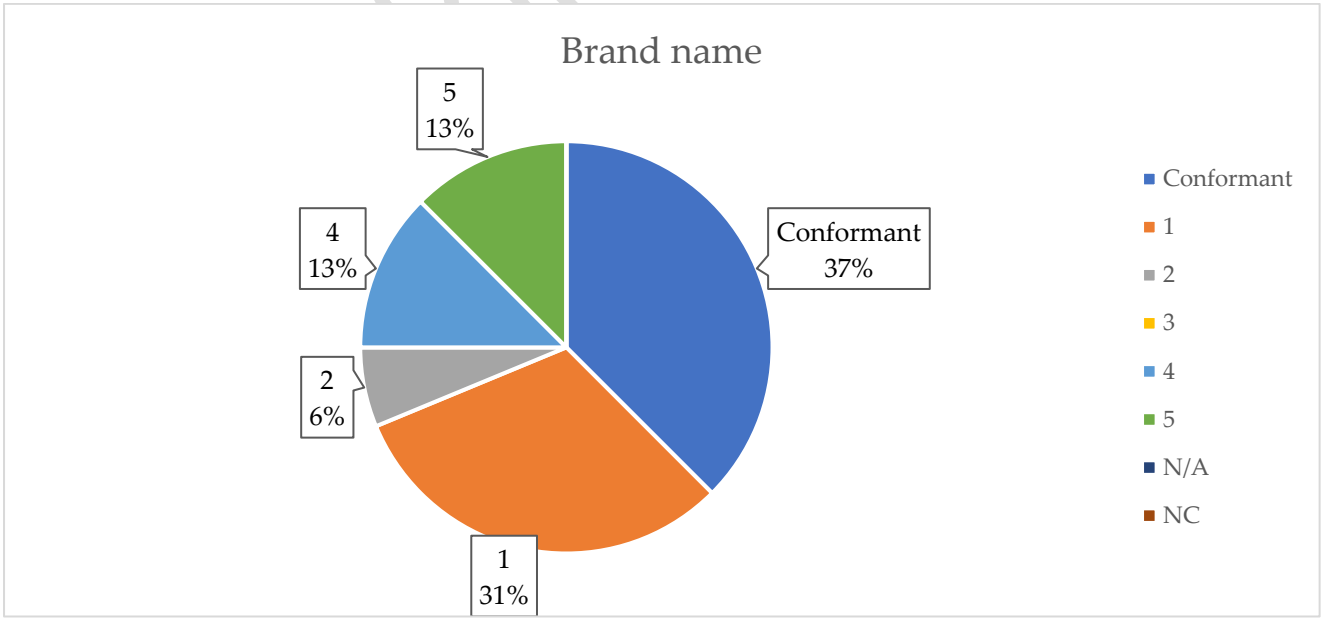
Regarding "Intended use" no MS responded to be conformant. Non-conformance reasons resulted to be as follows: reason n. 1 (81%), reason n. 2 (6%), non-specific reason "Non-conformant (NC)" (13%).

Intended use



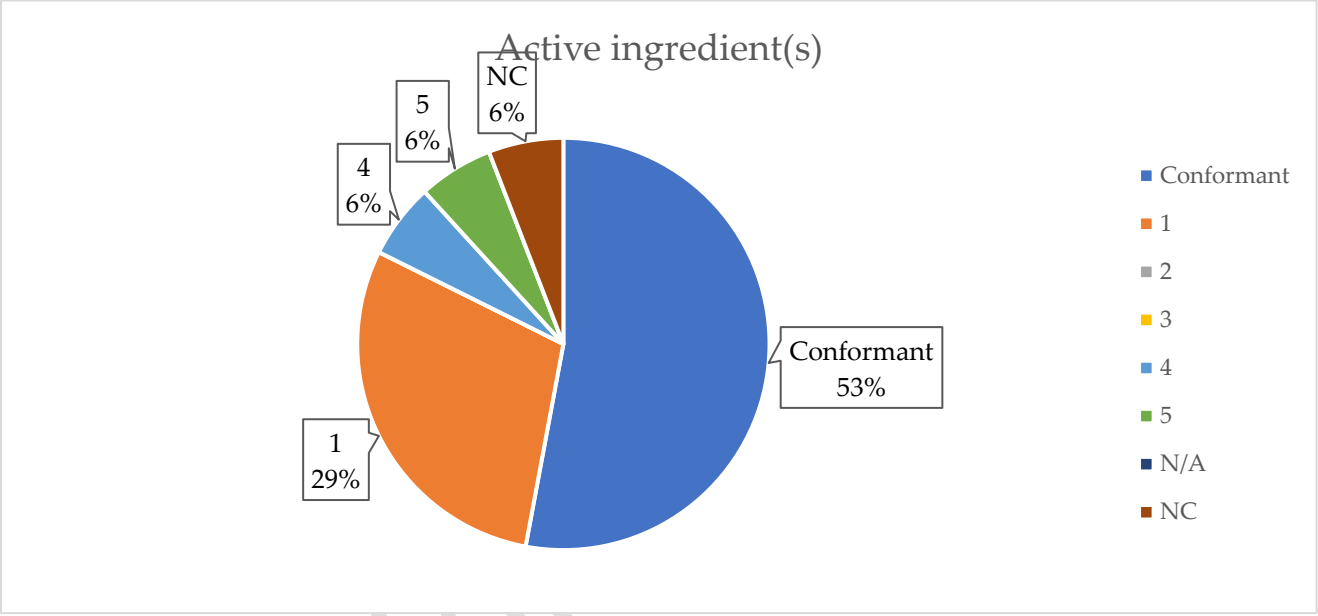
"Brand name" is associated with a conformance rate of 37%. Non-conformance reasons resulted to be as follows: reason n. 1 (31%), reason n. 2 (6%), reason n. 4 (13%), reason n. 5 (13%).

Brand name



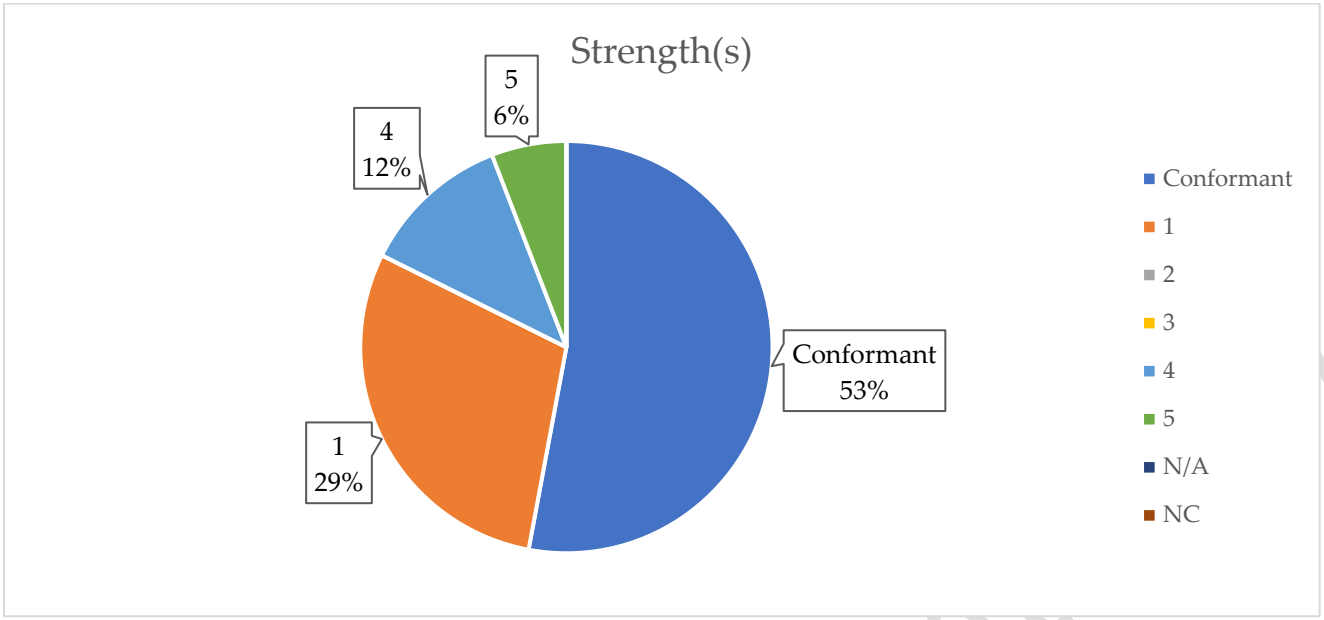
"Active ingredient(s)" is associated with a conformance rate of 53%. Non-conformance reasons resulted to be as follows: reason n. 1 (29%), reason n. 4 (6%), reason n. 5 (6%), non-specific reason "Non-conformant (NC)" (6%).

Active ingredient(s)



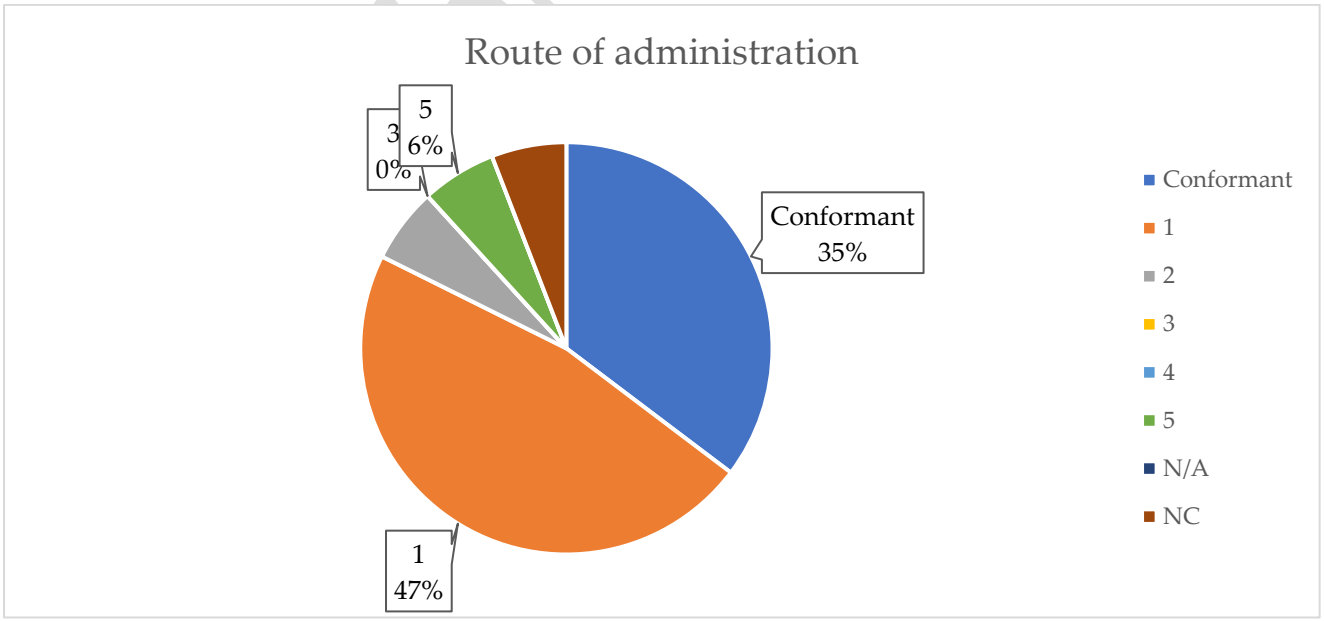
"Strength(s)" is associated with a conformance rate of 53%. Non-conformance reasons resulted to be as follows: reason n. 1 (29%), reason n. 4 (12%), reason n. 5 (6%).

Strength(s)



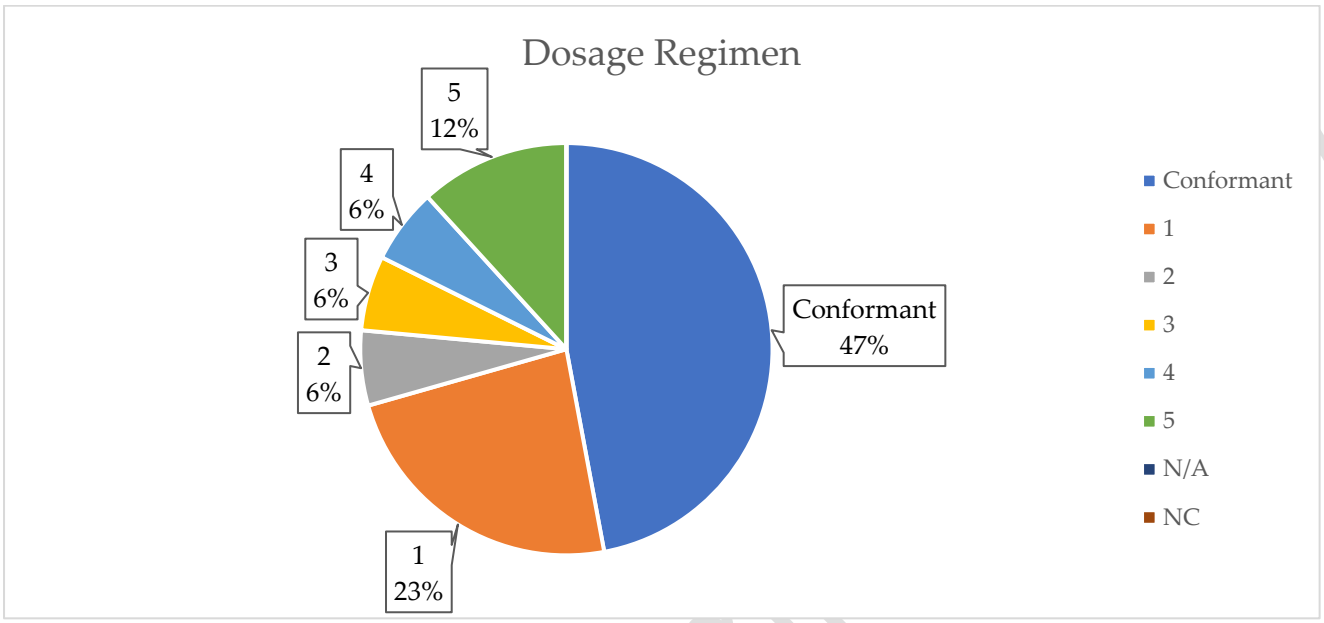
"Pharmaceutical dose form" is associated with a conformance rate of 56%. Non-conformance reasons resulted to be as follows: reason n. 1 (25%), reason n. 3 (6%), reason n. 5 (13%).

Pharmaceutical dose form



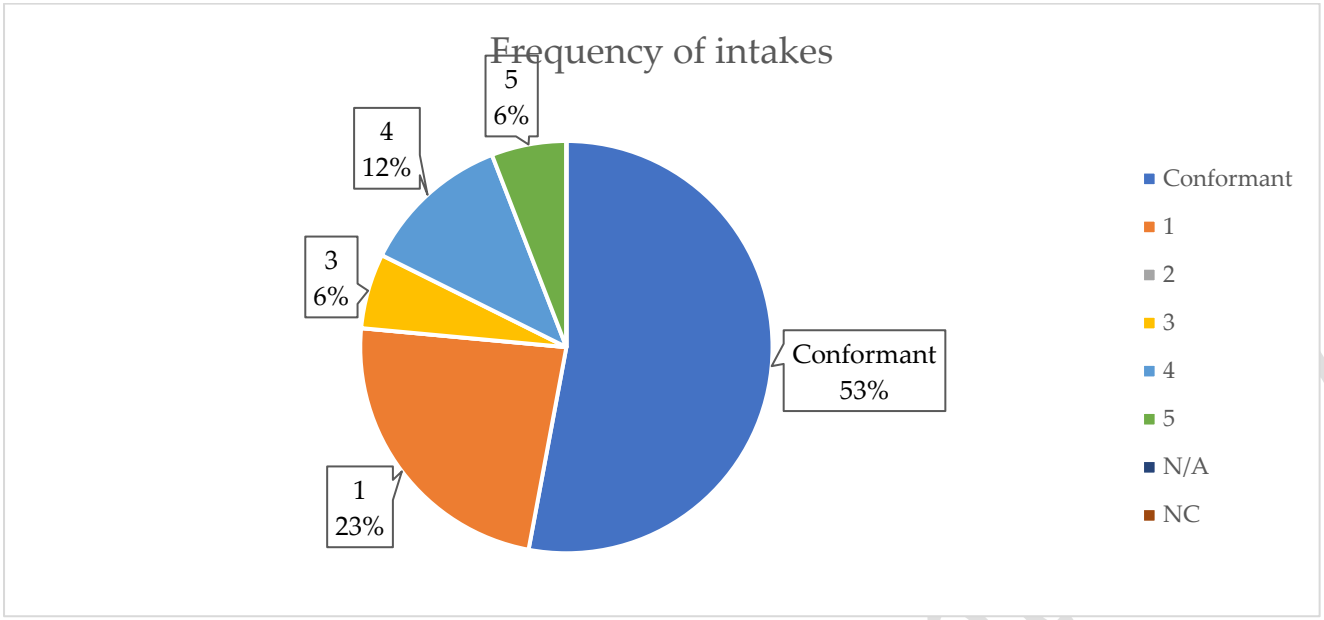
"Dosage Regimen" is associated with a conformance rate of 47%. Non-conformance reasons resulted to be as follows: reason n. 1 (23%), reason n. 2 (6%), reason n. 3 (6%), reason n. 4 (6%), reason n. 5 (12%).

Dosage regimen



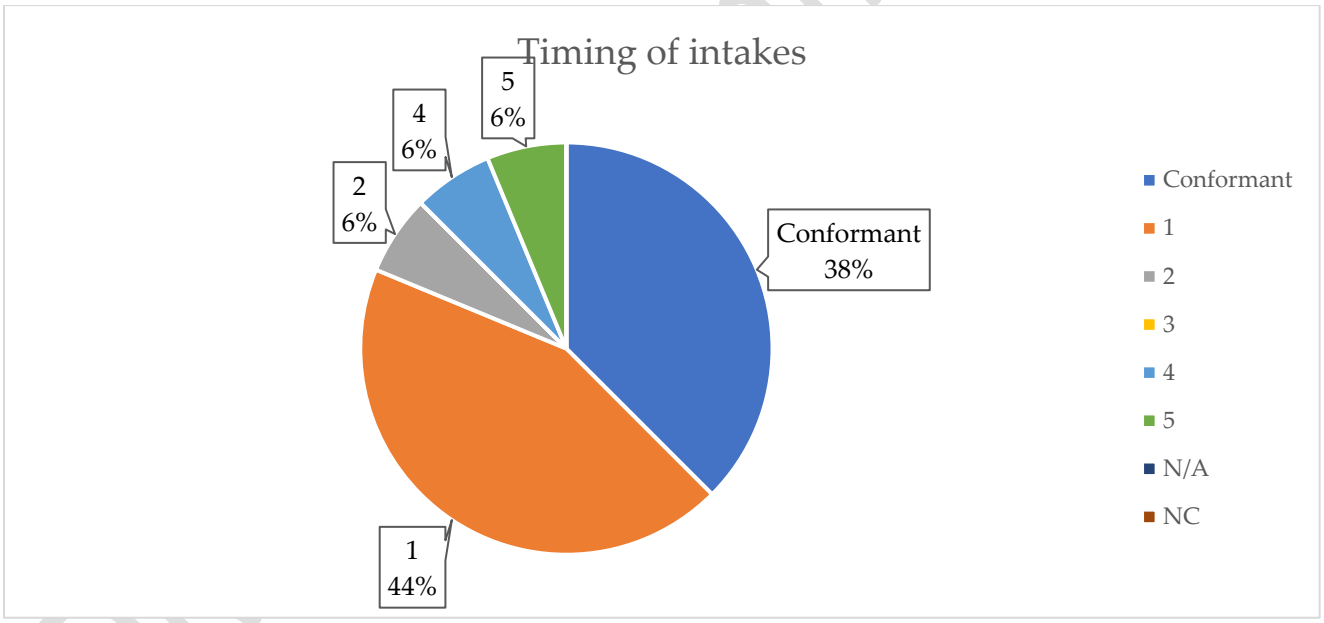
"Frequency of intakes" is associated with a conformance rate of 53%. Non-conformance reasons resulted to be as follows: reason n. 1 (23%), reason n. 3 (6%), reason n. 4 (12%), reason n. 5 (6%).

Frequency of intakes



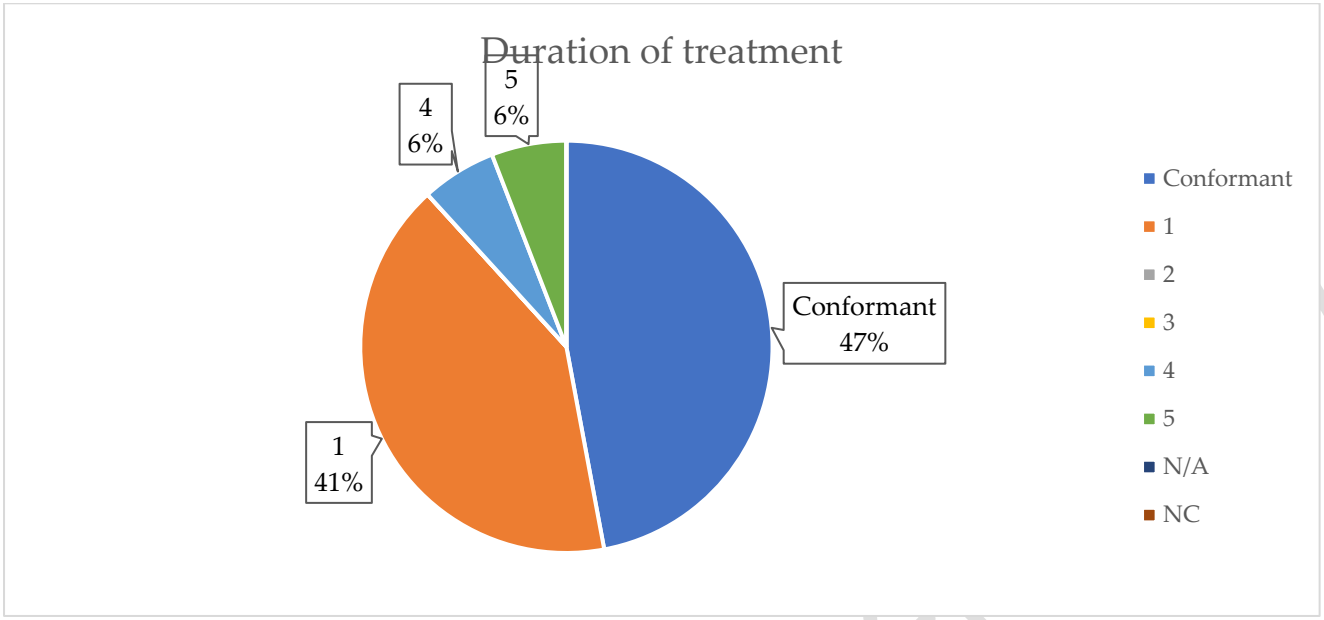
"Timing of intakes" is associated with a conformance rate of 38%. Non-conformance reasons resulted to be as follows: reason n. 1 (44%), reason n. 2 (6%), reason n. 4 (6%), reason n. 5 (6%).

Timing of intakes



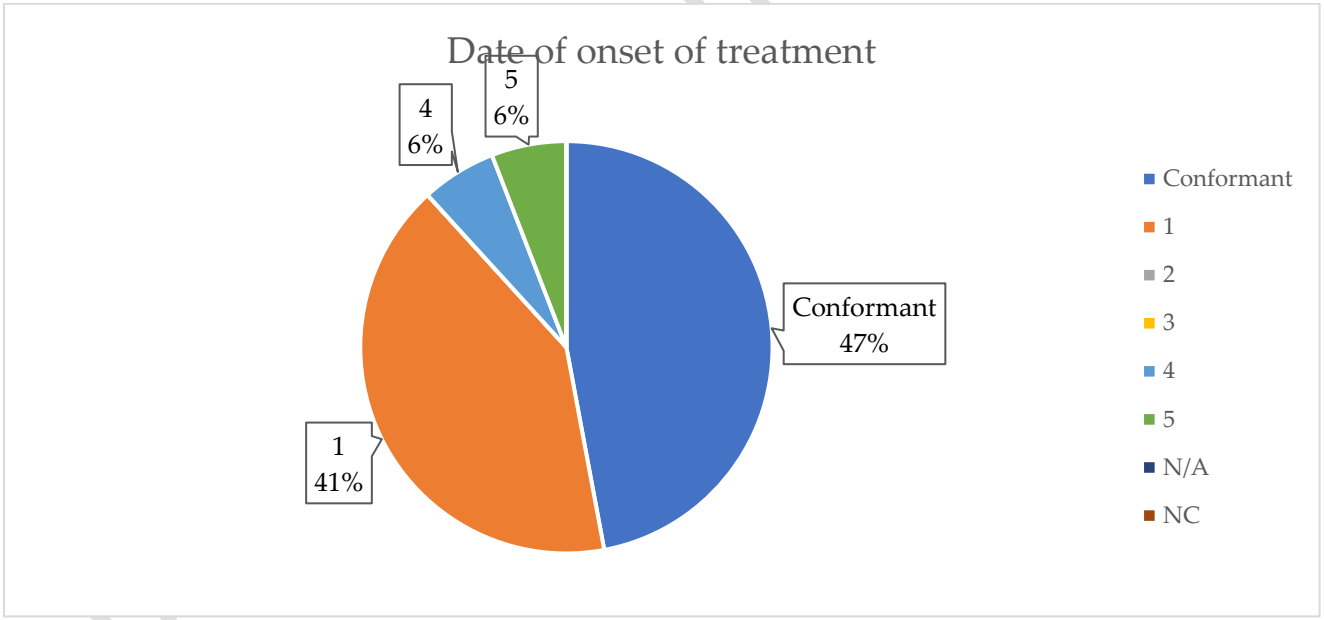
"Duration of treatment" is associated with a conformance rate of 47%. Non-conformance reasons resulted to be as follows: reason n. 1 (41%), reason n. 4 (6%), reason n. 5 (6%).

Duration of treatment



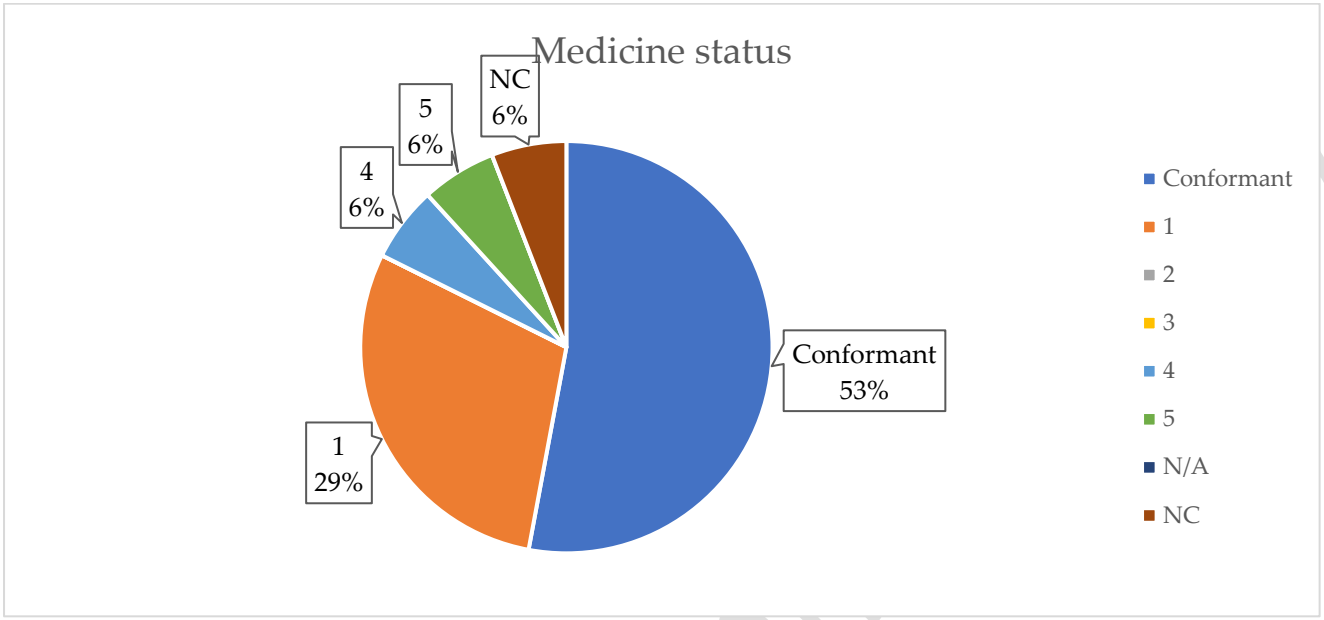
"Date of onset of treatment" is associated with a conformance rate of 47%. Non-conformance reasons resulted to be as follows: reason n. 1 (41%), reason n. 4 (6%), reason n. 5 (6%).

Date of onset of treatment



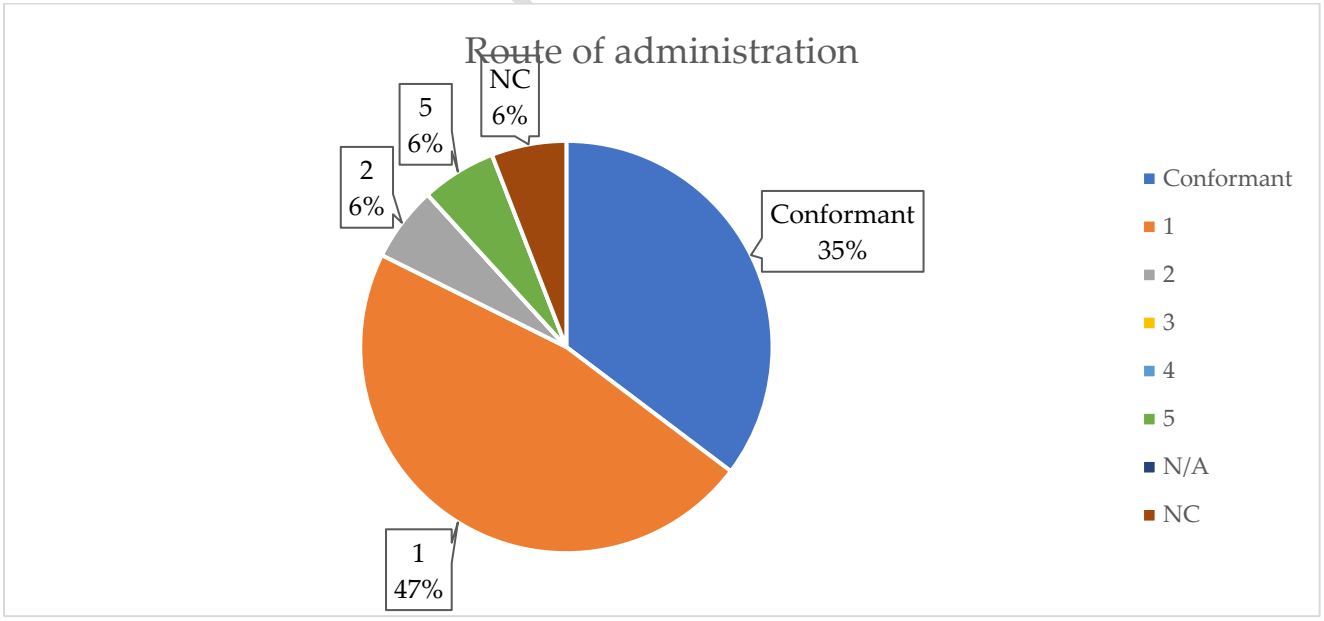
"Medicine status" is associated with a conformance rate of 53%. Non-conformance reasons resulted to be as follows: reason n. 1 (29%), reason n. 4 (6%), reason n. 5 (6%), non-specific reason "Non-conformant (NC)" (6%).

Medicine status



"Route of administration" is associated with a conformance rate of 35%. Non-conformance reasons resulted to be as follows: reason n. 1 (47%), reason n. 2 (6%), reason n. 5 (6%), non-specific reason "Non-conformant (NC)" (6%).

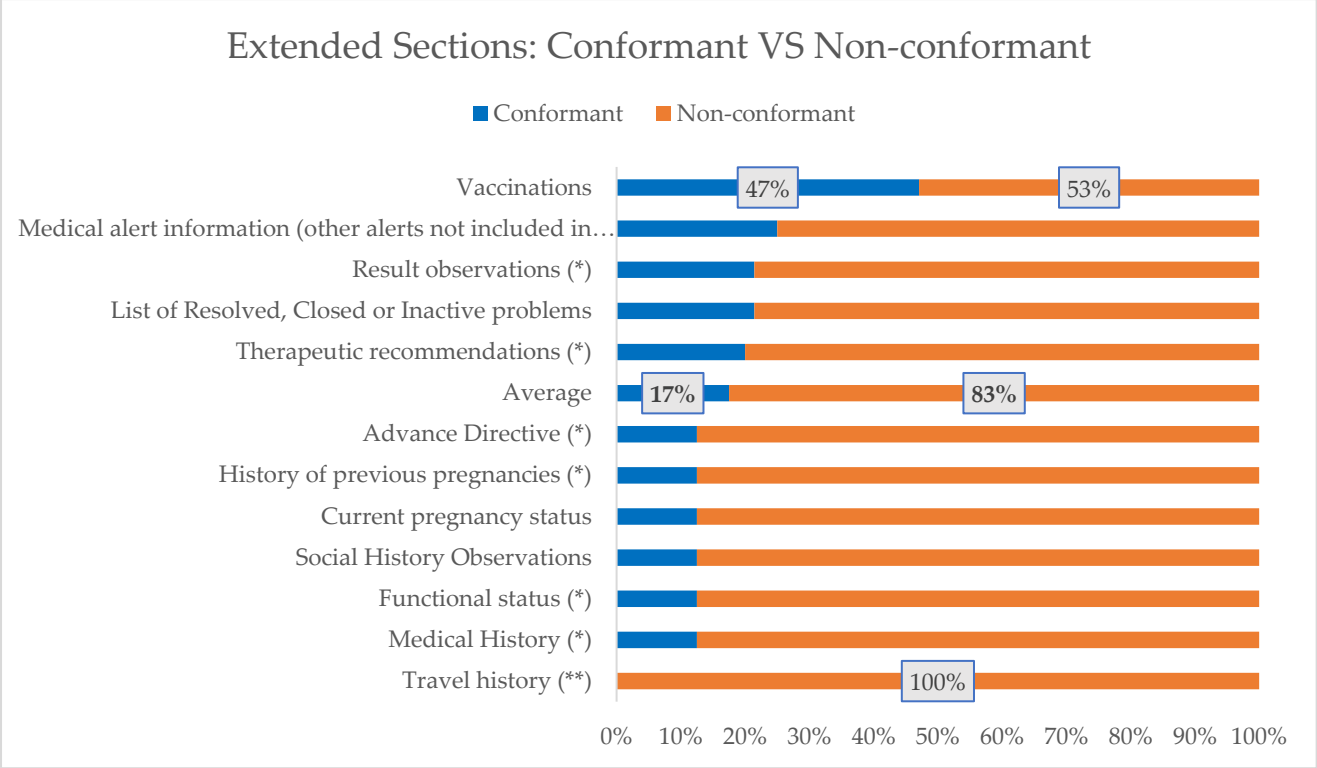
Route of administration



10.2.1.4 PS Questionnaire Extended Sections analysis: Section level

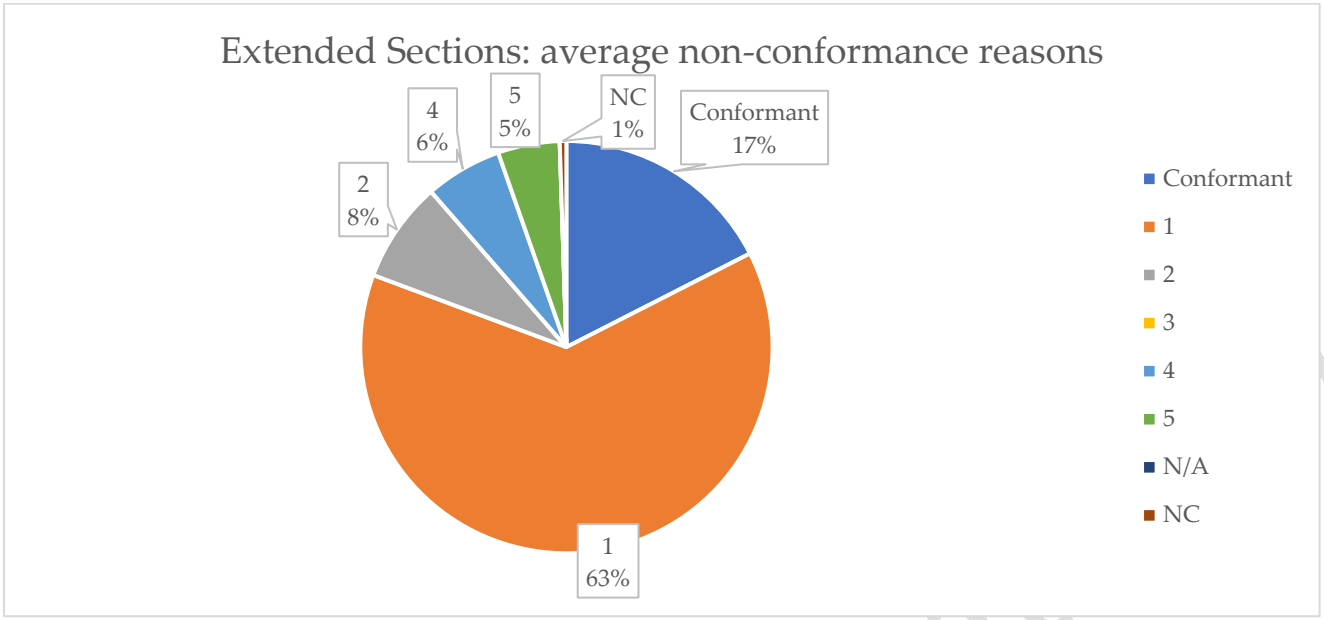
The average conformance rate for the Extended Sections is 17%, ranging from 0% for the section "Travel history" to 47% for the section "Vaccinations". The following graphic shows the results for all the Extended Sections.

Extended Sections: Conformant VS Non-conformant



The most relevant specific non-conformance reason on average for the Extended Sections resulted to be reason n. 1 "Source of information is not available" (63%), followed by reason n. 2 "Source of information is not structured (free text) – structure and coding issue" (8%) and reasons n. 4 and n. 5 follow with 6% and 5% respectively. Non-specific reason NC accounts for 1% only. The following graphic shows the overall distribution.

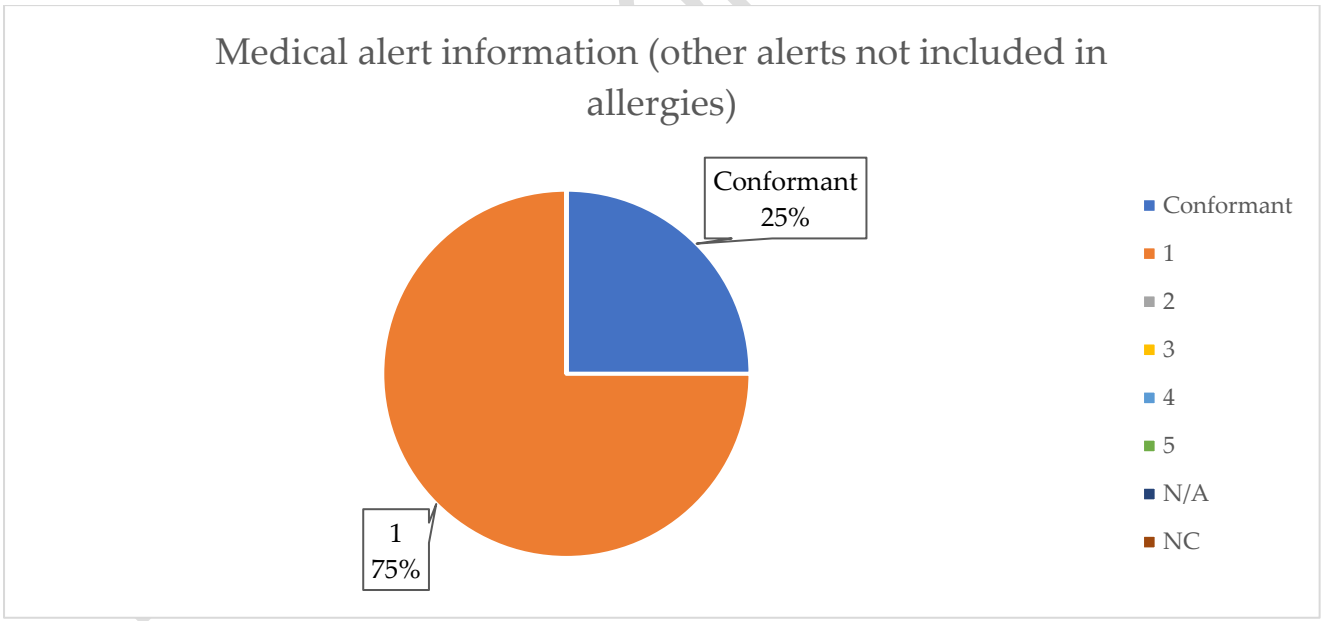
Extended Sections: average non-conformance reasons



The state of the art of non-conformance reasons for each specific Extended Section is reported in the following pages.

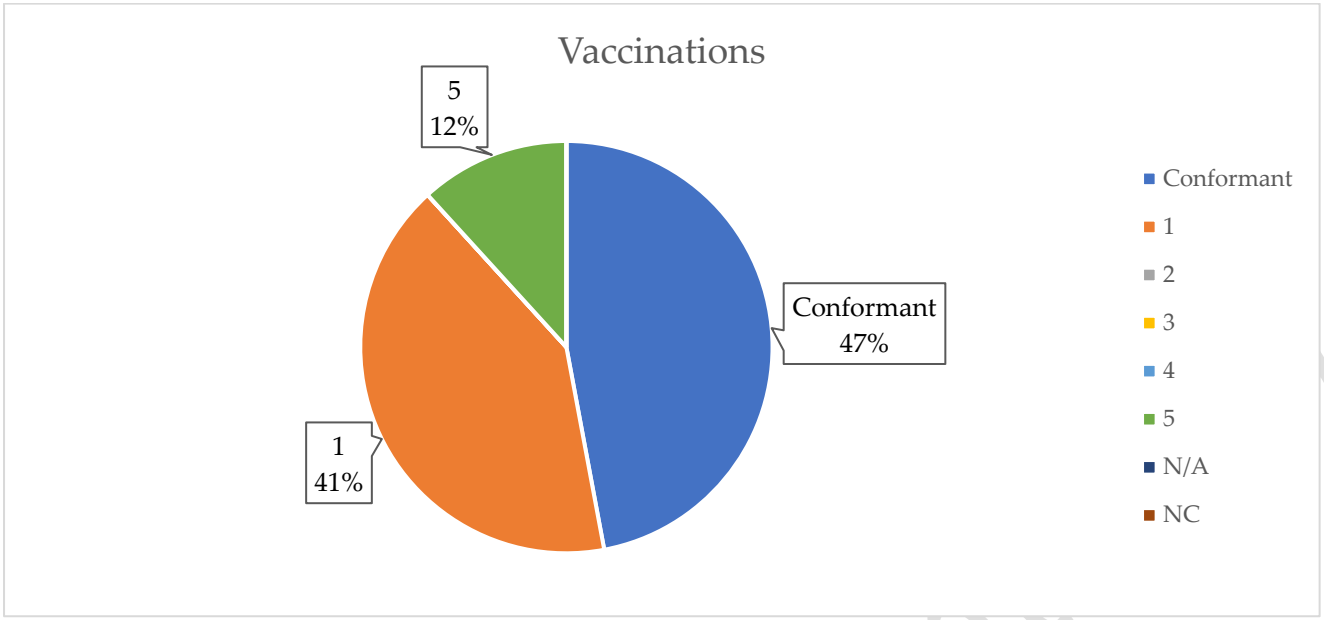
"Medical alert information (other alerts not included in allergies)" is associated with a conformance rate of 25%. Non-conformance reasons resulted to be as follows: reason n. 1 (75%).

Medical alert information



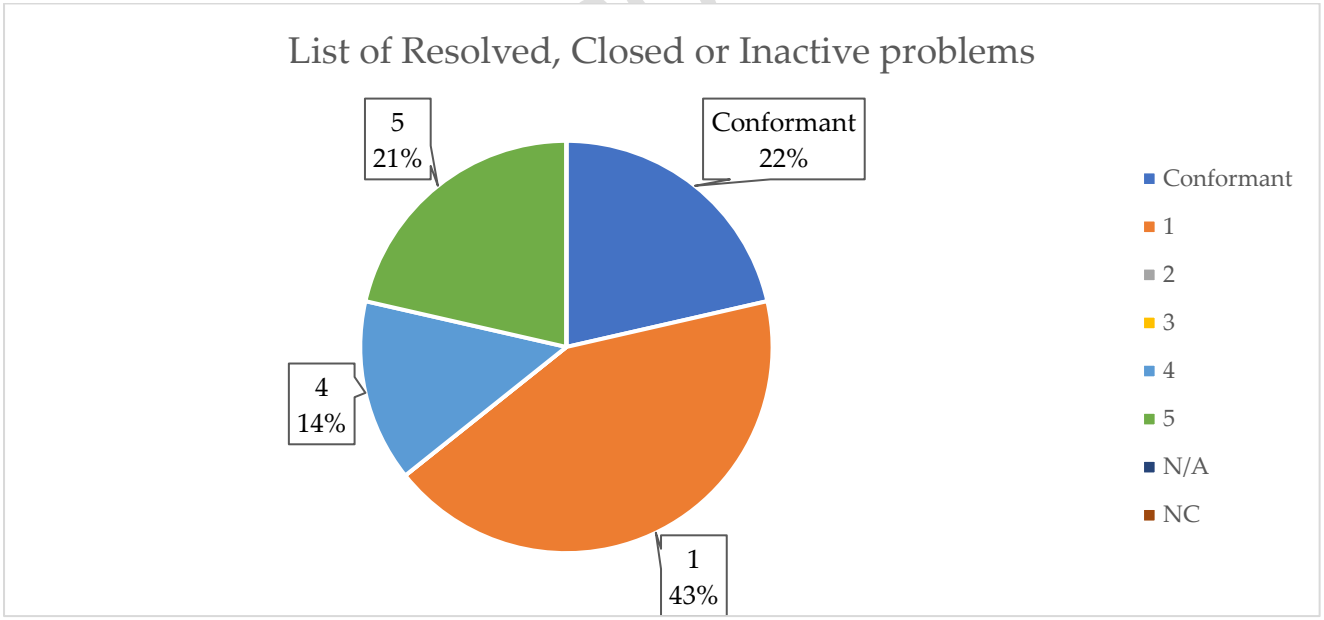
"Vaccinations" is associated with a conformance rate of 47%. Non-conformance reasons resulted to be as follows: reason n. 1 (41%), reason n. 5 (12%).

Vaccinations



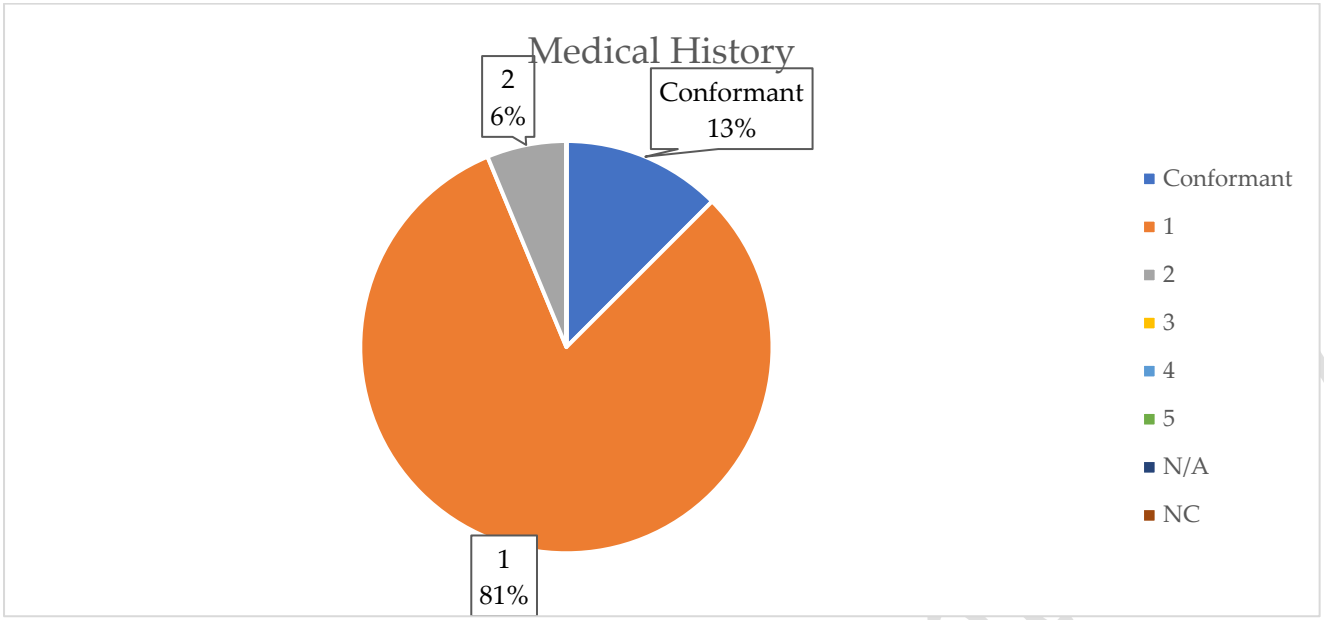
"List of Resolved, Closed or Inactive problems" is associated with a conformance rate of 22%. Non-conformance reasons resulted to be as follows: reason n. 1 (43%), reason n. 4 (14%), reason n. 5 (21%).

List of resolved, closed or inactive problems



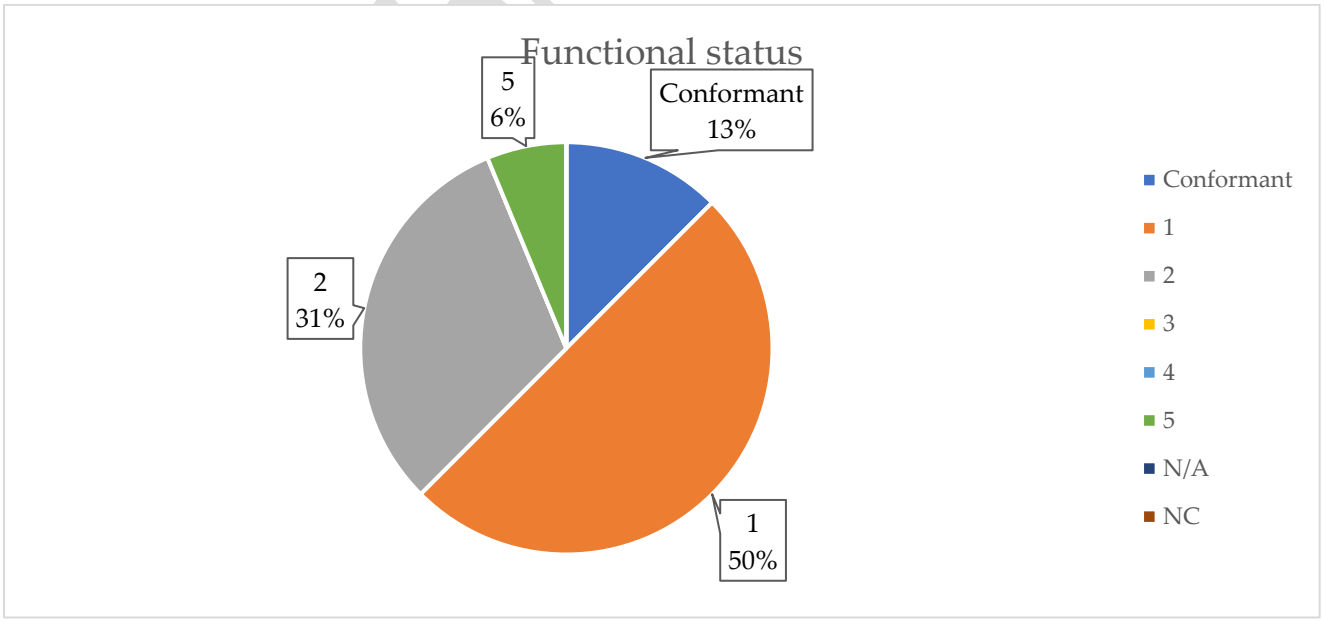
"Medical History" is associated with a conformance rate of 13%. Non-conformance reasons resulted to be as follows: reason n. 1 (81%), reason n. 2 (6%).

Medical history



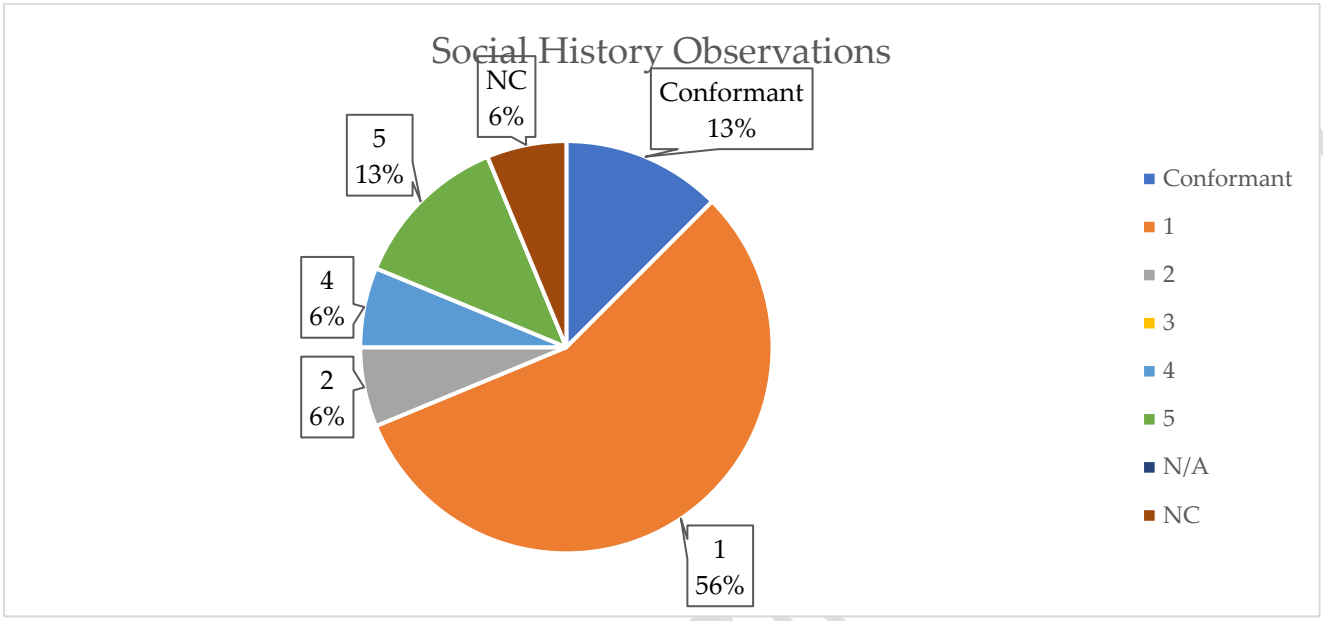
"Functional status" is associated with a conformance rate of 13%. Non-conformance reasons resulted to be as follows: reason n. 1 (50%), reason n. 2 (31%), reason n. 5 (6%).

Functional status



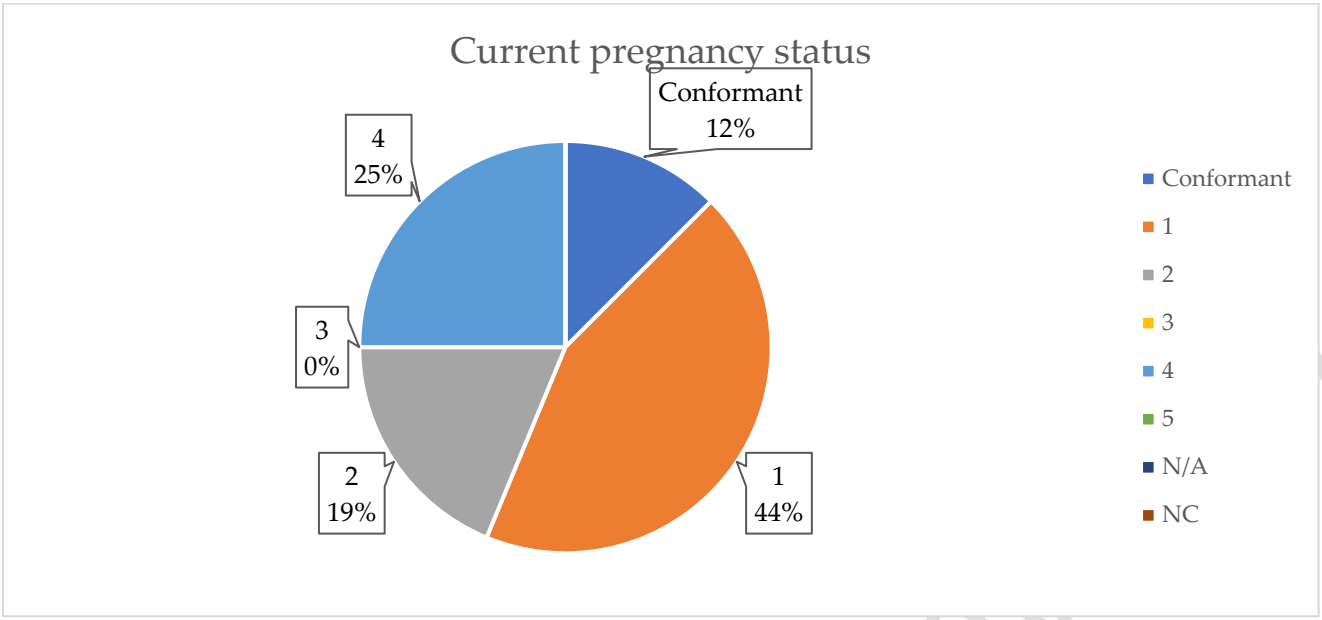
"Social History Observations" is associated with a conformance rate of 13%. Non-conformance reasons resulted to be as follows: reason n. 1 (56%), reason n. 2 (6%), reason n. 4 (6%), reason n. 5 (13%), non-specific reason "Non-conformant (NC)" (6%).

Social history observations



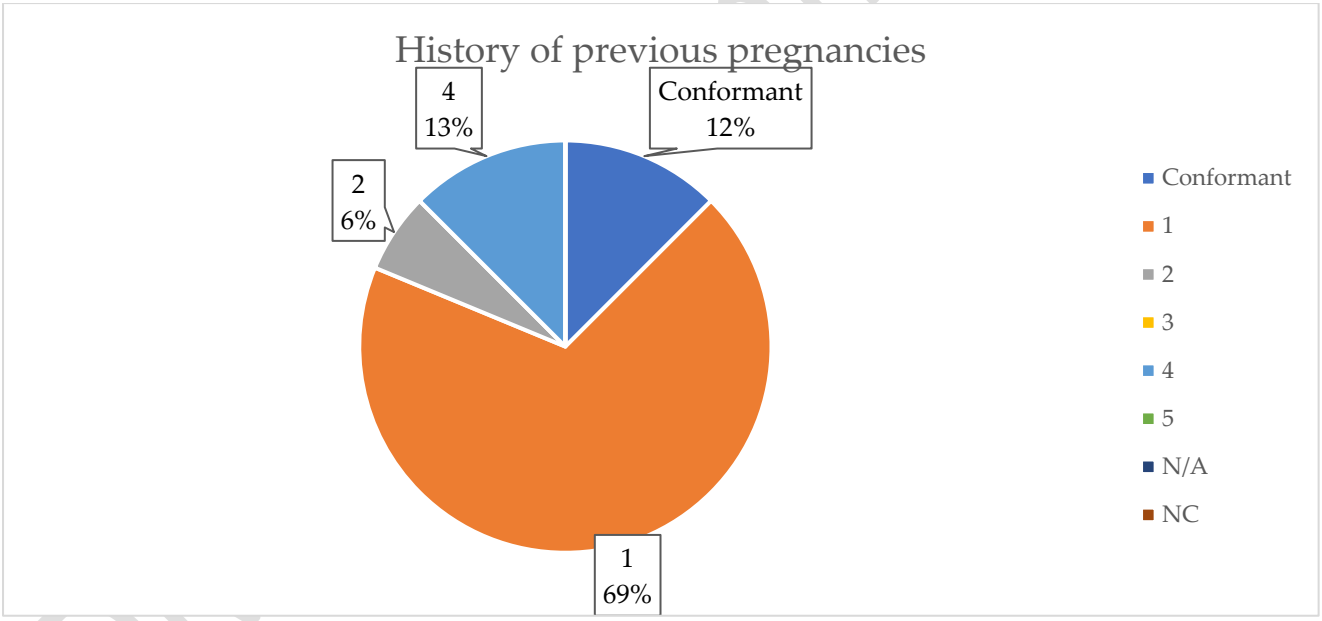
"Current pregnancy status" is associated with a conformance rate of 12%. Non-conformance reasons resulted to be as follows: reason n. 1 (44%), reason n. 2 (19%), reason n. 4 (25%).

Current pregnancy status



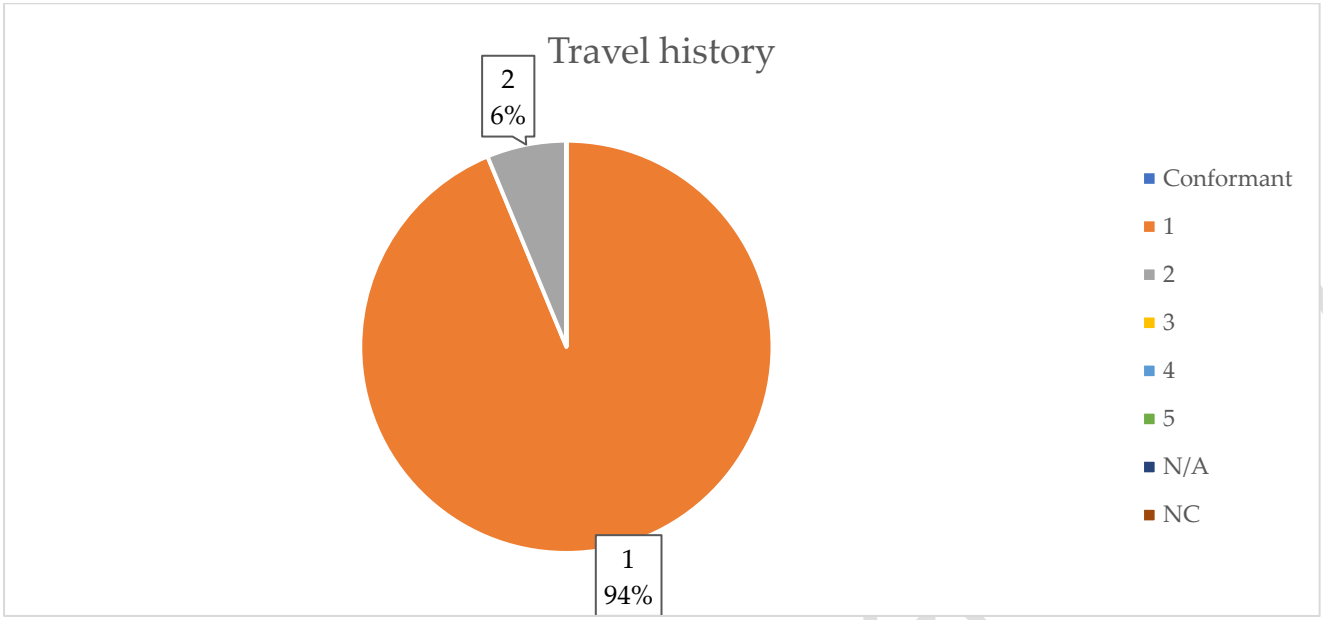
"History of previous pregnancies" is associated with a conformance rate of 12%. Non-conformance reasons resulted to be as follows: reason n. 1 (69%), reason n. 2 (6%), reason n. 4 (13%).

History of previous pregnancies



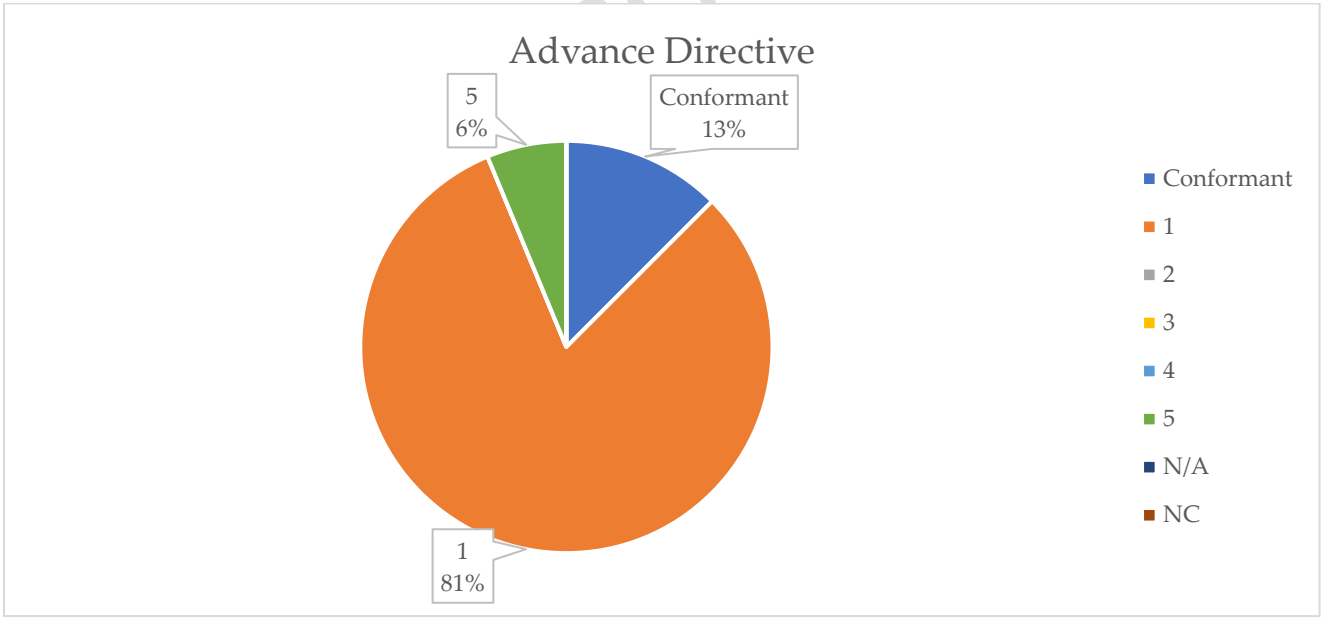
For "Travel history" no MS responded to be conformant. Non-conformance reasons resulted to be as follows: reason n. 1 (94%), reason n. 2 (6%).

Travel history



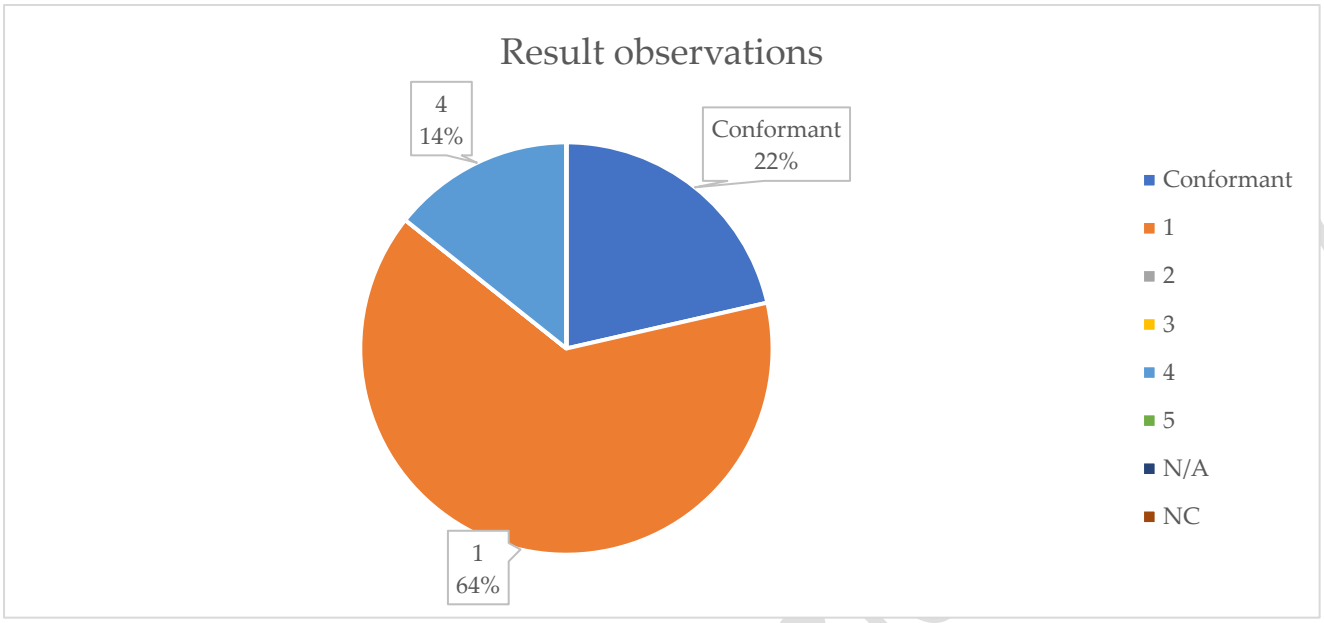
"Advance Directive" is associated with a conformance rate of 13%. Non-conformance reasons resulted to be as follows: reason n. 1 (81%), reason n. 5 (6%).

Advance directive



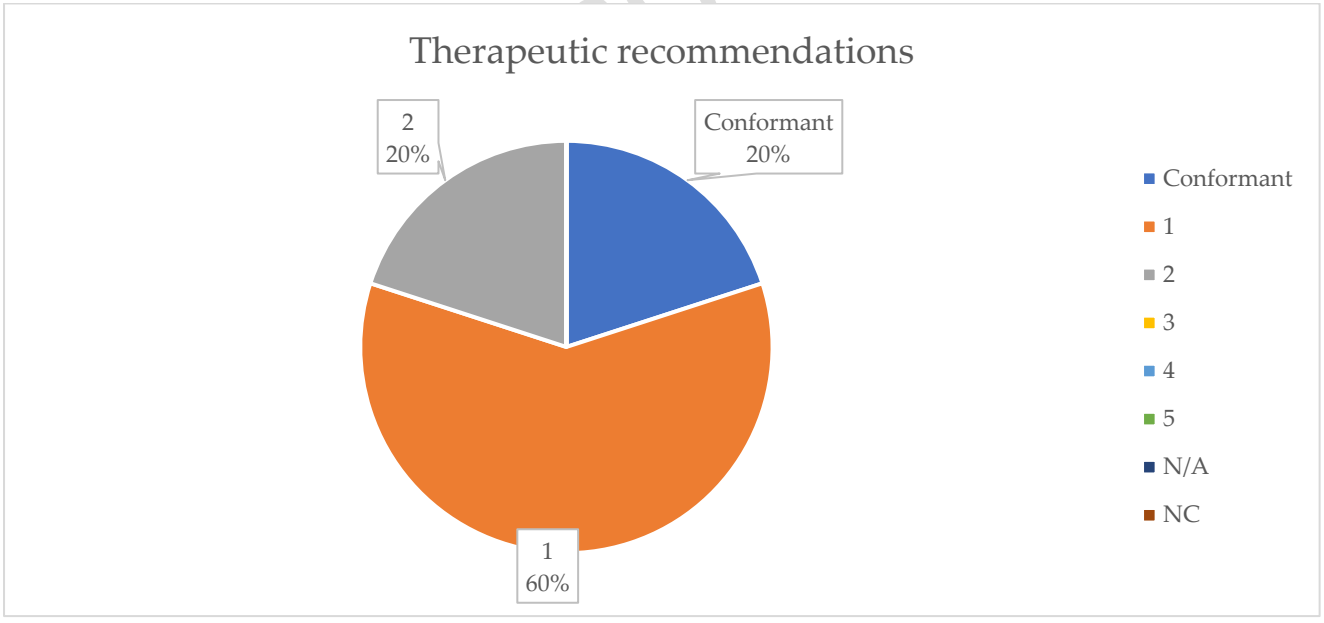
"Result observations" is associated with a conformance rate of 22%. Non-conformance reasons resulted to be as follows: reason n. 1 (64%), reason n. 4 (14%).

Result observations



"Therapeutic recommendations" is associated with a conformance rate of 20%. Non-conformance reasons resulted to be as follows: reason n. 1 (60%), reason n. 2 (20%).

Therapeutic recommendations

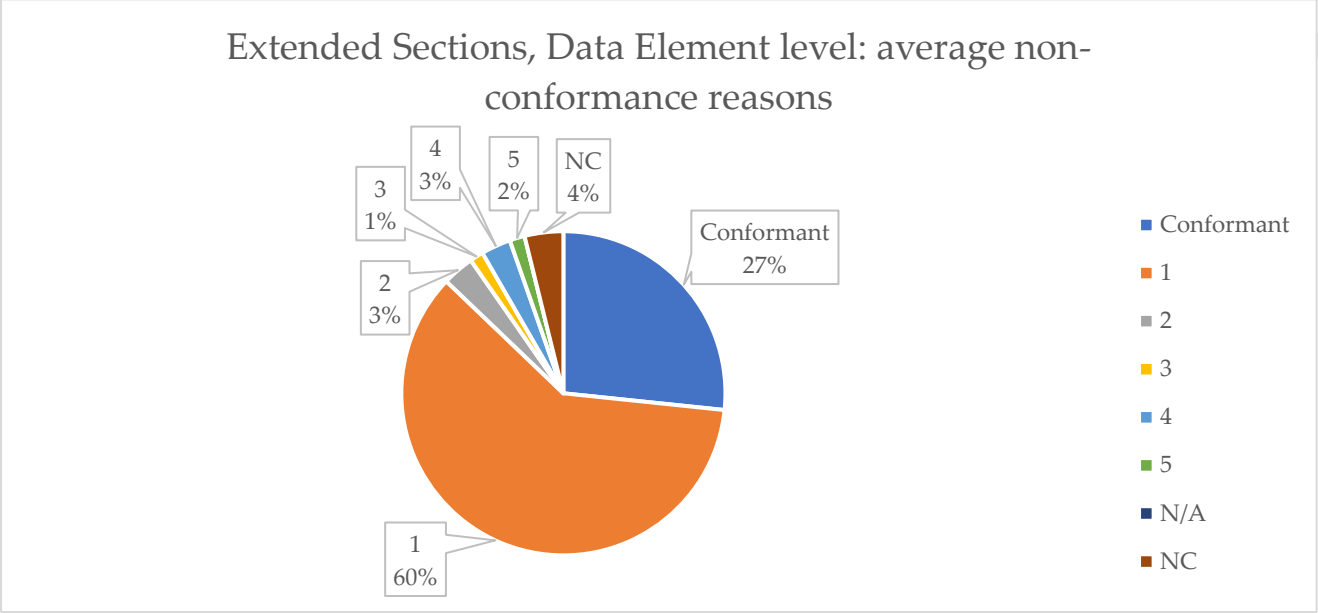


10.2.1.5 PS Questionnaire Extended Sections analysis: Data Element level

This section is devoted to the analysis of non-conformance reasons conducted at Data Element level for Extended Sections. Extended Sections counts 53 Data Elements in total, distributed among 12 Extended Sections.

The overall state of the art at Data Element level brings out an average conformance rate of 27% and a non-conformance rate of 73%. The prevalent non-conformance reason is n. 1 “Source of data is not available” which represents 60% of the cases, followed by reasons n. 4 and n. 2 accounting for 3% both, reason n. 5 (2%), and n. 3 (1%). The remaining 4% of non-conformance responses is associated with non-specific NC.

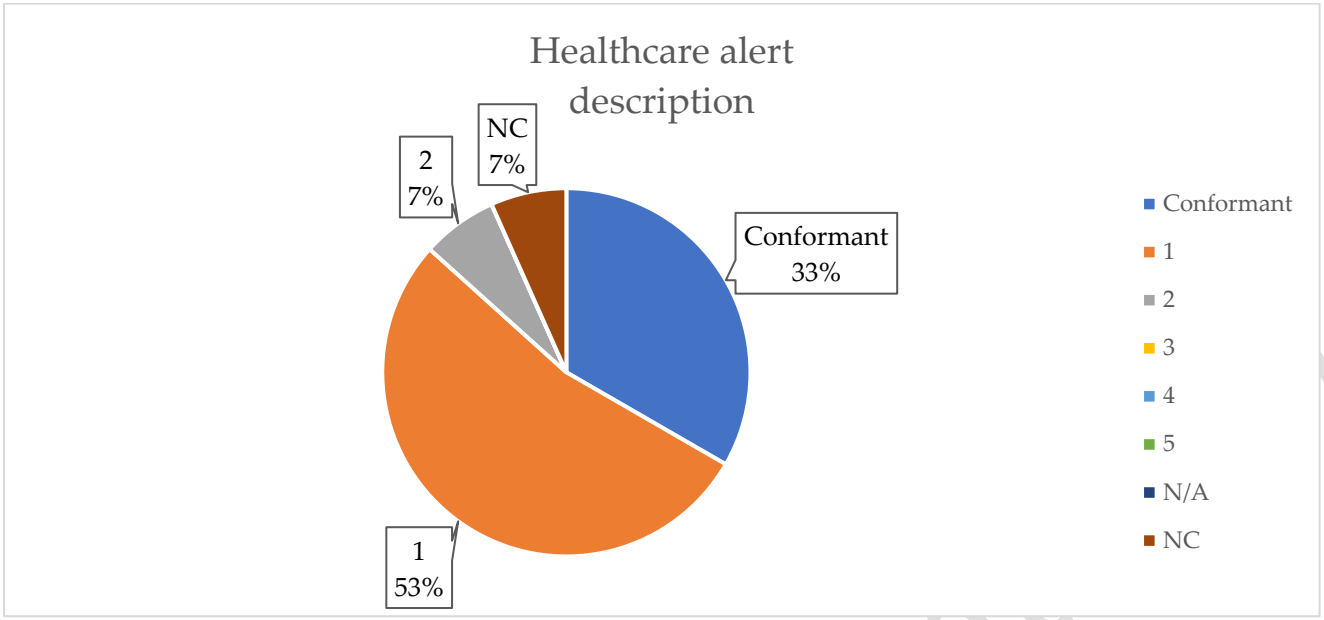
Extended Sections, Data Element level: average non-conformance reasons



In the following pages the situation of the non-conformance reasons for each Data Element is reported.

Data Element "Healthcare alert description" relates to Extended Section “Medical alert information (other alerts not included in allergies)” and is associated with a conformance rate of 33%. Non-conformance reasons resulted to be as follows: reason n. 1 (53%), reason n. 2 (7%), non-specific reason “Non-conformant (NC)” (7%).

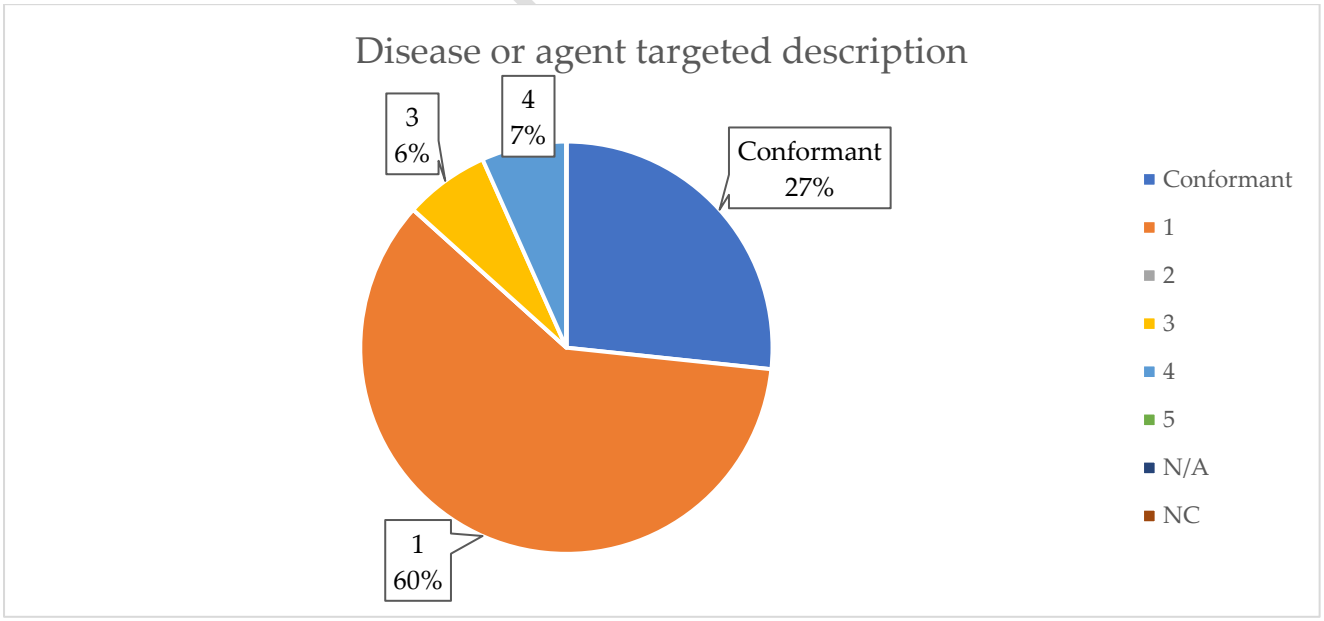
Healthcare alert description



The Data Elements "Disease or agent targeted description", "Disease or agent targeted code", "Vaccine/prophylaxis description", "Vaccination code", "Vaccine medicinal product", "Marketing Authorization Holder", "Vaccination date", "Number in a series of vaccinations / doses", "Batch/lot number", "Administering centre", "Health Professional identification", "Country of vaccination", "Next vaccination date" are part of the Extended Section "Vaccinations".

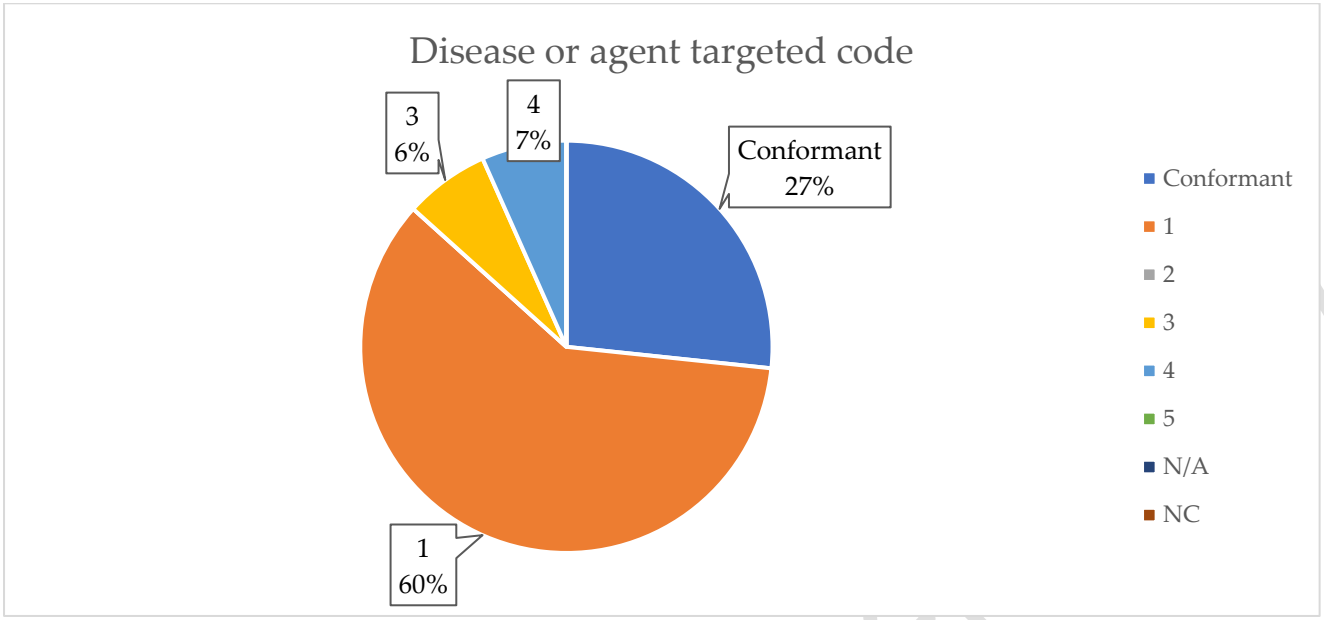
"Disease or agent targeted description" is associated with a conformance rate of 27%. Non-conformance reasons resulted to be as follows: reason n. 1 (60%), reason n. 3 (6%), reason n. 4 (7%).

Disease or agent targeted description



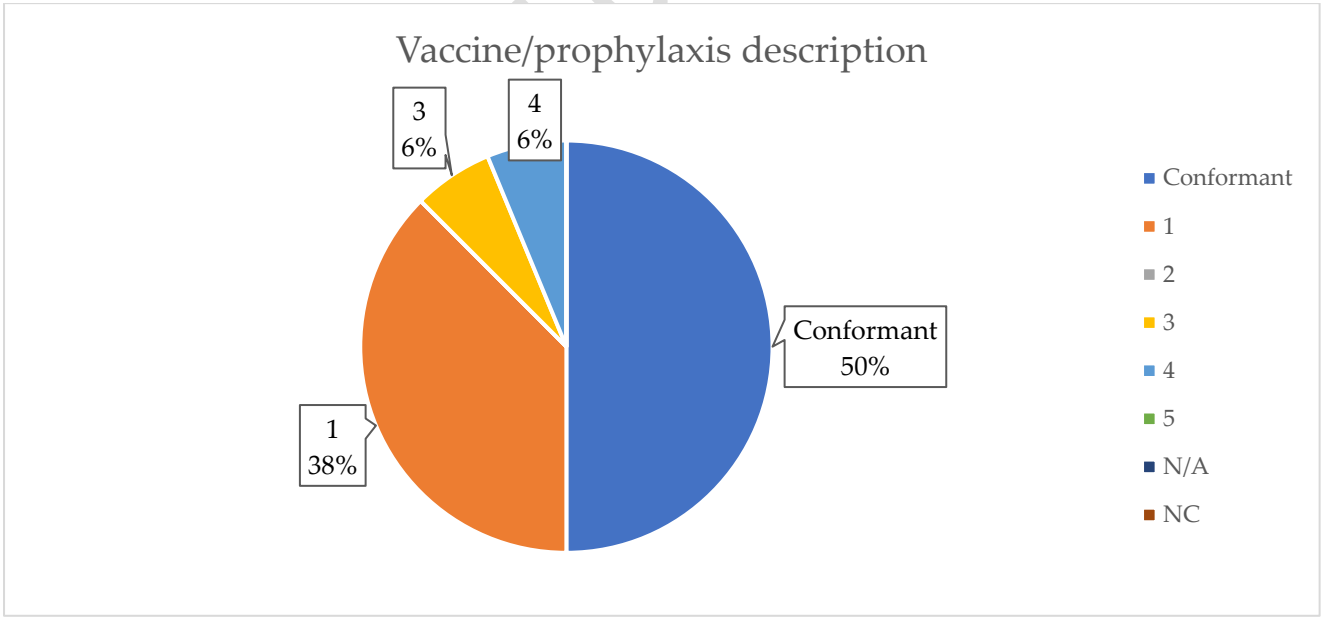
"Disease or agent targeted code" is associated with a conformance rate of 27%. Non-conformance reasons resulted to be as follows: reason n. 1 (60%), reason n. 3 (6%), reason n. 4 (7%).

Disease or agent targeted code



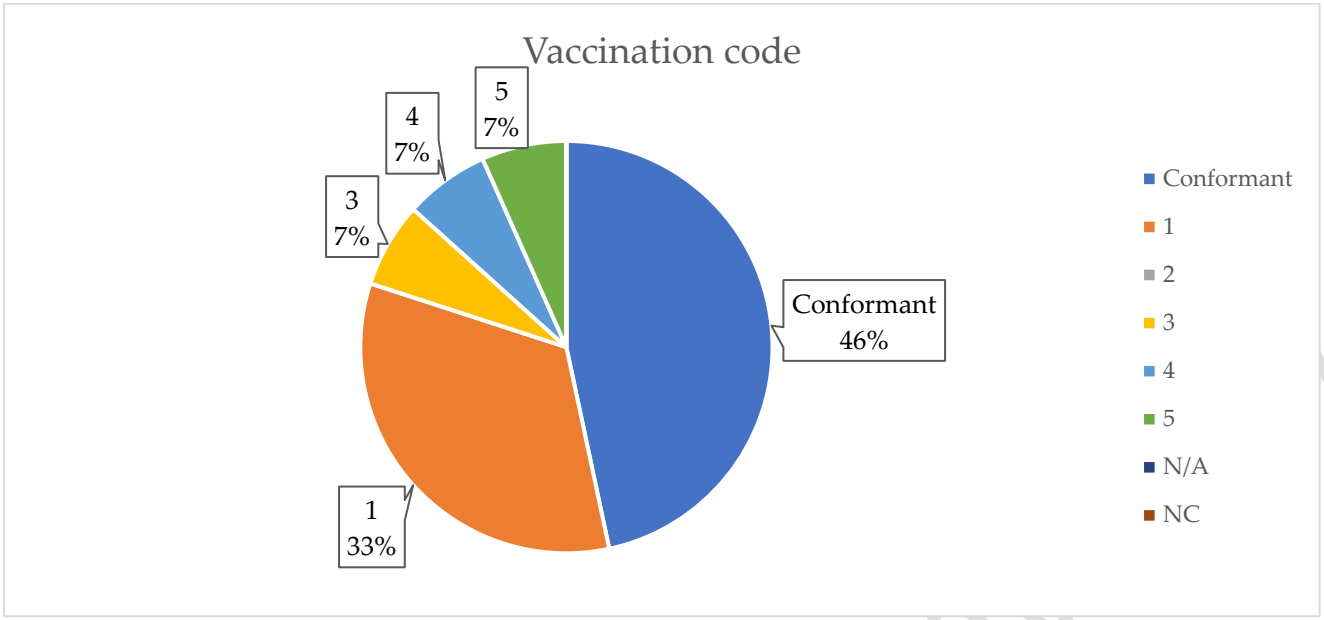
"Vaccine/prophylaxis description" is associated with a conformance rate of 50%. Non-conformance reasons resulted to be as follows: reason n. 1 (38%), reason n. 3 (6%), reason n. 4 (6%).

Vaccine/prophylaxis description



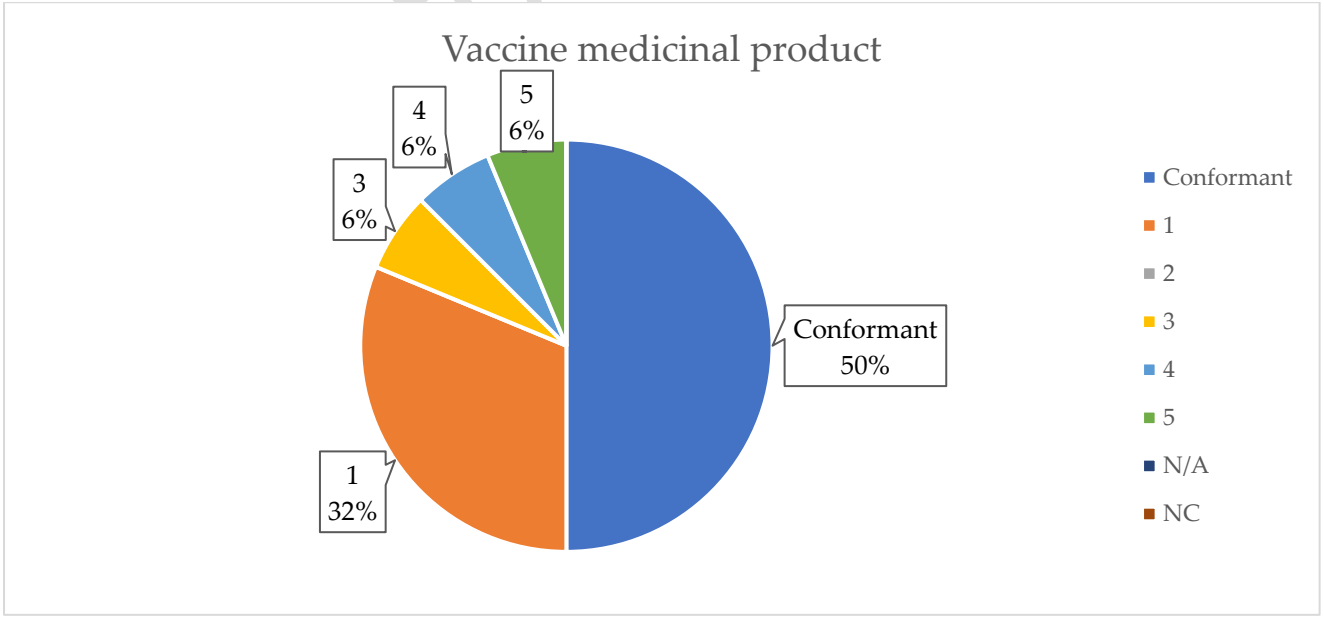
"Vaccination code" is associated with a conformance rate of 46%. Non-conformance reasons resulted to be as follows: reason n. 1 (33%), reason n. 3 (7%), reason n. 4 (7%), reason n. 5 (7%).

Vaccination code



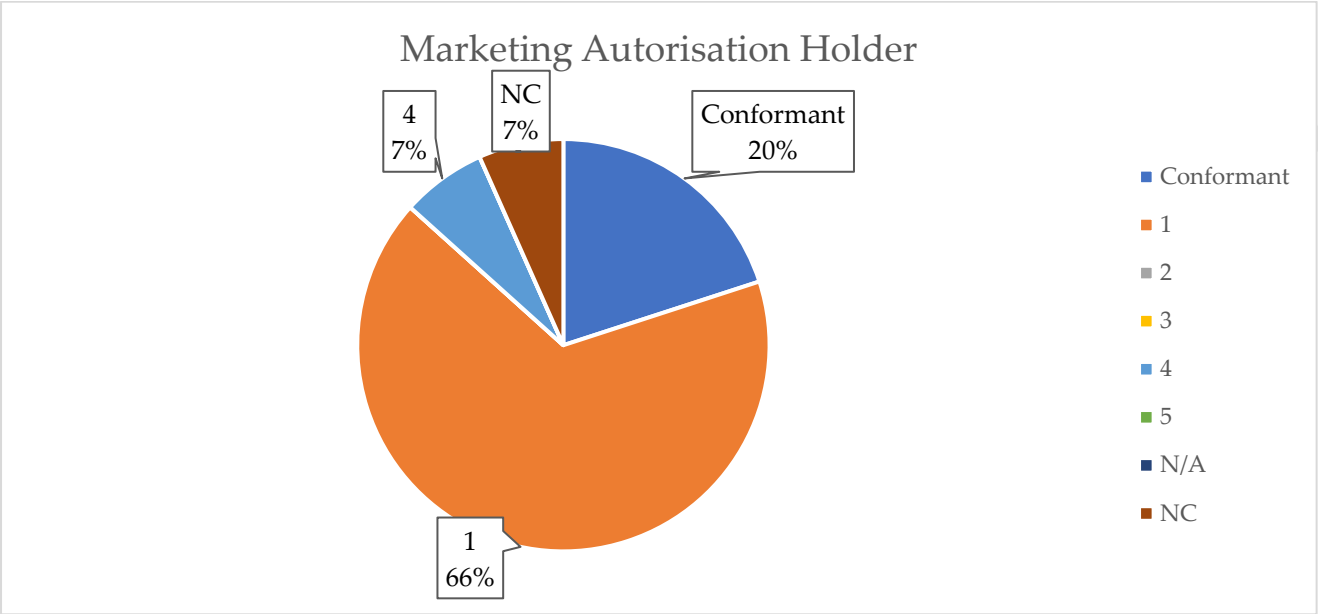
"Vaccine medicinal product" is associated with a conformance rate of 50%. Non-conformance reasons resulted to be as follows: reason n. 1 (32%), reason n. 3 (6%), reason n. 4 (6%), reason n. 5 (6%).

Vaccine medicinal product



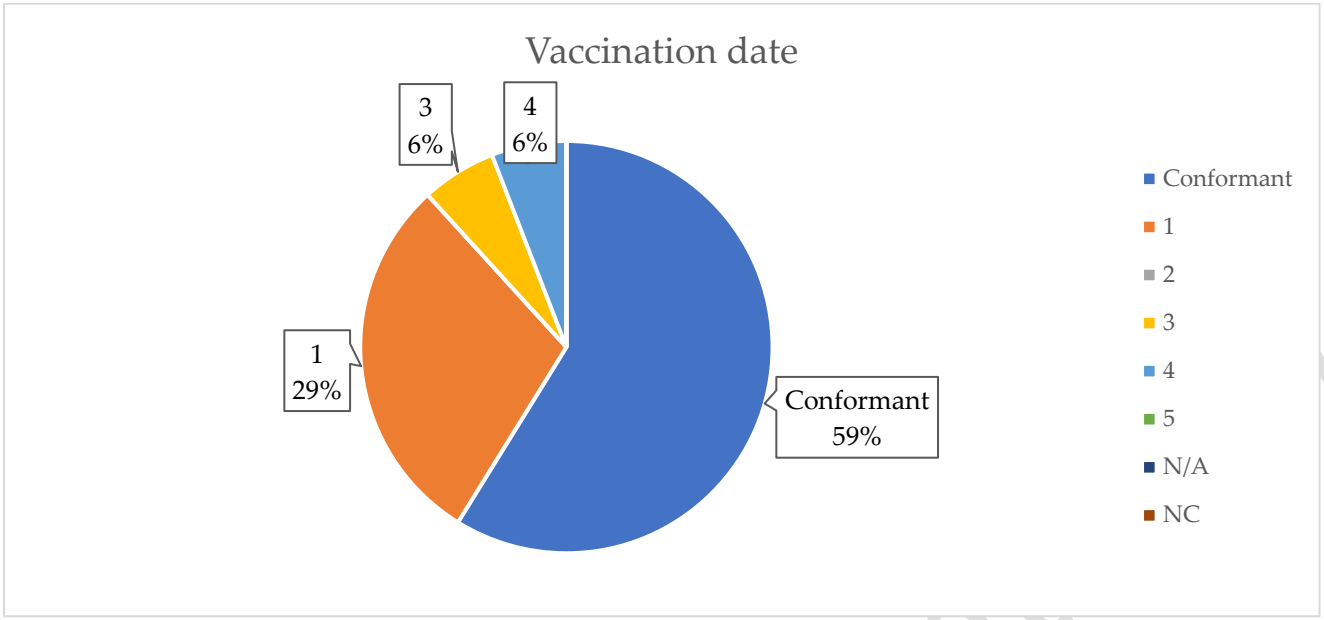
"Marketing Autorisation Holder" is associated with a conformance rate of 20%. Non-conformance reasons resulted to be as follows: reason n. 1 (66%), reason n. 4 (7%), non-specific reason "Non-conformant (NC)" (7%).

Marketing autorisation holder



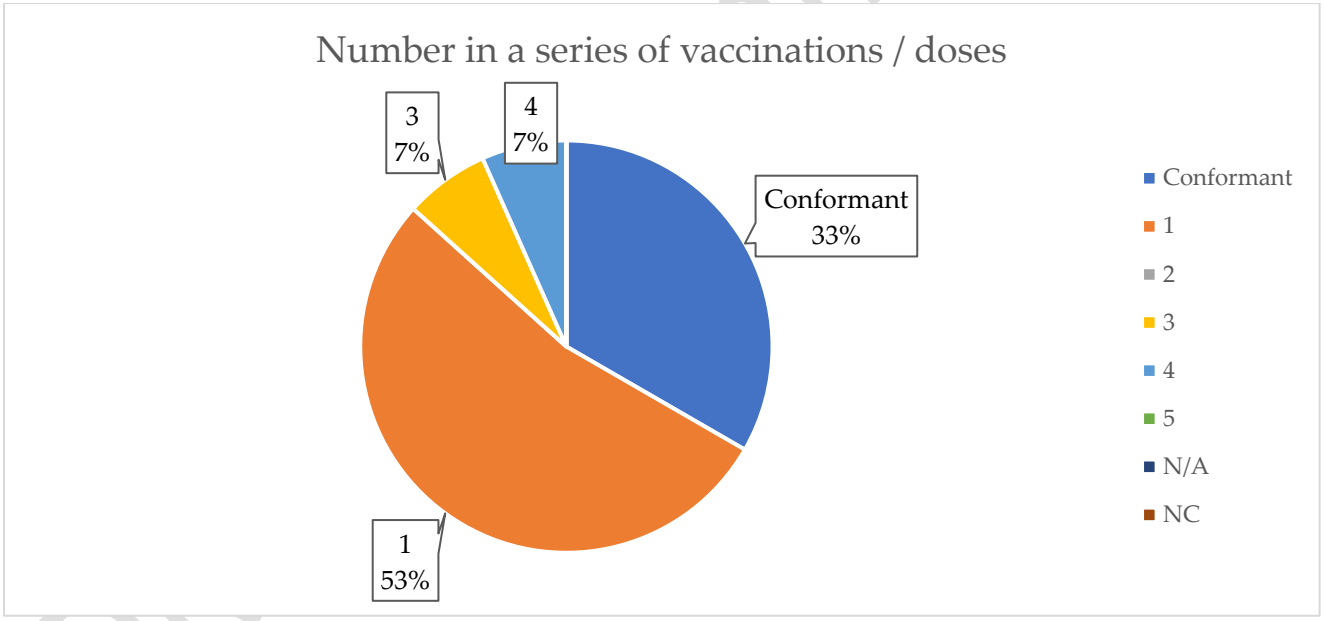
"Vaccination date" is associated with a conformance rate of 59%. Non-conformance reasons resulted to be as follows: reason n. 1 (29%), reason n. 3 (6%), reason n. 4 (6%).

Vaccine date



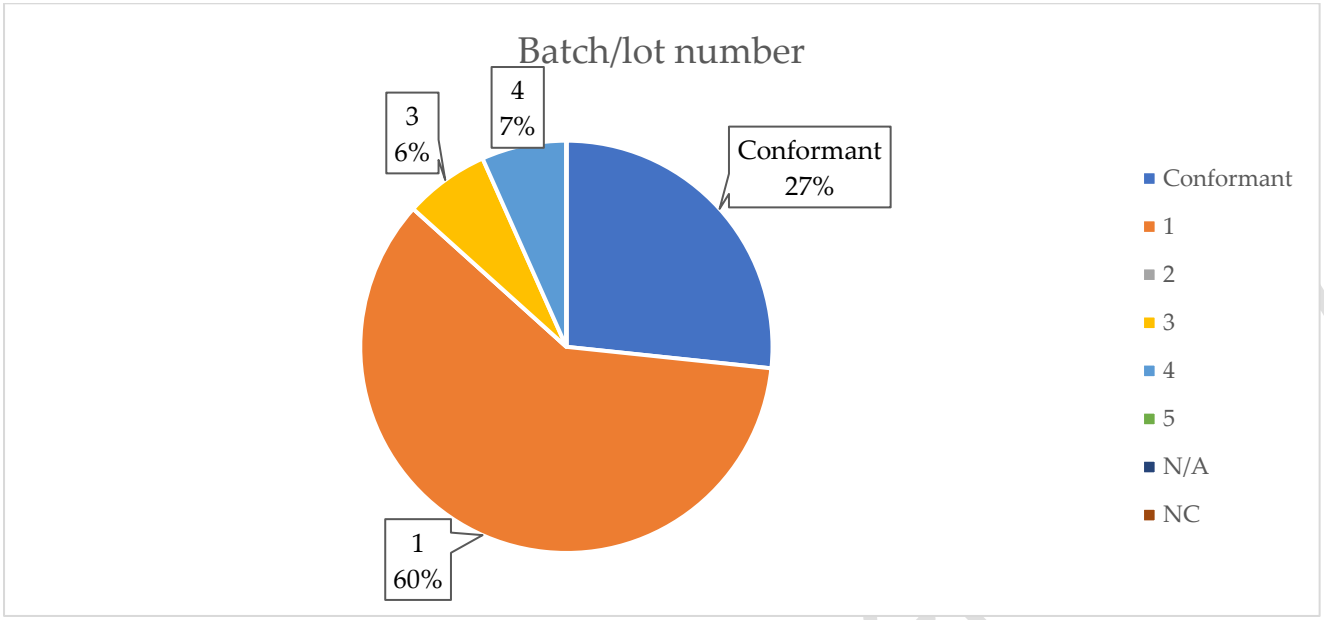
"Number in a series of vaccinations / doses" is associated with a conformance rate of 33%. Non-conformance reasons resulted to be as follows: reason n. 1 (53%), reason n. 3 (7%), reason n. 4 (7%).

Number in a series of vaccinations/doses



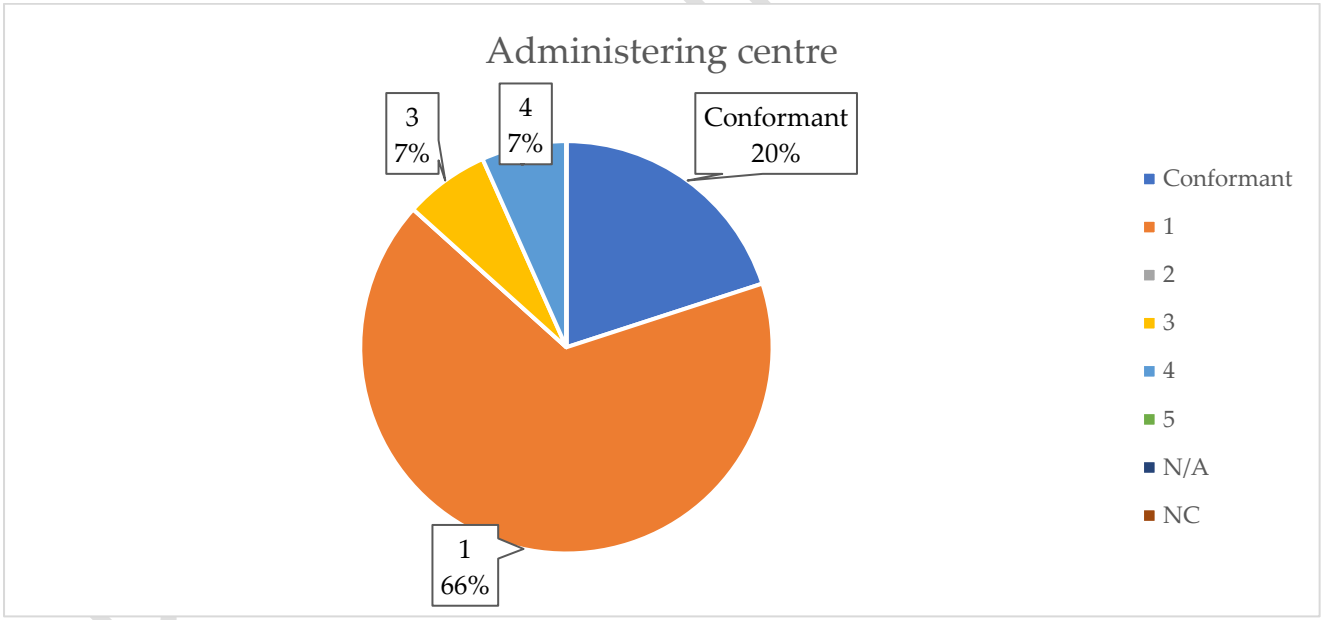
"Batch/lot number" is associated with a conformance rate of 27%. Non-conformance reasons resulted to be as follows: reason n. 1 (60%), reason n. 3 (6%), reason n. 4 (7%).

Batch/lot number



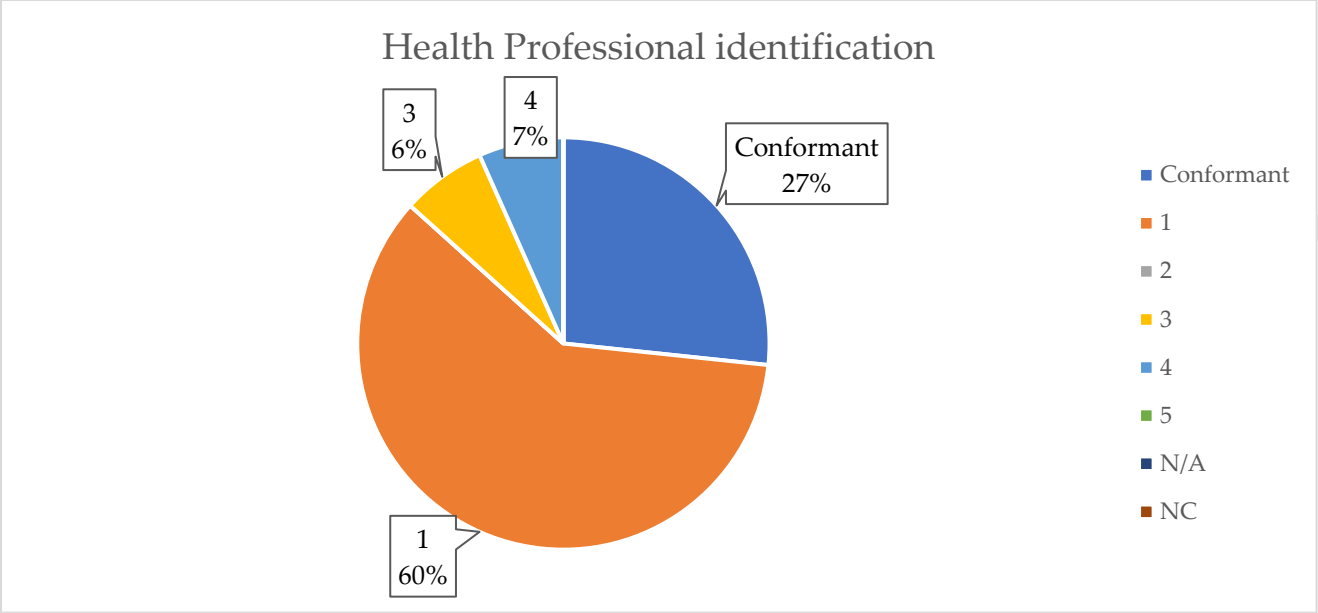
"Administering centre" is associated with a conformance rate of 20%. Non-conformance reasons resulted to be as follows: reason n. 1 (66%), reason n. 3 (7%), reason n. 4 (7%).

Administering centre



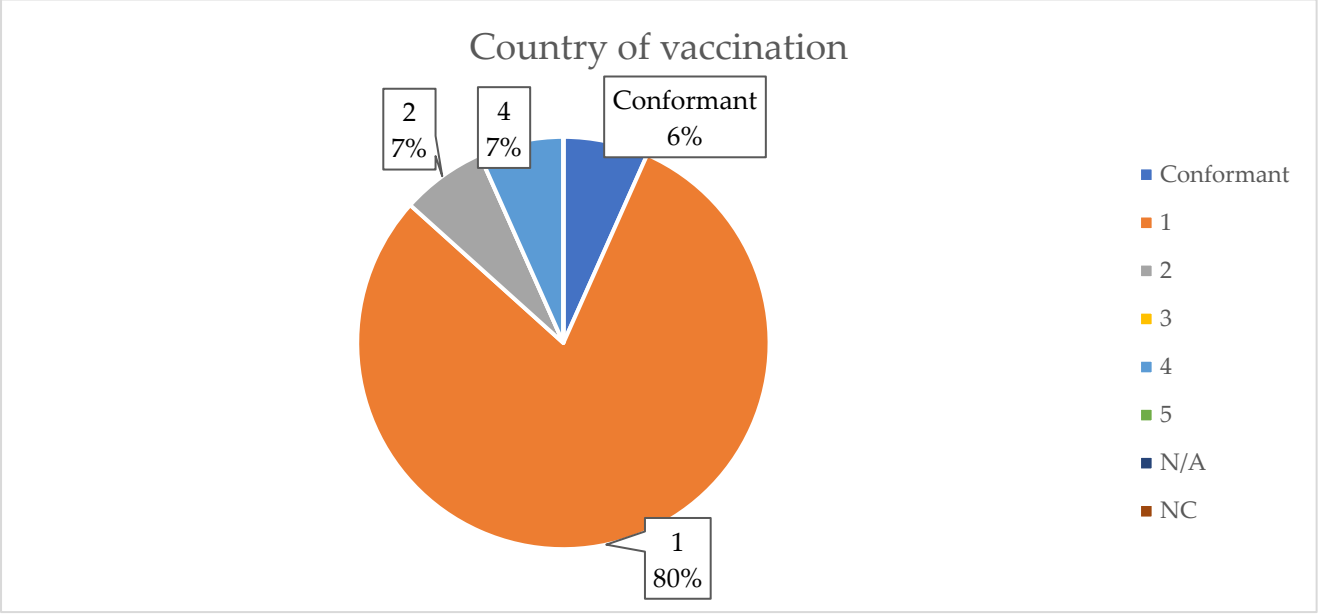
"Health Professional identification" is associated with a conformance rate of 27%. Non-conformance reasons resulted to be as follows: reason n. 1 (60%), reason n. 3 (6%), reason n. 4 (7%).

Health Professional identification



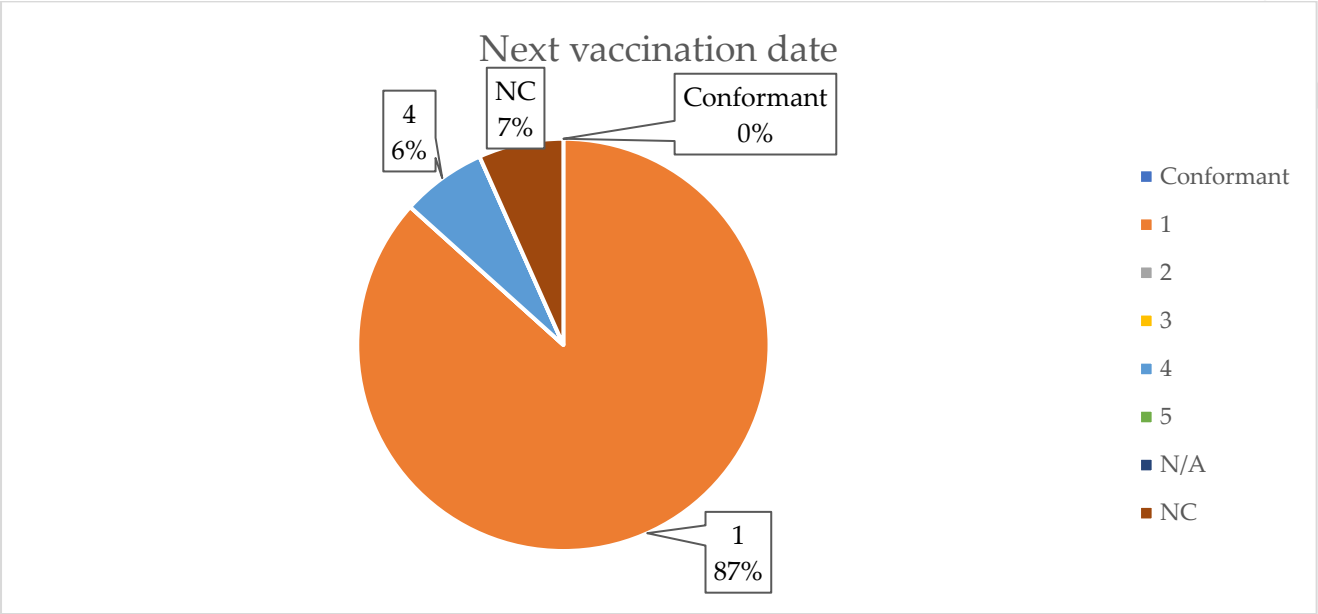
"Country of vaccination" is associated with a conformance rate of 6%. Non-conformance reasons resulted to be as follows: reason n. 1 (80%), reason n. 2 (7%), reason n. 4 (7%).

Country of vaccination



For "Next vaccination date" no MS responded to be conformant. Non-conformance reasons resulted to be as follows: reason n. 1 (87%), reason n. 4 (6%), non-specific reason "Non-conformant (NC)" (7%).

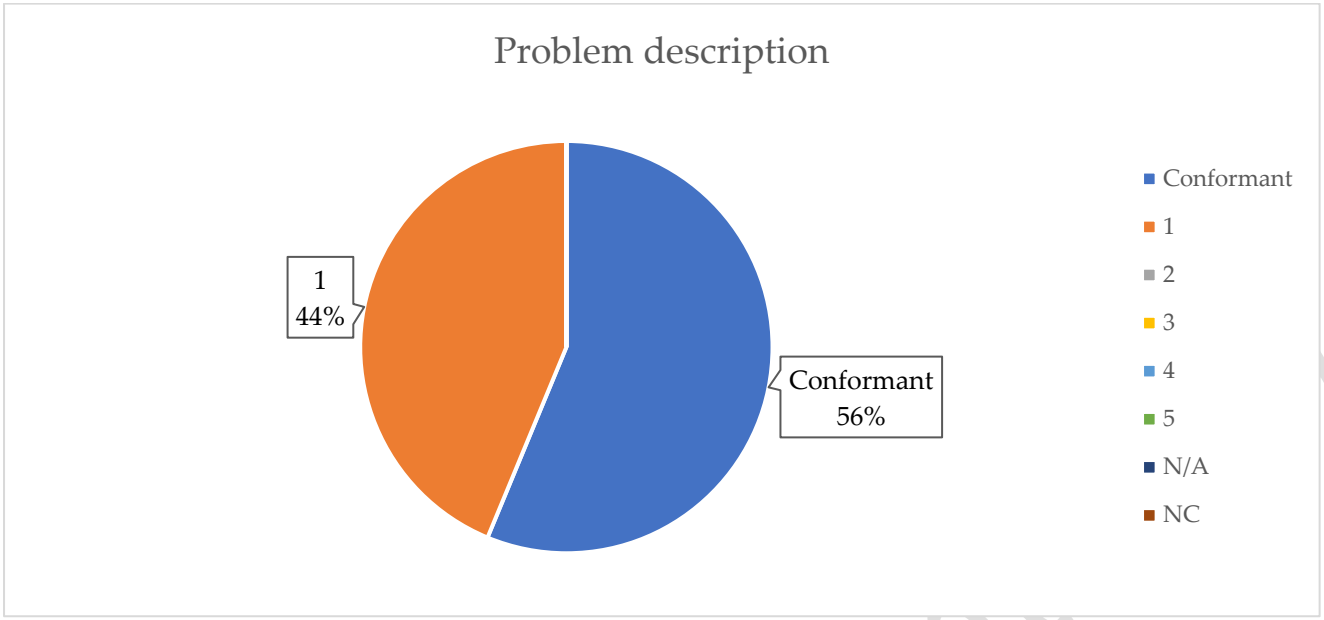
Next vaccination date



The Data Elements “Problem description”, “Problem code”, “Onset date”, “End Date”, “Resolution Circumstances”, “Problem Status code”, “Health Professional related with”, “External Resource related with” are part of the Extended Section “List of Resolved, Closed or Inactive problems”.

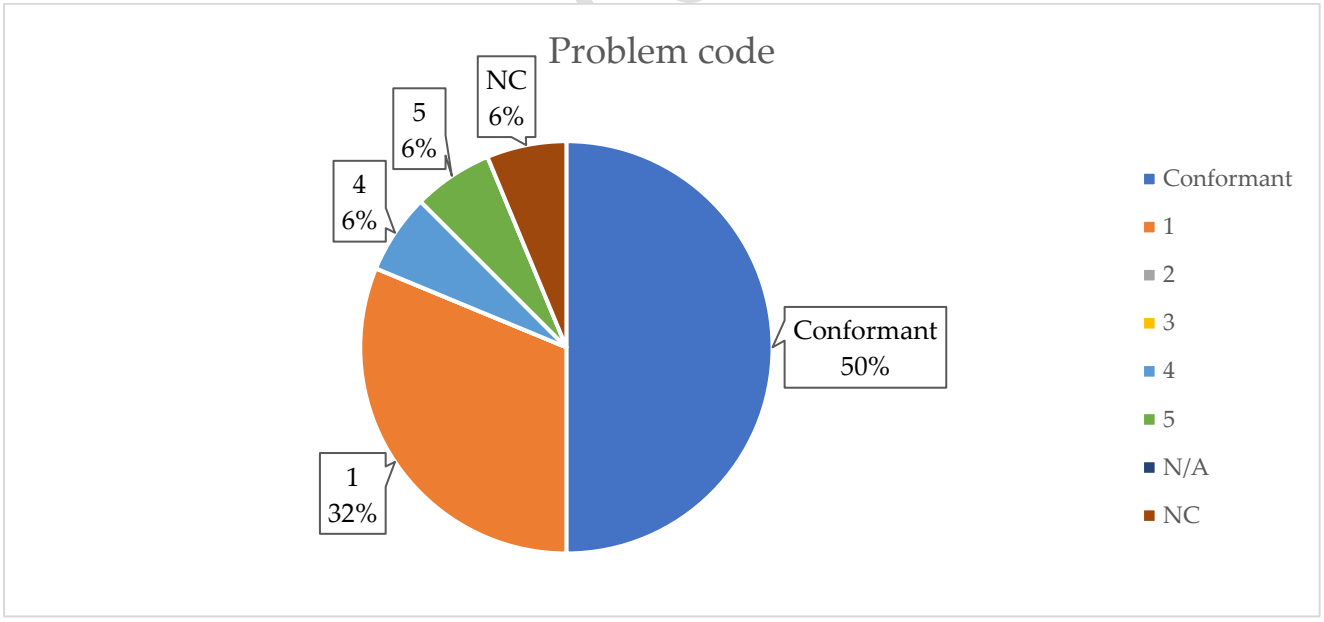
“Problem description” is associated with a conformance rate of 56%. Non-conformance reasons resulted to be as follows: reason n. 1 (44%).

Problem description



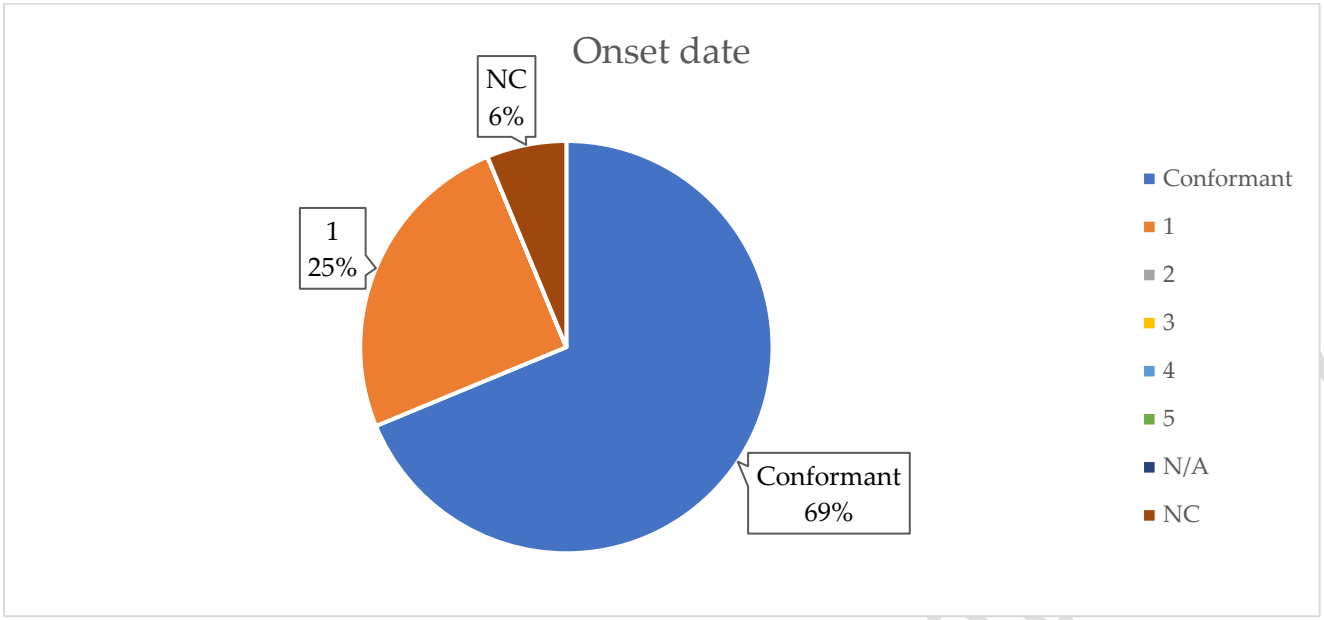
"Problem code" is associated with a conformance rate of 50%. Non-conformance reasons resulted to be as follows: reason n. 1 (32%), reason n. 4 (6%), reason n. 5 (6%), non-specific reason "Non-conformant (NC)" (6%).

Problem code



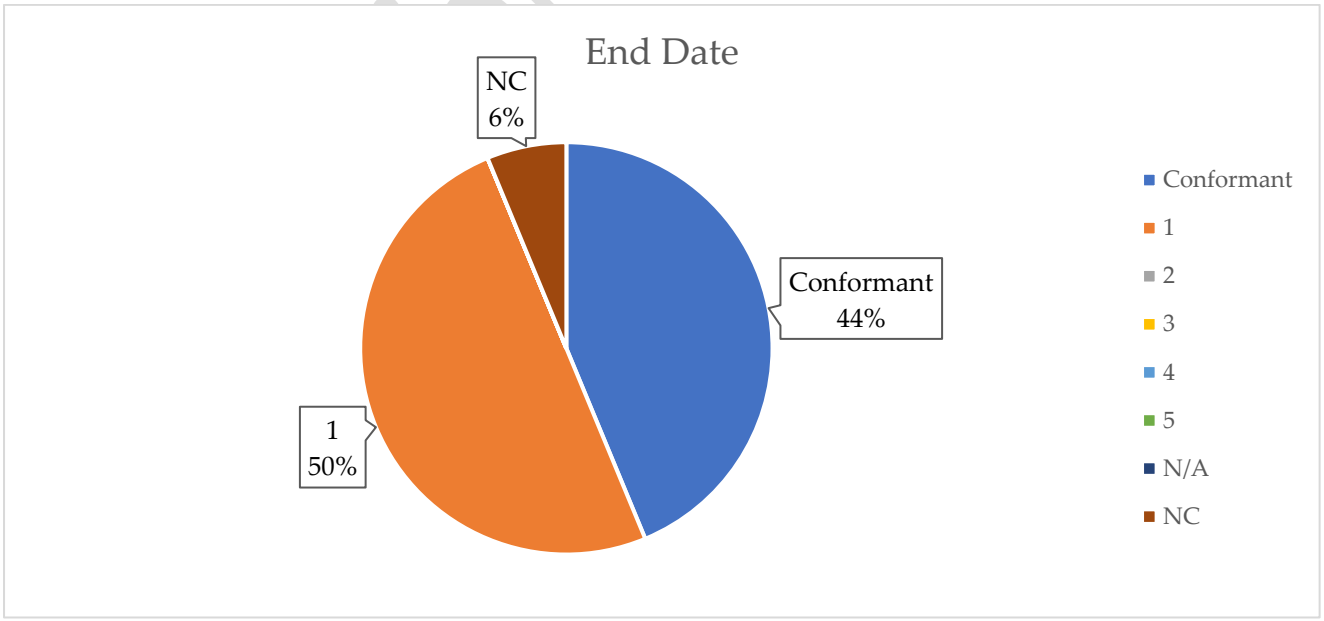
"Onset date" is associated with a conformance rate of 69%. Non-conformance reasons resulted to be as follows: reason n. 1 (25%), non-specific reason "Non-conformant (NC)" (6%).

Onset date



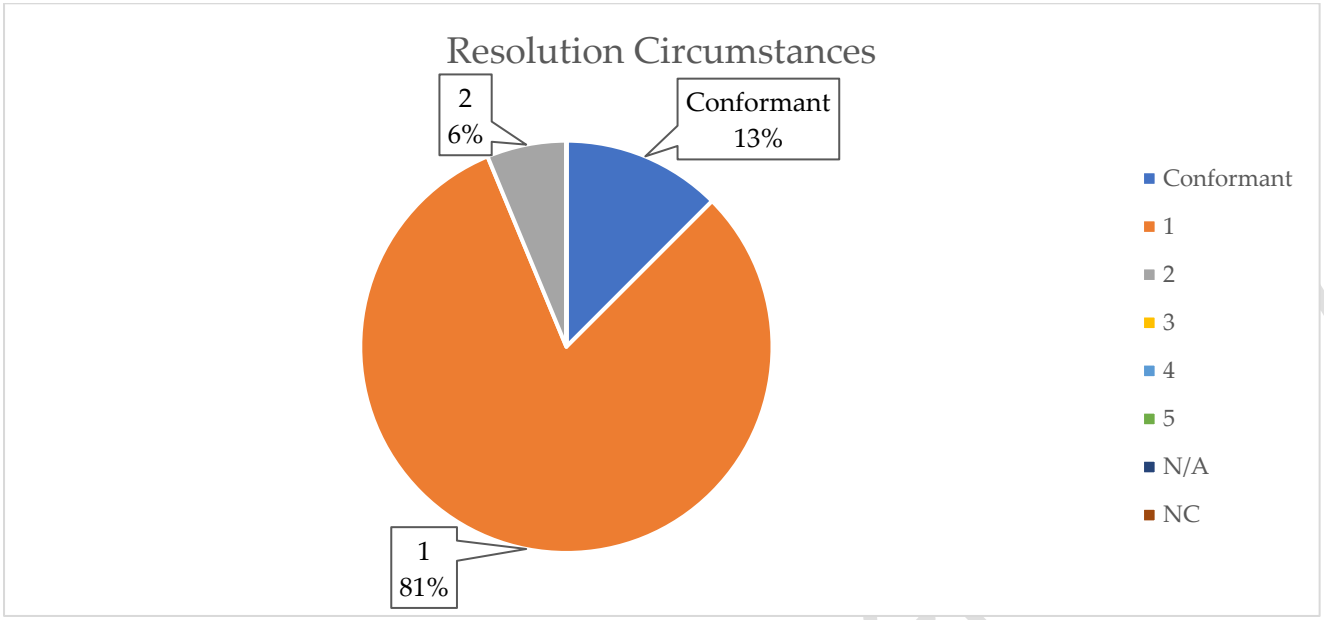
"End Date" is associated with a conformance rate of 44%. Non-conformance reasons resulted to be as follows: reason n. 1 (50%), non-specific reason "Non-conformant (NC)" (6%).

End date



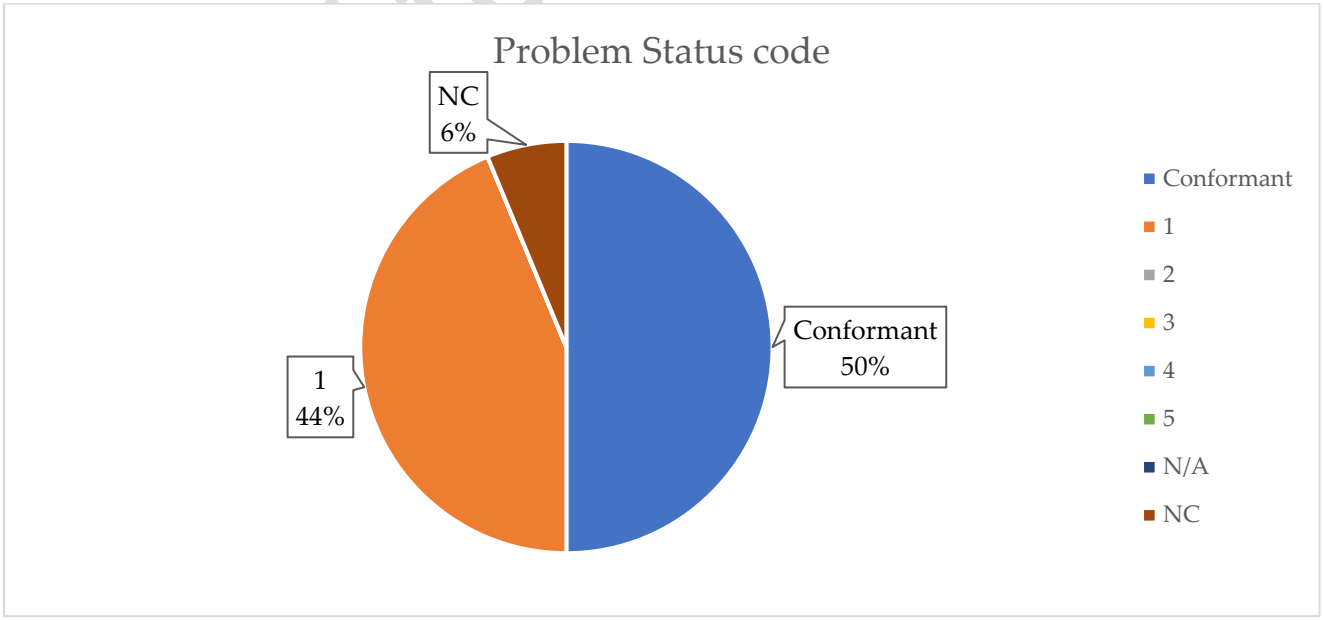
"Resolution Circumstances" is associated with a conformance rate of 13%. Non-conformance reasons resulted to be as follows: reason n. 1 (81%), reason n. 2 (6%).

Resolution circumstances



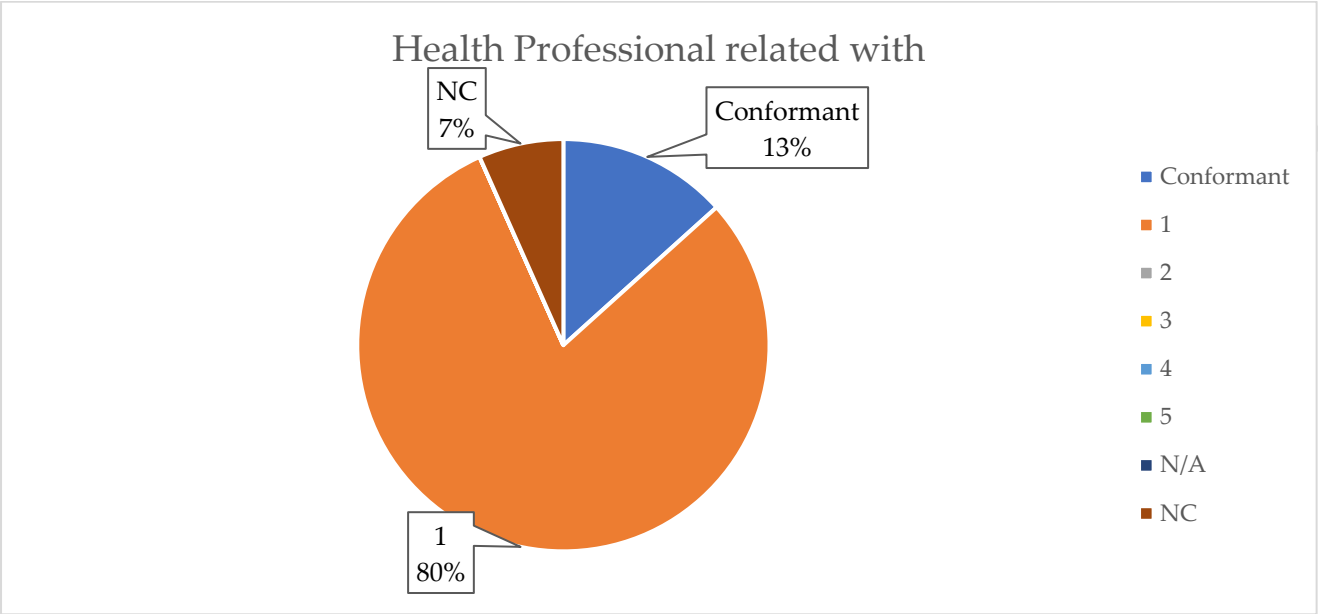
"Problem Status code" is associated with a conformance rate of 50%. Non-conformance reasons resulted to be as follows: reason n. 1 (44%), non-specific reason "Non-conformant (NC)" (6%).

Problem status code



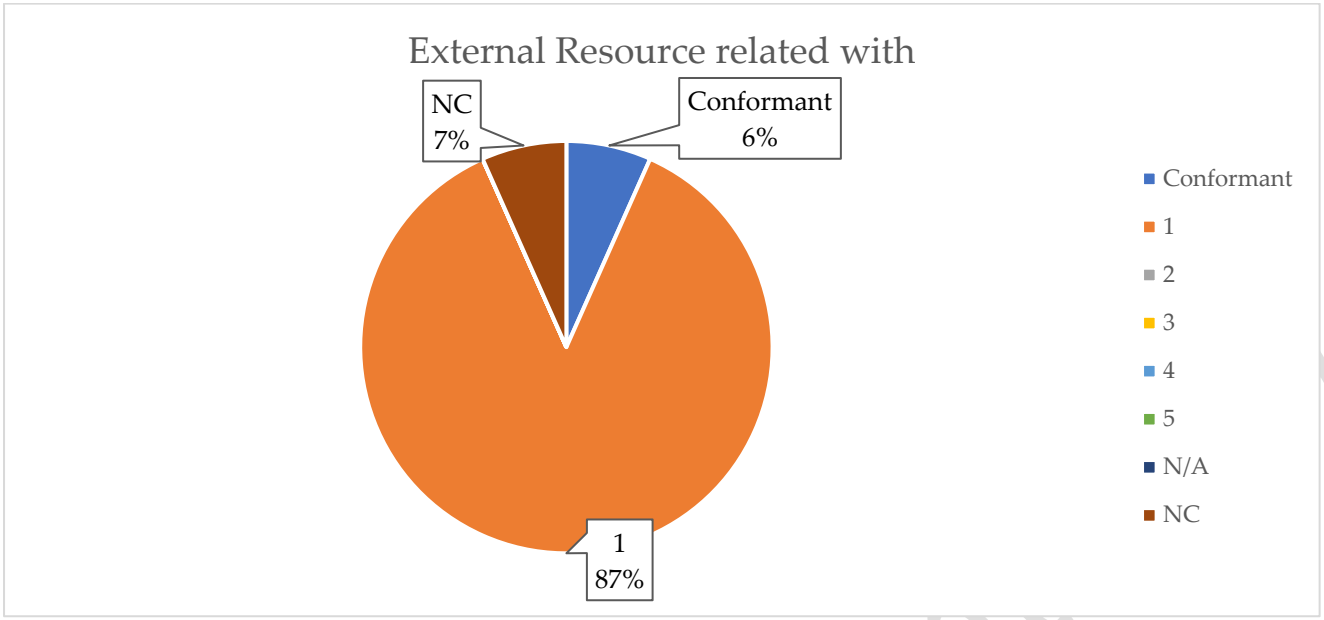
"Health Professional related with" is associated with a conformance rate of 13%. Non-conformance reasons resulted to be as follows: reason n. 1 (80%), non-specific reason "Non-conformant (NC)" (7%).

Health Professional related with



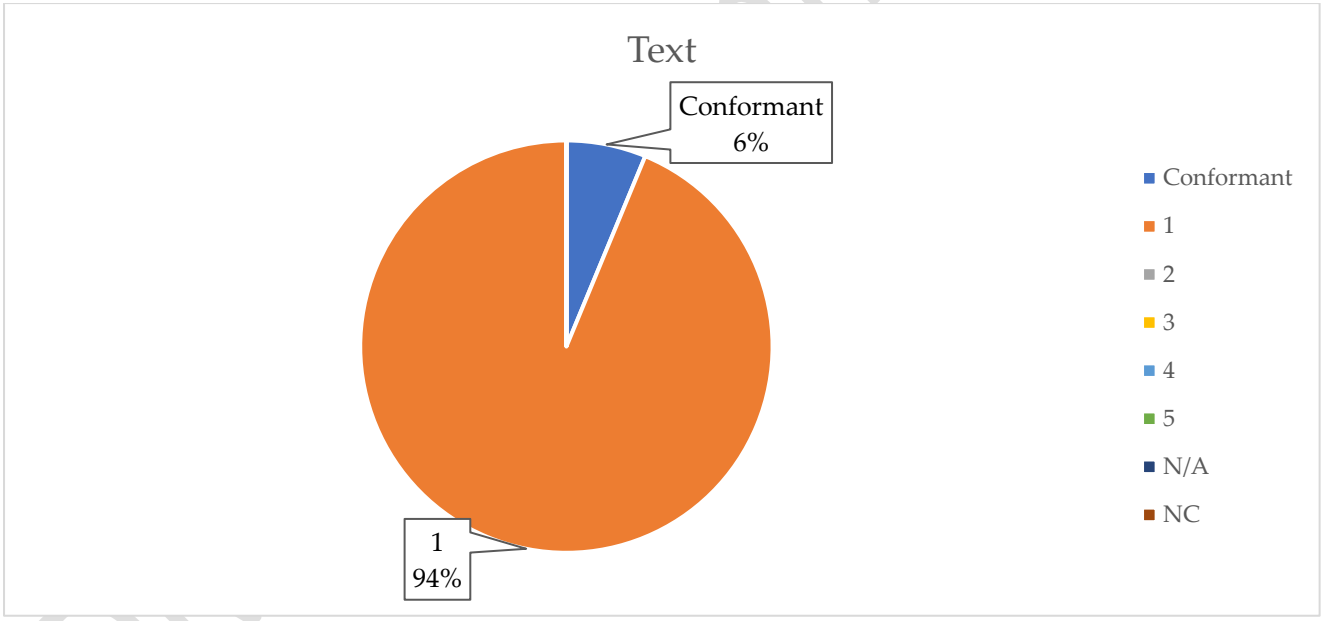
"External Resource related with" is associated with a conformance rate of 6%. Non-conformance reasons resulted to be as follows: reason n. 1 (87%), non-specific reason "Non-conformant (NC)" (7%).

External resource related with



Data Element "Text" relate to Extended Section "Medical History" and is associated with a conformance rate of 6%. Non-conformance reasons resulted to be as follows: reason n. 1 (94%).

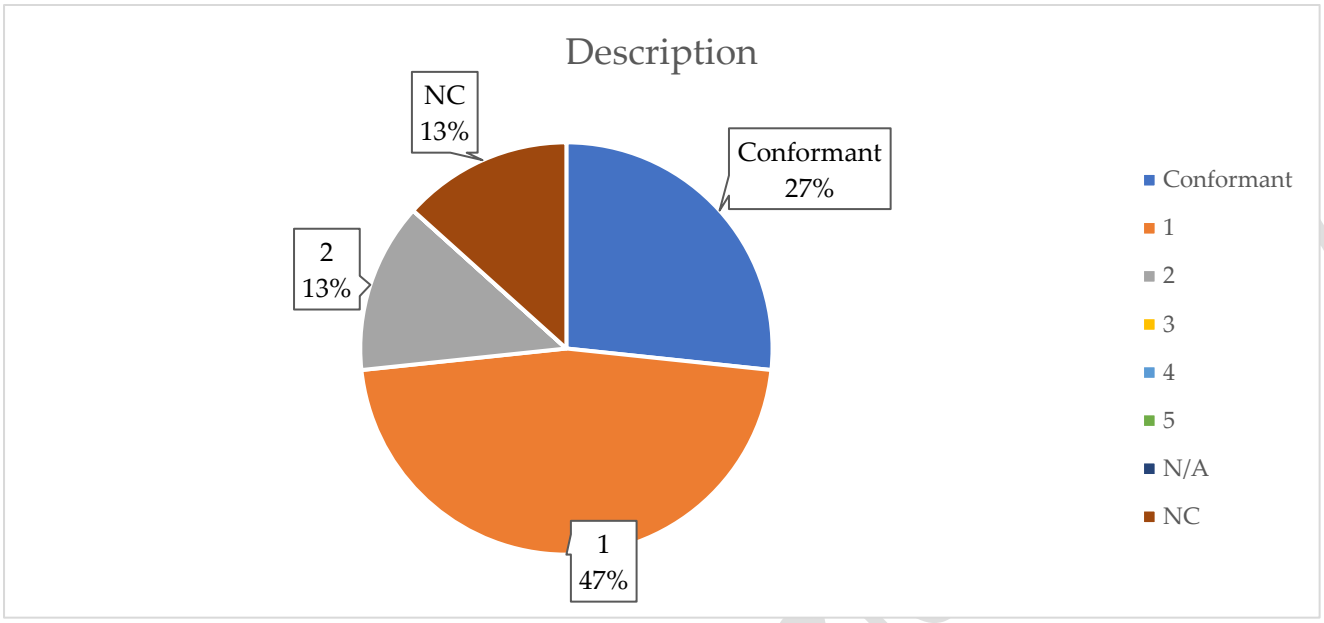
Text



The Data Elements "Description", "Onset Date", "Functional assessment description", "Functional assessment code", "Functional assessment date", "Functional assessment result" are part of the Extended Section "Functional status".

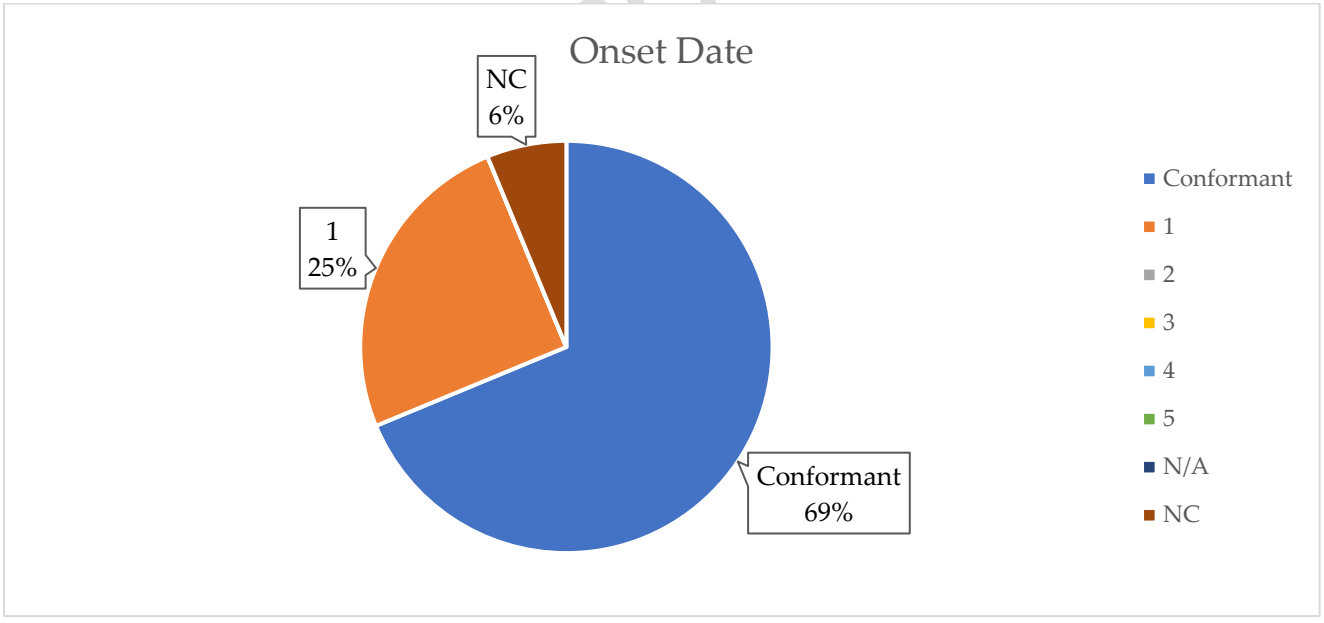
"Description" is associated with a conformance rate of 27%. Non-conformance reasons resulted to be as follows: reason n. 1 (47%), reason n. 2 (13%), non-specific reason "Non-conformant (NC)" (%).

Description



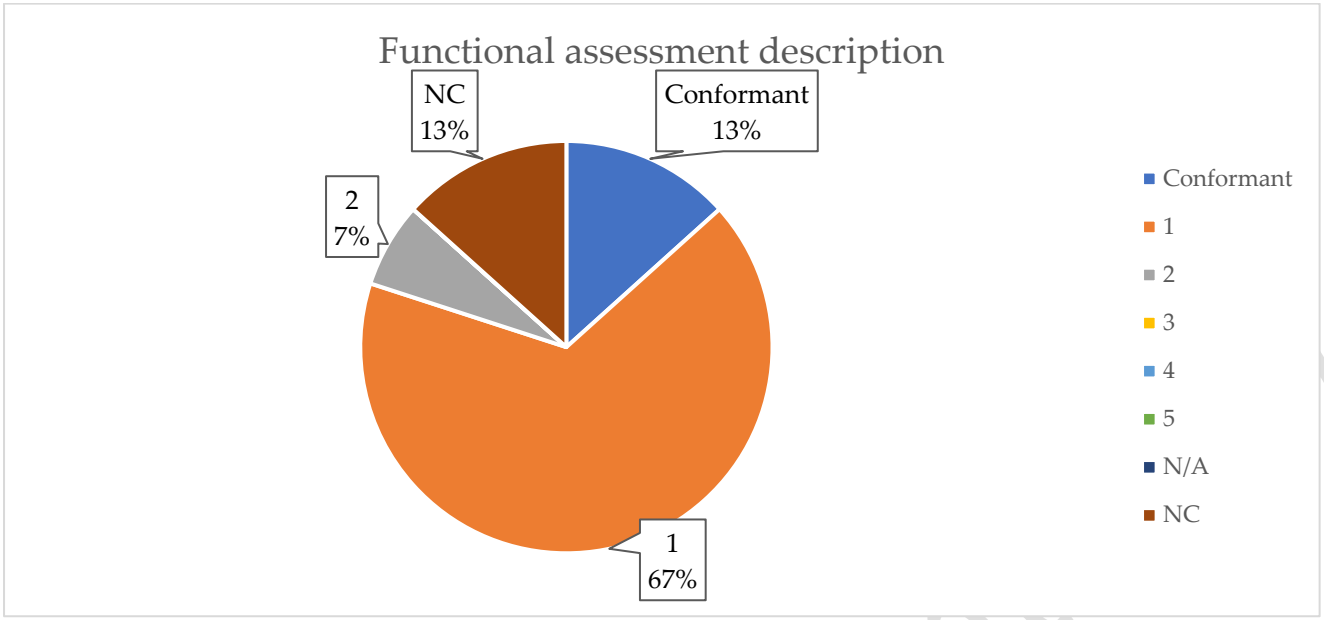
"Onset Date" is associated with a conformance rate of 69%. Non-conformance reasons resulted to be as follows: reason n. 1 (25%), non-specific reason "Non-conformant (NC)" (6%).

Onset date



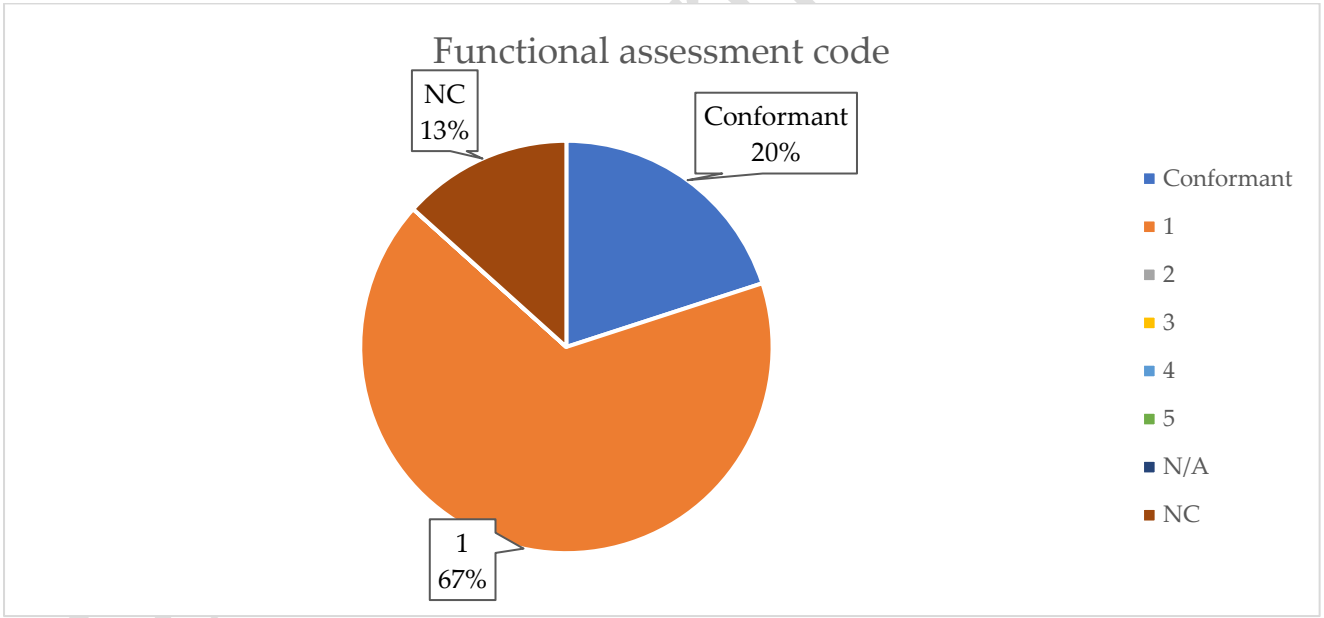
"Functional assessment description" is associated with a conformance rate of 13%. Non-conformance reasons resulted to be as follows: reason n. 1 (67%), reason n. 2 (7%), non-specific reason "Non-conformant (NC)" (13%).

Functional assessment description



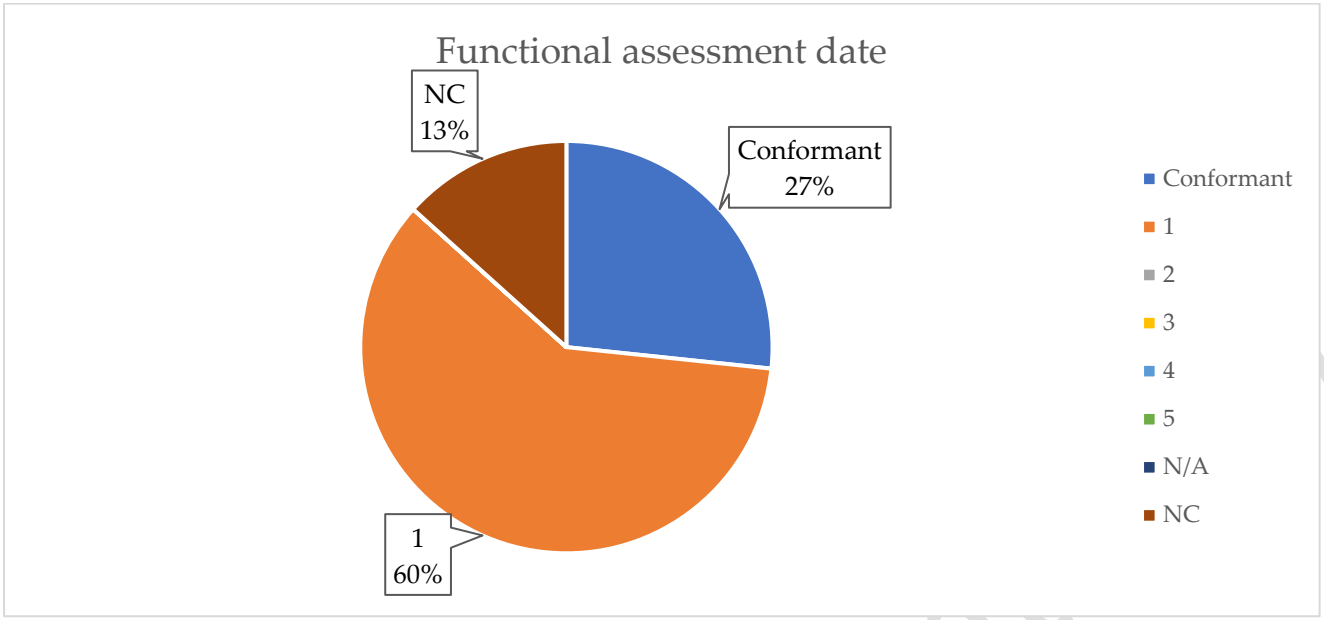
"Functional assessment code" is associated with a conformance rate of 20%. Non-conformance reasons resulted to be as follows: reason n. 1 (67%), non-specific reason "Non-conformant (NC)" (13%).

Functional assessment code



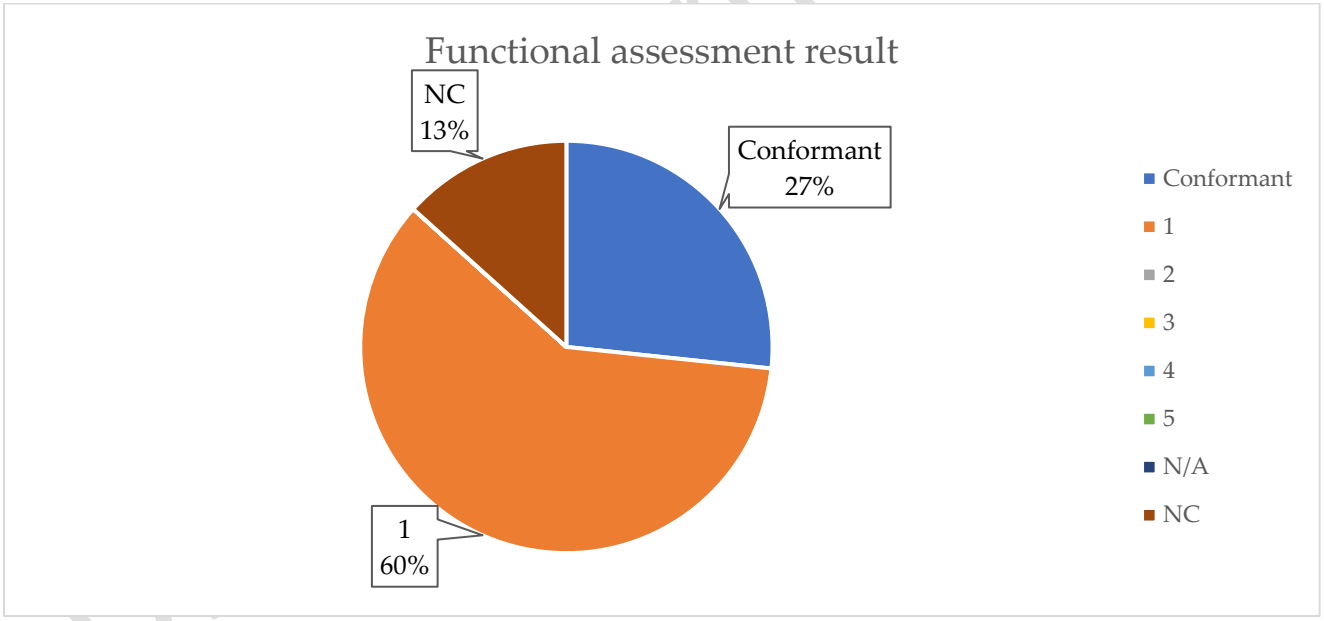
"Functional assessment date" is associated with a conformance rate of 27%. Non-conformance reasons resulted to be as follows: reason n. 1 (60%), non-specific reason "Non-conformant (NC)" (13%).

Functional assessment date



"Functional assessment result" is associated with a conformance rate of 27%. Non-conformance reasons resulted to be as follows: reason n. 1 (60%), non-specific reason "Non-conformant (NC)" (13%).

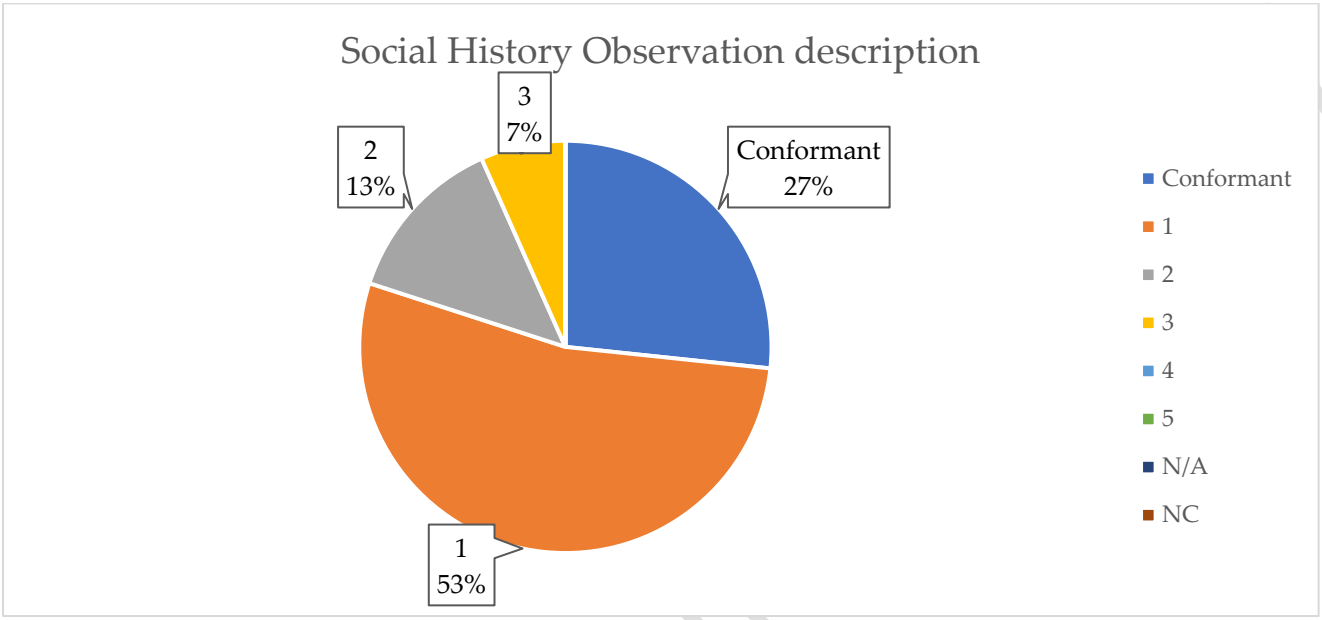
Functional assessment result



The Data Elements "Social History Observation description", "Social History Observation code", "Social History Observation value", "Reference date range" are part of the Extended Section "Social History Observations".

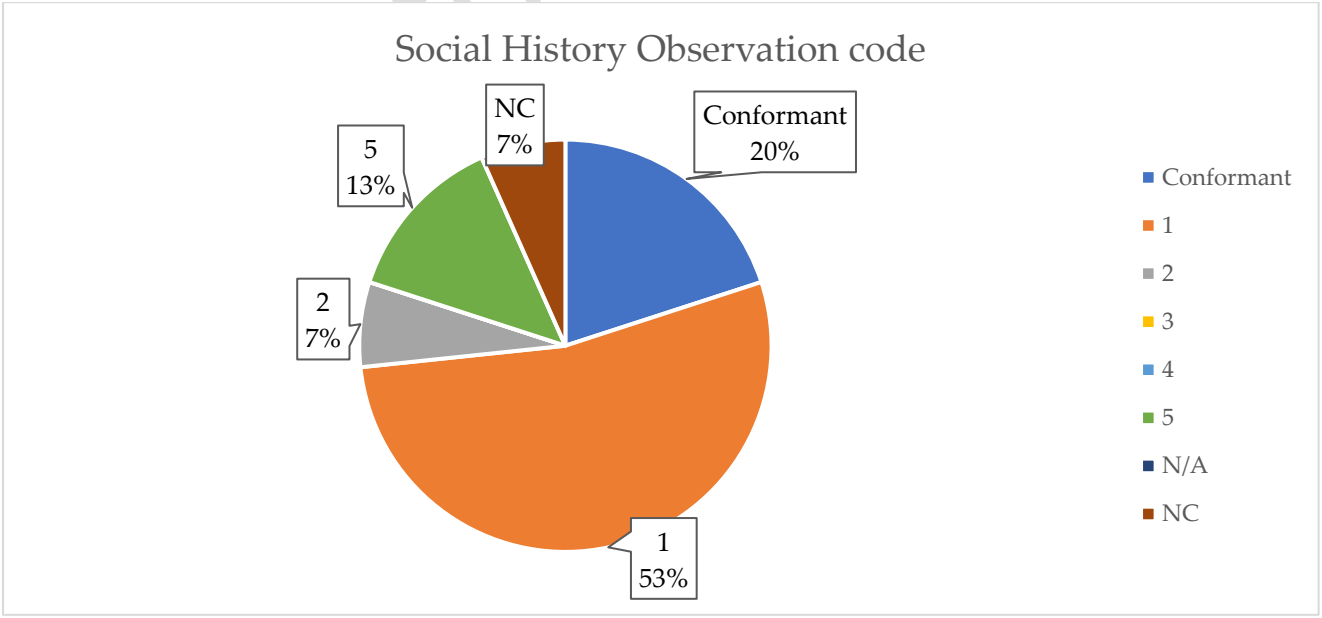
"Social History Observation description" is associated with a conformance rate of 27%. Non-conformance reasons resulted to be as follows: reason n. 1 (53%), reason n. 2 (13%), reason n. 3 (7%).

Social history observation description



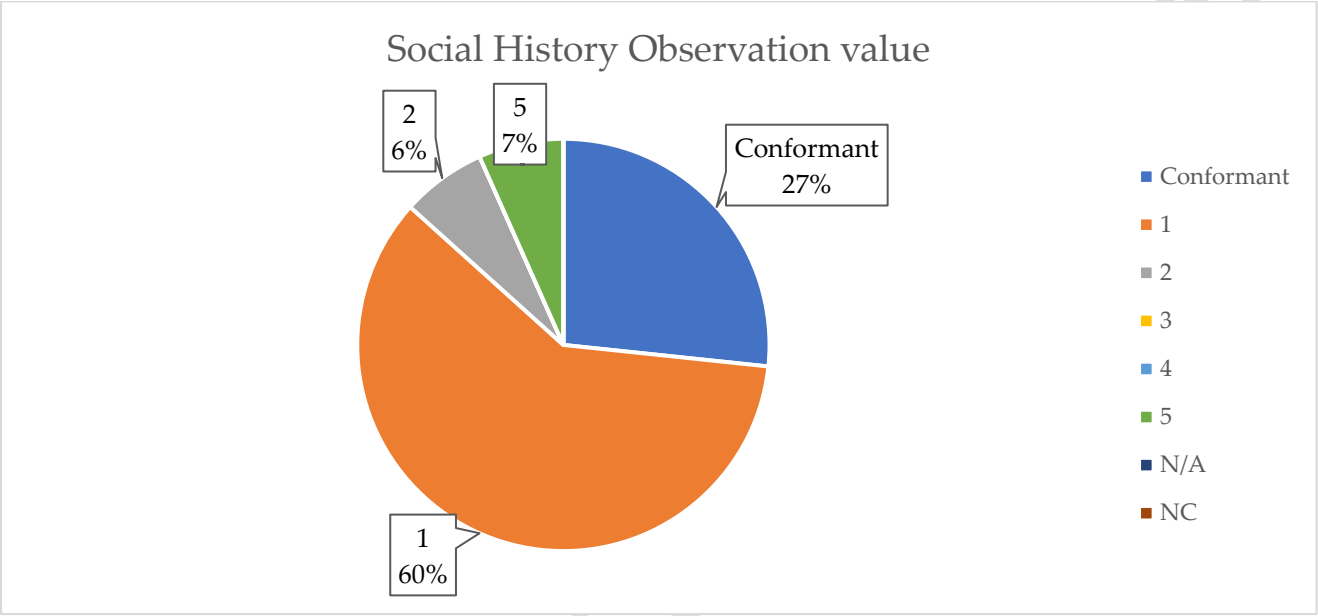
"Social History Observation code" is associated with a conformance rate of 20%. Non-conformance reasons resulted to be as follows: reason n. 1 (53%), reason n. 2 (7%), reason n. 5 (13%), non-specific reason "Non-conformant (NC)" (7%).

Social history observation code



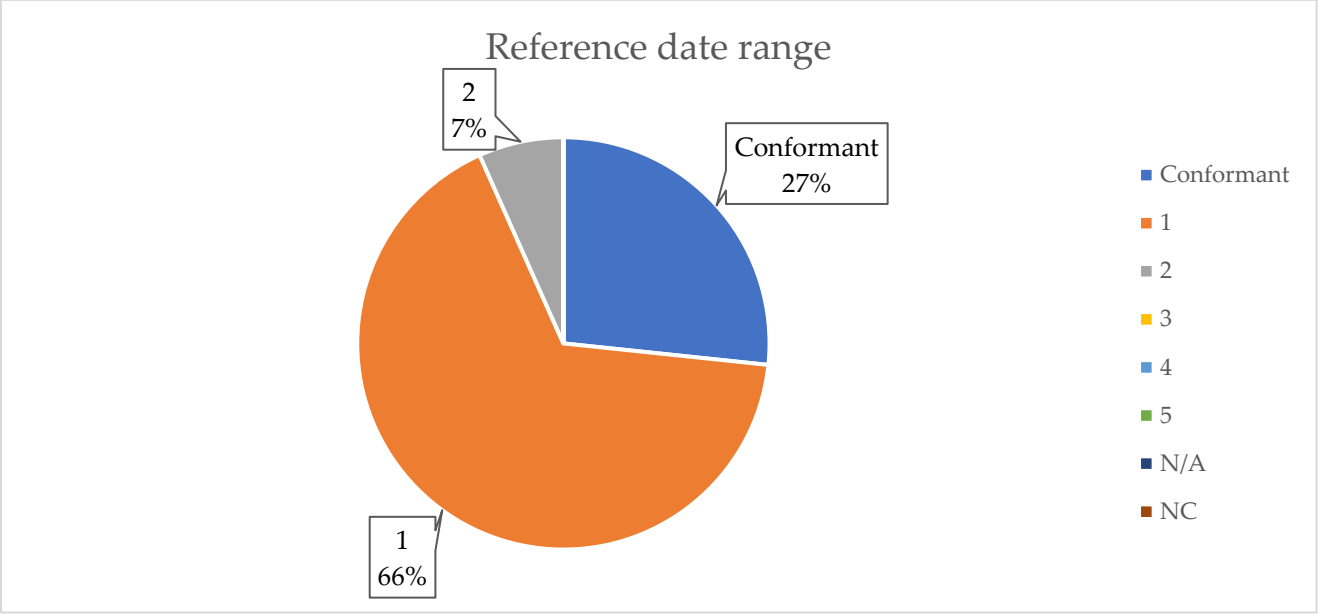
"Social History Observation value" is associated with a conformance rate of 27%. Non-conformance reasons resulted to be as follows: reason n. 1 (60%), reason n. 2 (6%), reason n. 5 (7%).

Social history observation value



"Reference date range" is associated with a conformance rate of 27%. Non-conformance reasons resulted to be as follows: reason n. 1 (66%), reason n. 2 (7%).

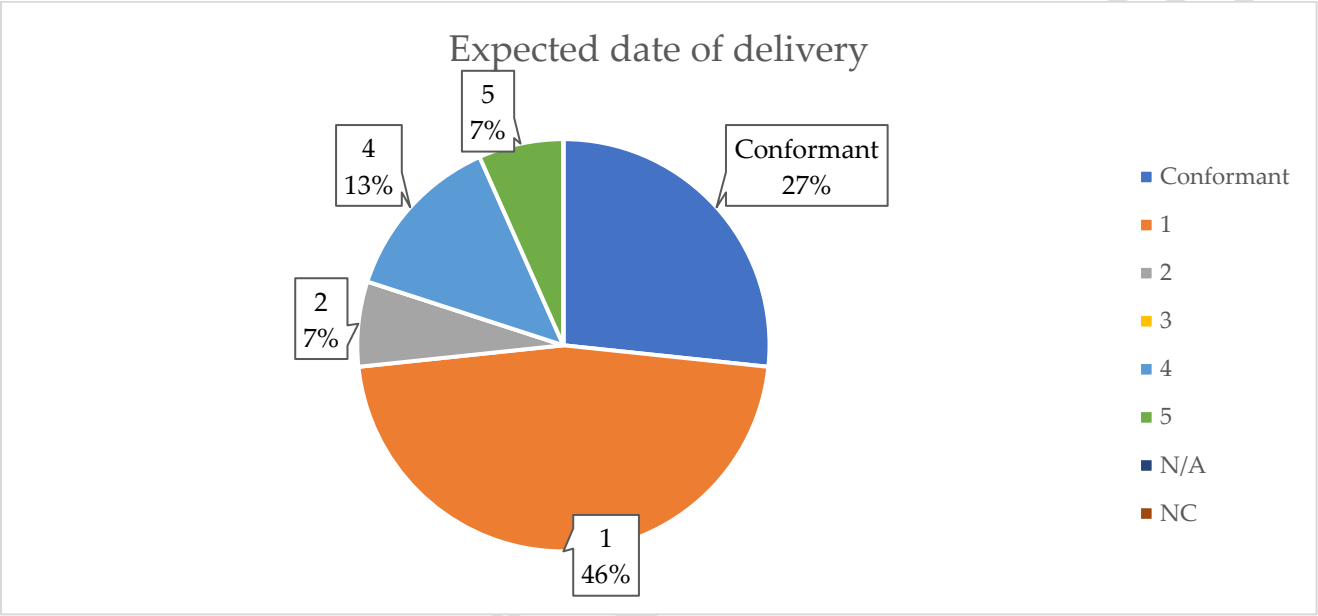
Reference date range



The Data Elements "Expected date of delivery", "Pregnancy observation code", "Date of observation", "Status" are part of the o Extended Section "Current pregnancy status"

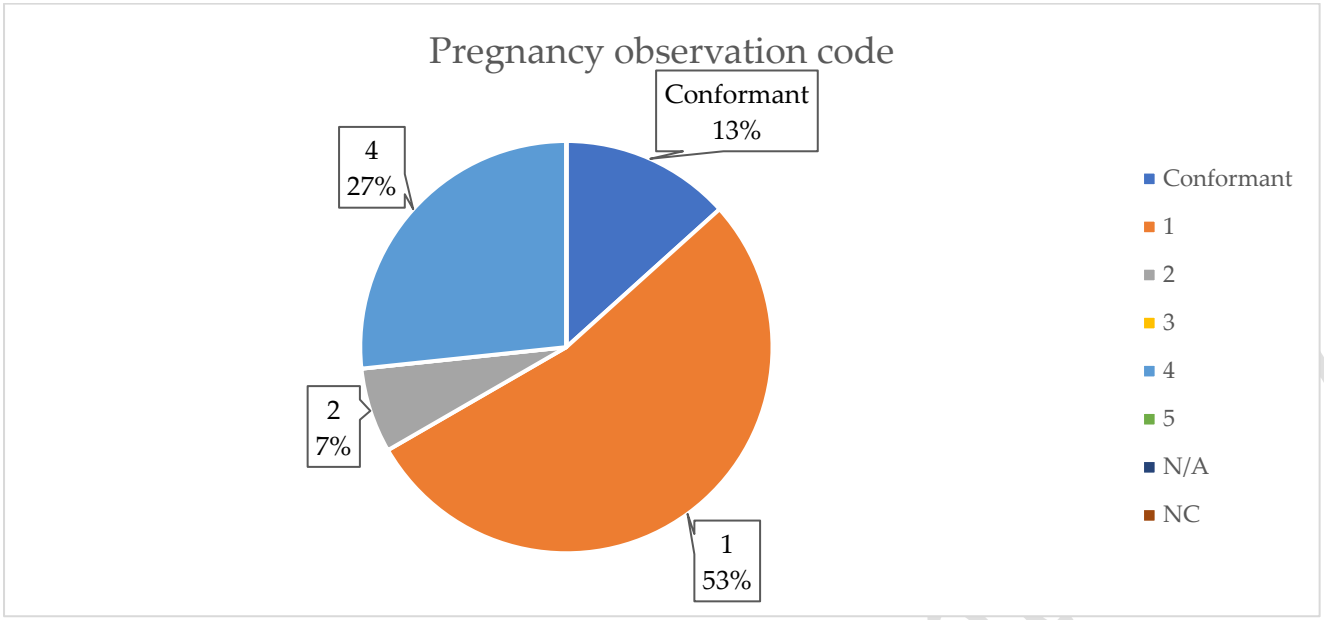
"Expected date of delivery" is associated with a conformance rate of 27%. Non-conformance reasons resulted to be as follows: reason n. 1 (46%), reason n. 2 (7%), reason n. 4 (13%), reason n. 5 (7%).

Expected date of delivery



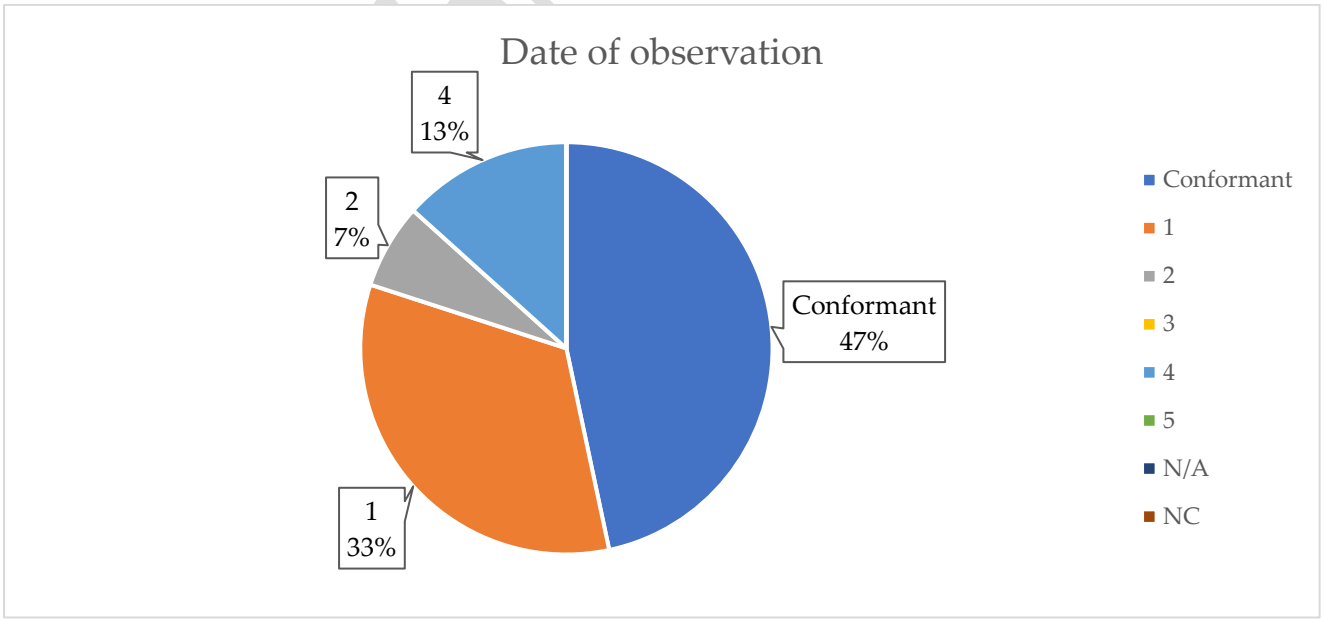
"Pregnancy observation code" is associated with a conformance rate of 13%. Non-conformance reasons resulted to be as follows: reason n. 1 (53%), reason n. 2 (7%), reason n. 4 (27%).

Pregnancy observation code



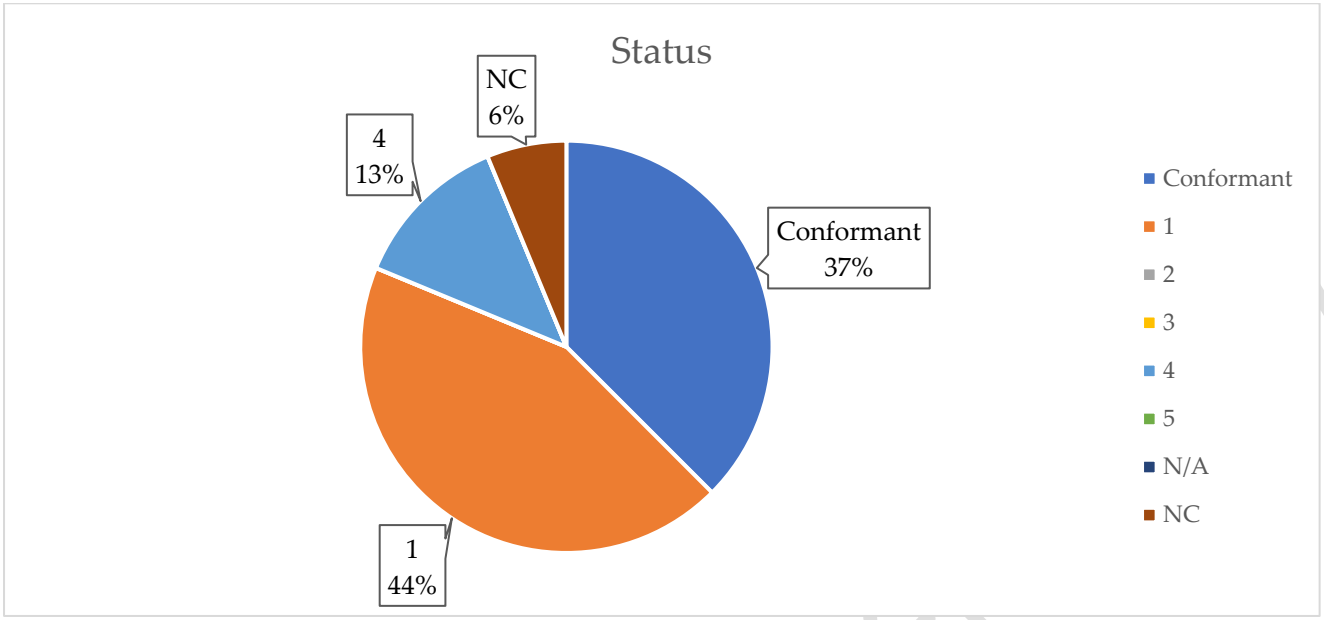
"Date of observation" is associated with a conformance rate of 47%. Non-conformance reasons resulted to be as follows: reason n. 1 (33%), reason n. 2 (7%), reason n. 4 (13%).

Date of observation



"Status" is associated with a conformance rate of 37%. Non-conformance reasons resulted to be as follows: reason n. 1 (44%), reason n. 4 (13%), non-specific reason "Non-conformant (NC)" (6%).

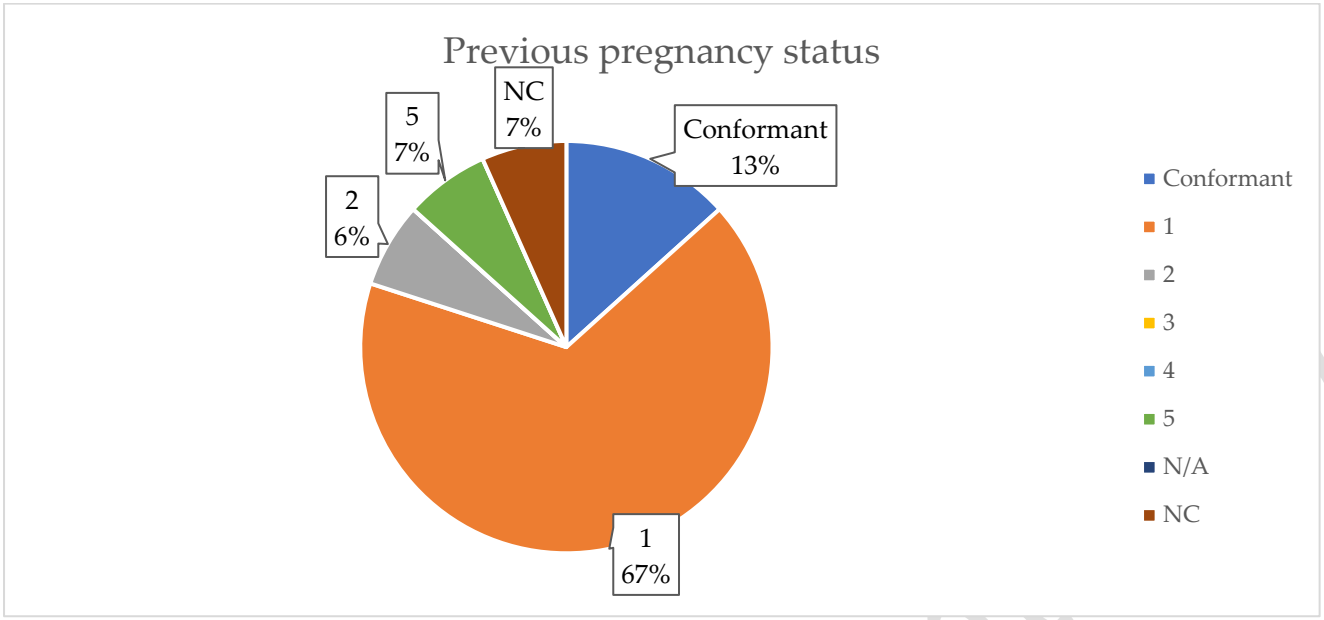
Status



The Data Elements "Previous pregnancy status", "Previous pregnancy description", "Outcome date", "Outcome", "Number of children" are part of the Extended Section "History of previous pregnancies"

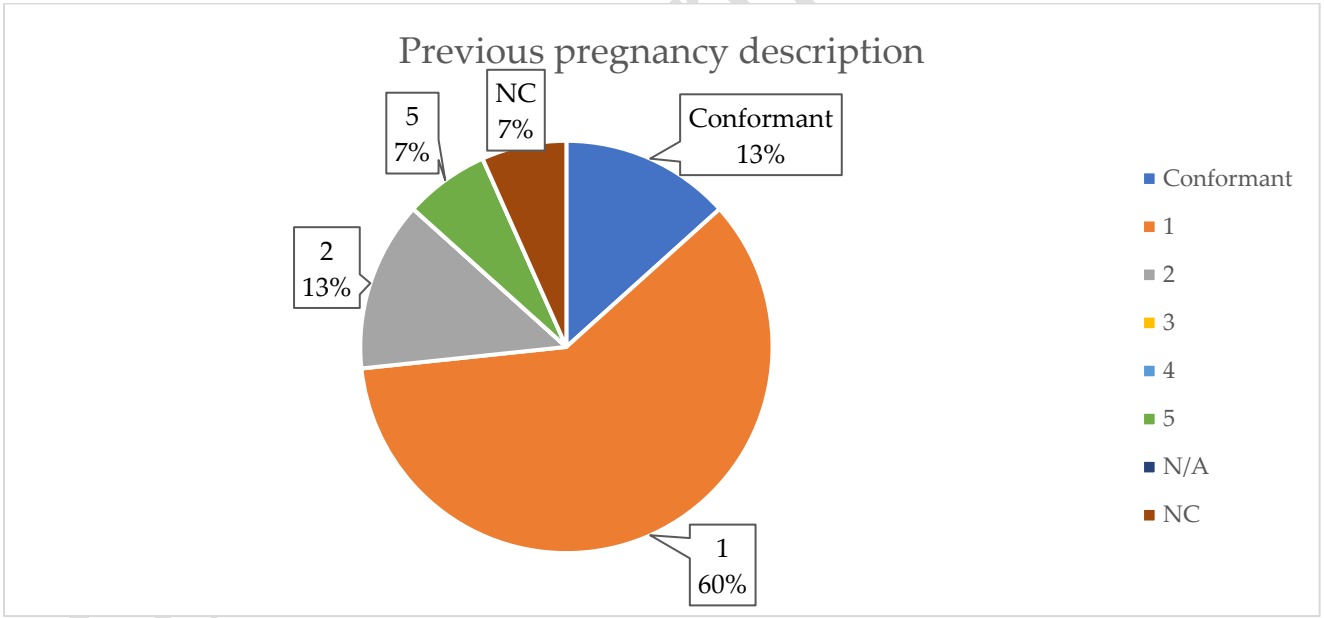
"Previous pregnancy status" is associated with a conformance rate of 13%. Non-conformance reasons resulted to be as follows: reason n. 1 (67%), reason n. 2 (6%), reason n. 5 (7%), non-specific reason "Non-conformant (NC)" (7%).

Previous pregnancy status



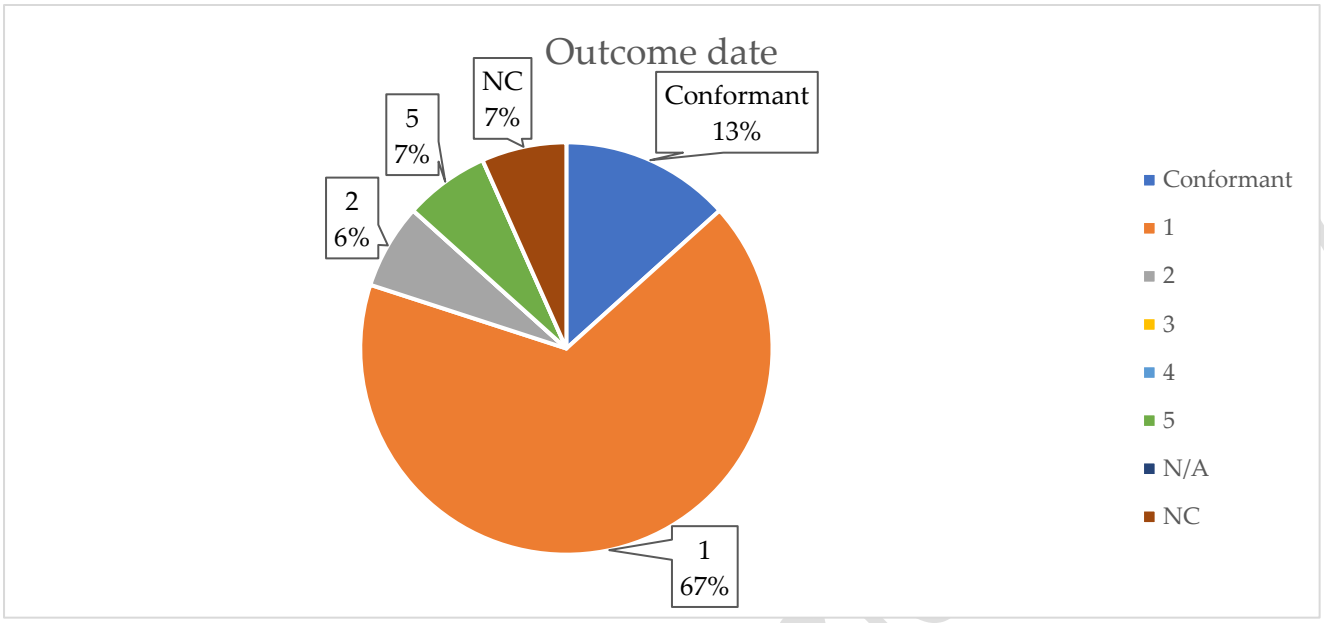
"Previous pregnancy description" is associated with a conformance rate of 13%. Non-conformance reasons resulted to be as follows: reason n. 1 (60%), reason n. 2 (13%), reason n. 5 (7%), non-specific reason "Non-conformant (NC)" (7%).

Previous pregnancy description



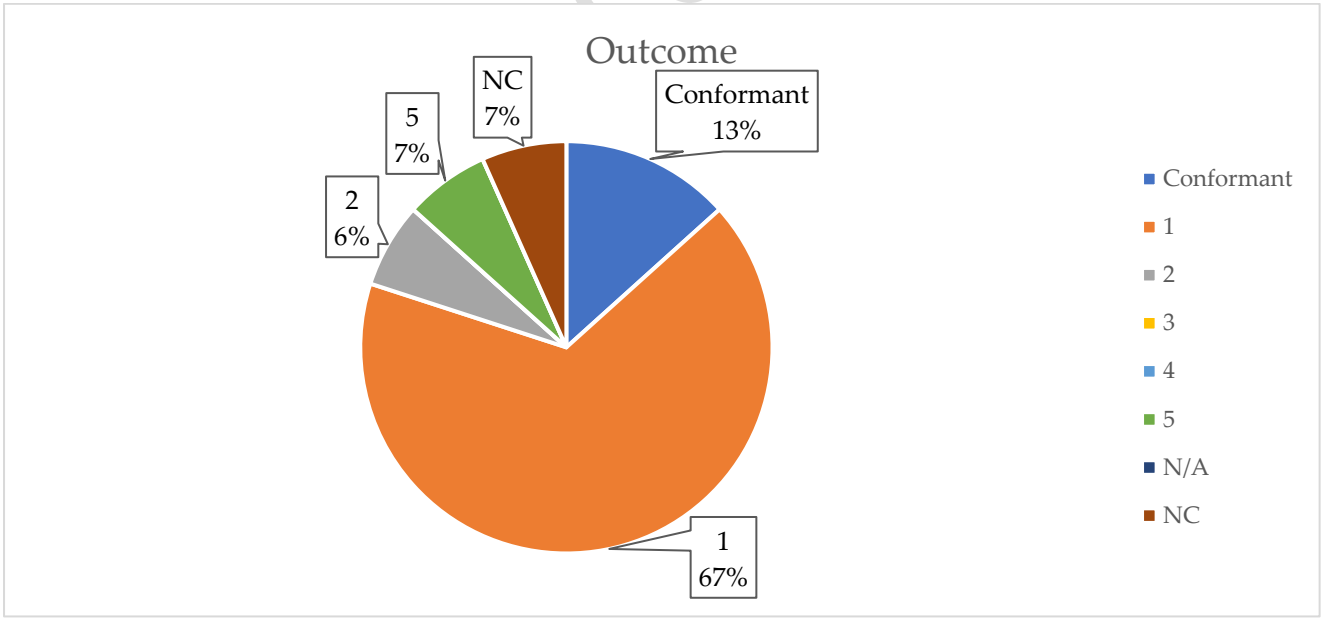
"Outcome date" is associated with a conformance rate of 13%. Non-conformance reasons resulted to be as follows: reason n. 1 (67%), reason n. 2 (6%), reason n. 5 (7%), non-specific reason "Non-conformant (NC)" (7%).

Outcome date



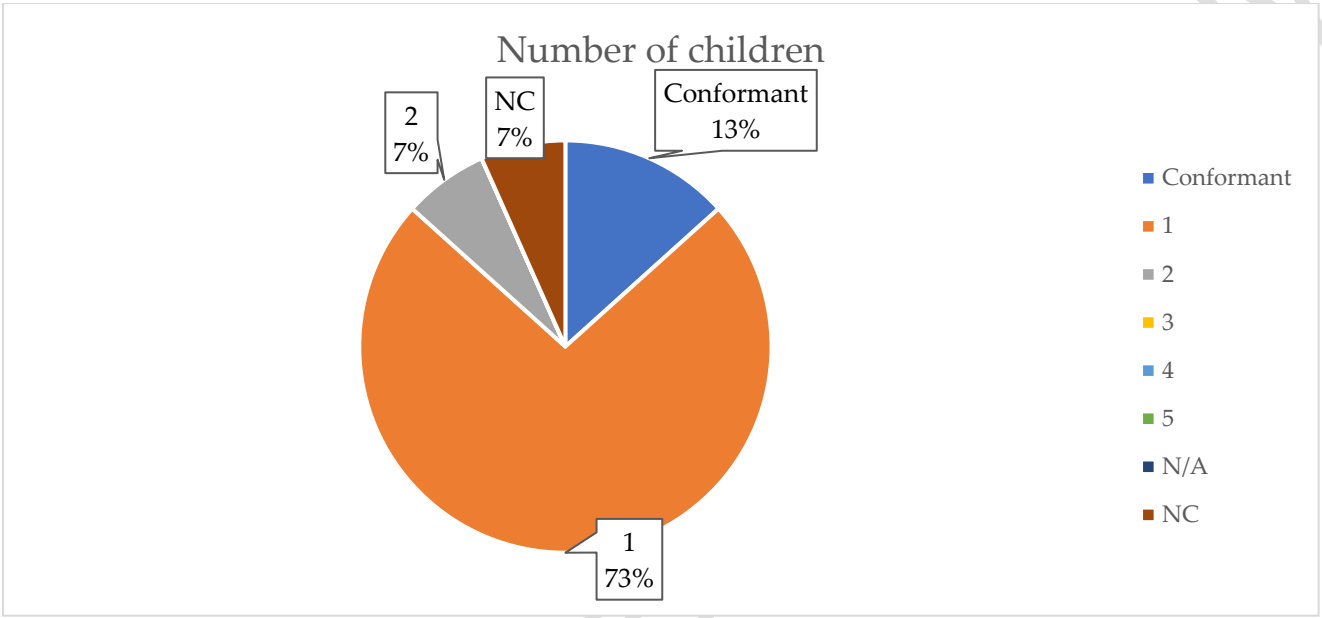
"Outcome" is associated with a conformance rate of 13%. Non-conformance reasons resulted to be as follows: reason n. 1 (67%), reason n. 2 (6%), reason n. 5 (7%), non-specific reason "Non-conformant (NC)" (7%).

Outcome



"Number of children" is associated with a conformance rate of 13%. Non-conformance reasons resulted to be as follows: reason n. 1 (73%), reason n. 2 (7%), non-specific reason "Non-conformant (NC)" (7%).

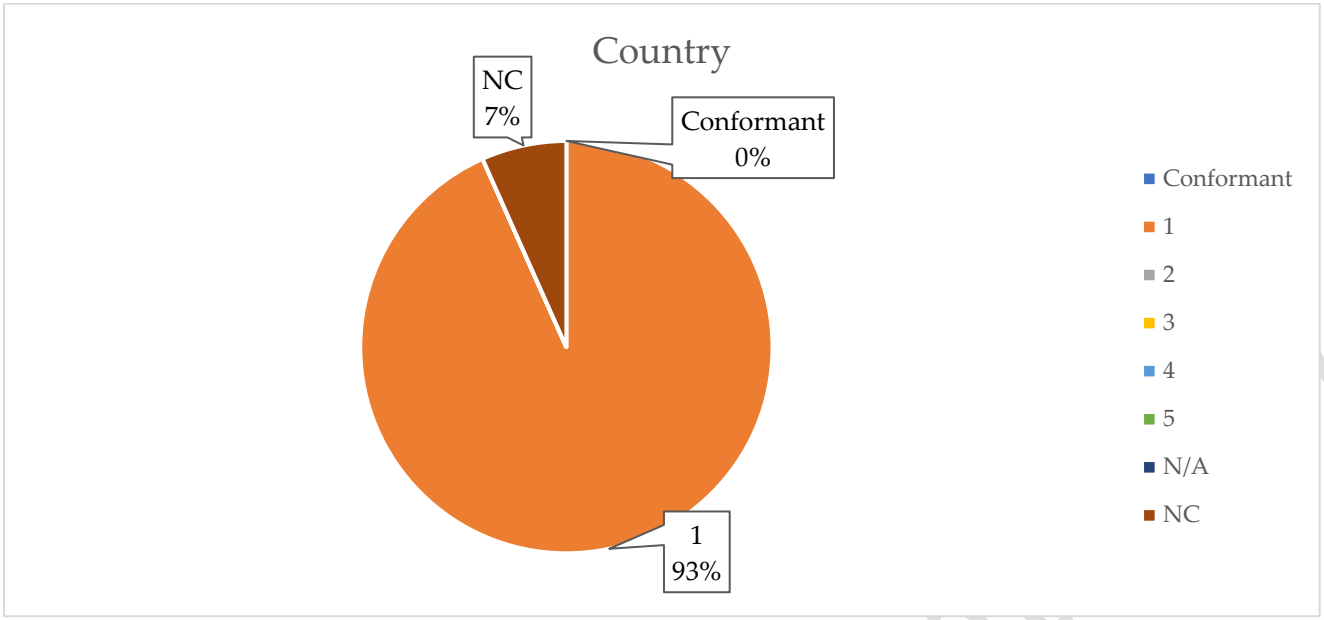
Number of children



The Data Elements “Country”, “Period” are part of the Extended Section “Travel history”

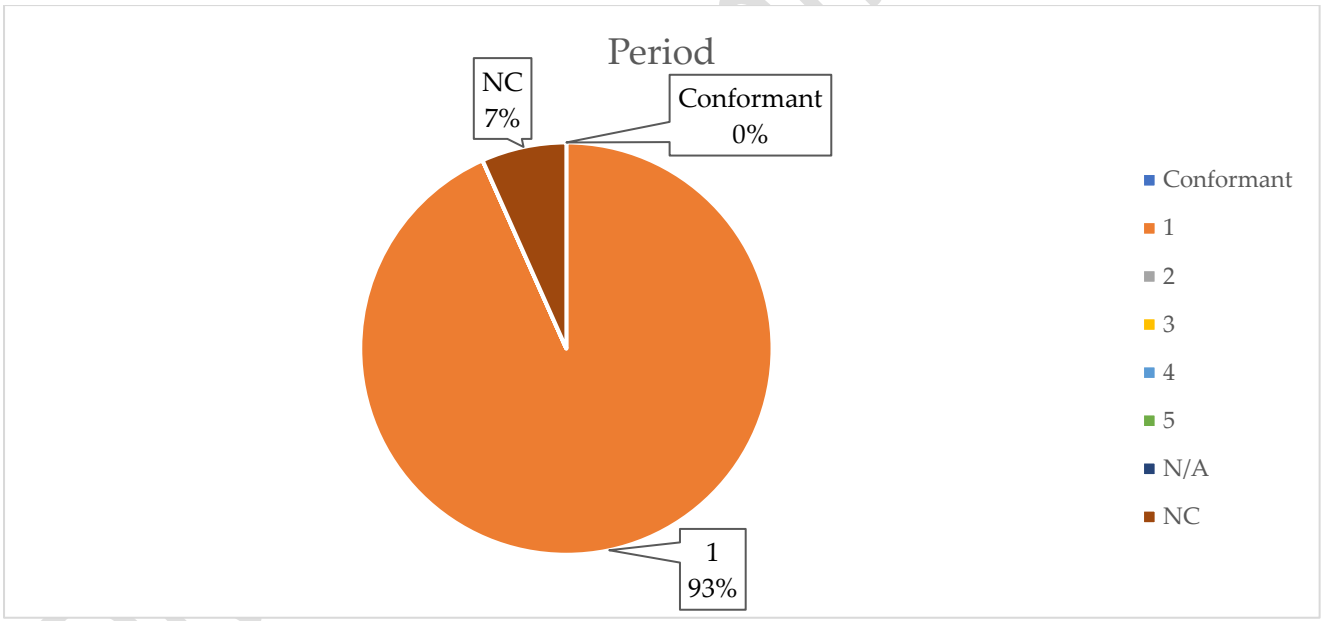
For “Country” no MS responded to be conformant. Non-conformance reasons resulted to be as follows: reason n. 1 (93%), non-specific reason “Non-conformant (NC)” (7%).

Country



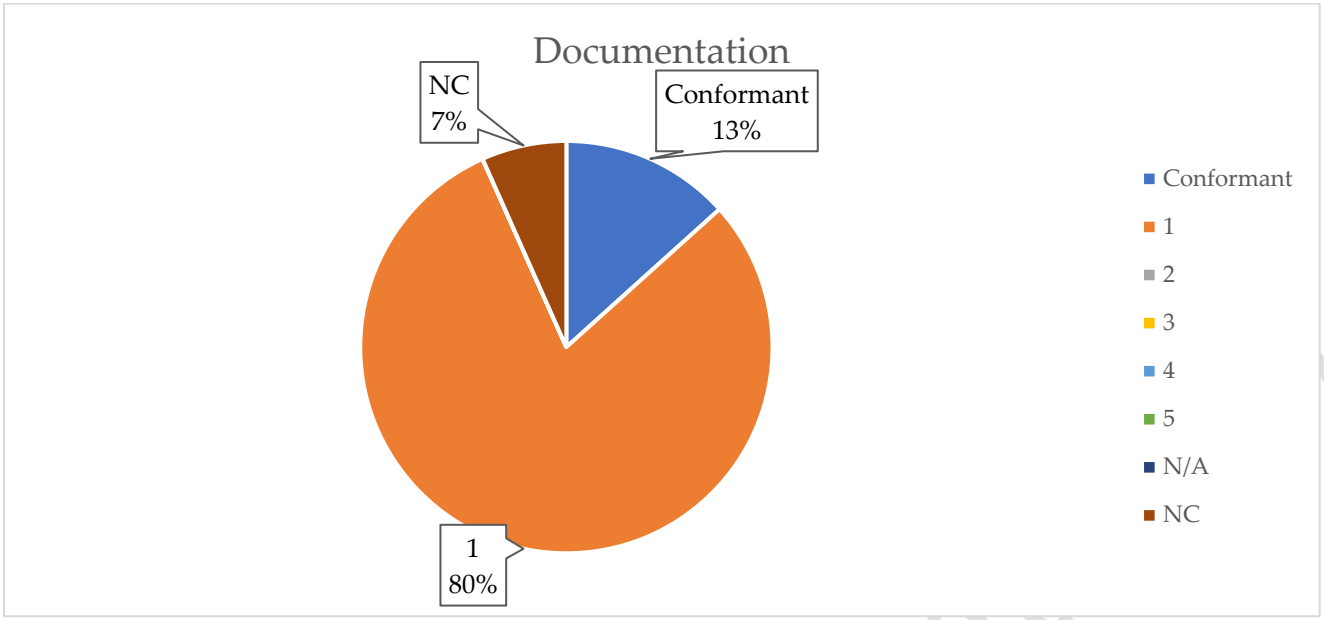
For "Period" no MS responded to be conformant. Non-conformance reasons resulted to be as follows: reason n. 1 (93%), non-specific reason "Non-conformant (NC)" (7%).

Period



The Data Element "Documentation" is part of the Extended Section "Advance Directive" and is associated with a conformance rate of 13%. Non-conformance reasons resulted to be as follows: reason n. 1 (80%), non-specific reason "Non-conformant (NC)" (7%).

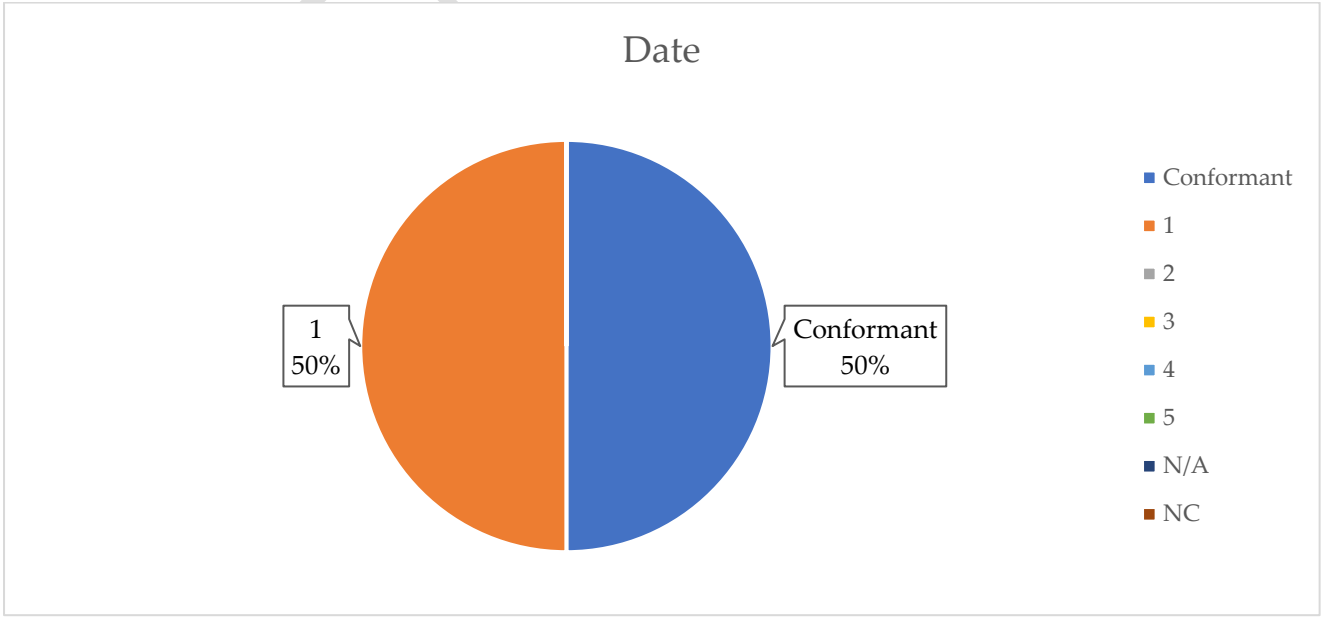
Documentation



The Data Elements: "Date", "Observation type", "Result description", "Observation details", "Observation results", "Performer", "Reporter" are part of the Extended Section "Result observations"

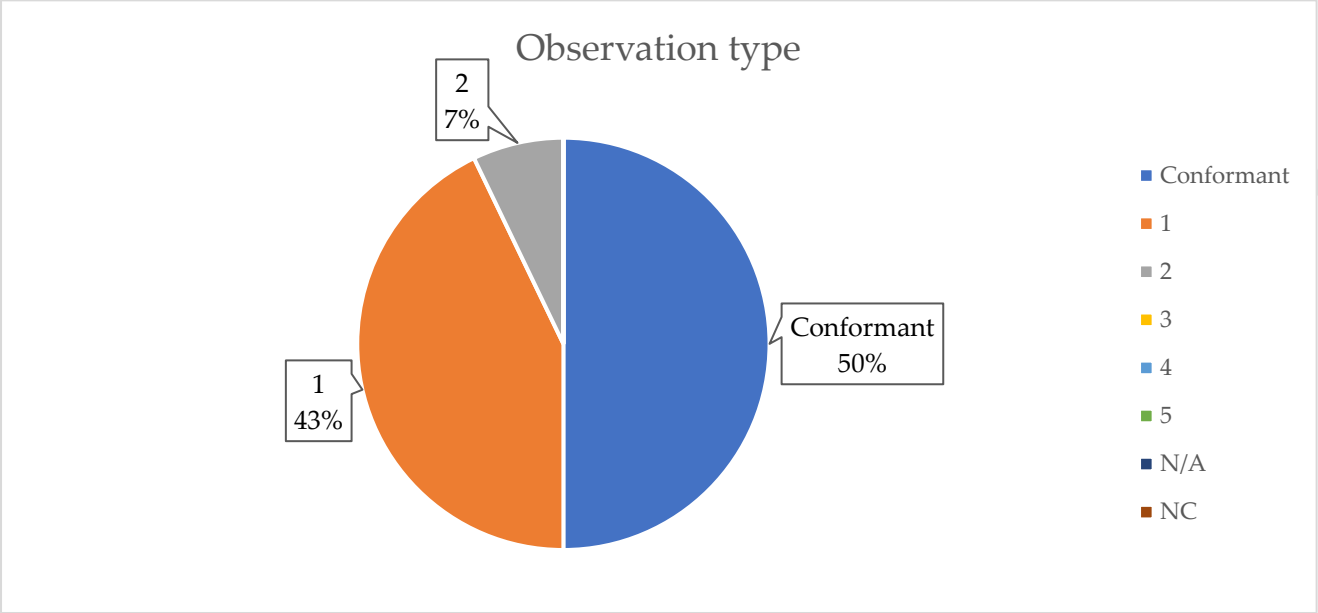
"Date" is associated with a conformance rate of 50%. Non-conformance reasons resulted to be as follows: reason n. 1 (50%).

Date



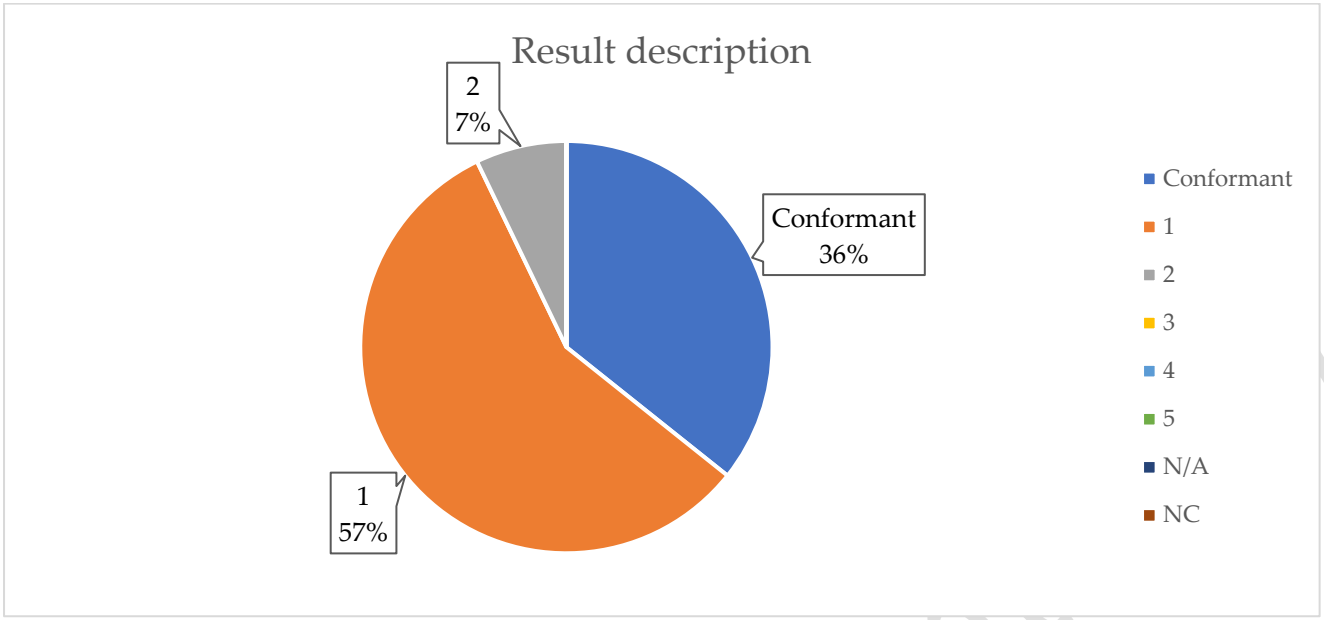
"Observation type" is associated with a conformance rate of 50%. Non-conformance reasons resulted to be as follows: reason n. 1 (43%), reason n. 2 (7%).

Observation type



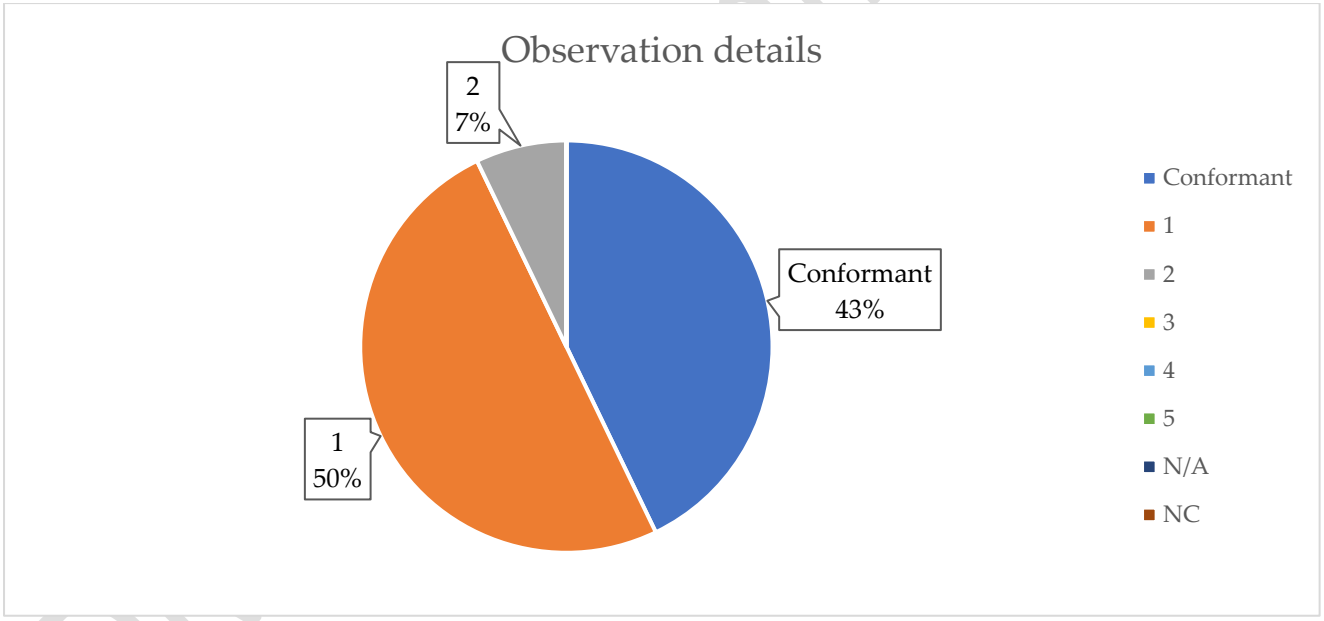
"Result description" is associated with a conformance rate of 36%. Non-conformance reasons resulted to be as follows: reason n. 1 (57%), reason n. 2 (7%).

Result description



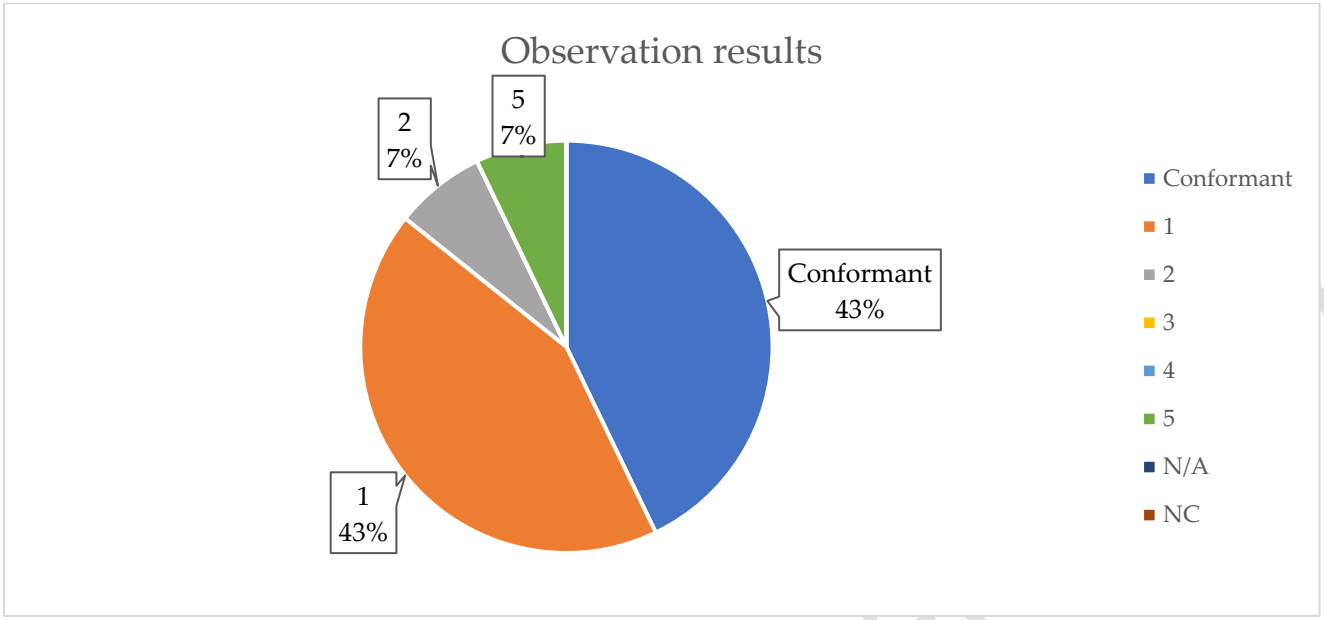
"Observation details" is associated with a conformance rate of 43%. Non-conformance reasons resulted to be as follows: reason n. 1 (50%), reason n. 2 (7%).

Observation details



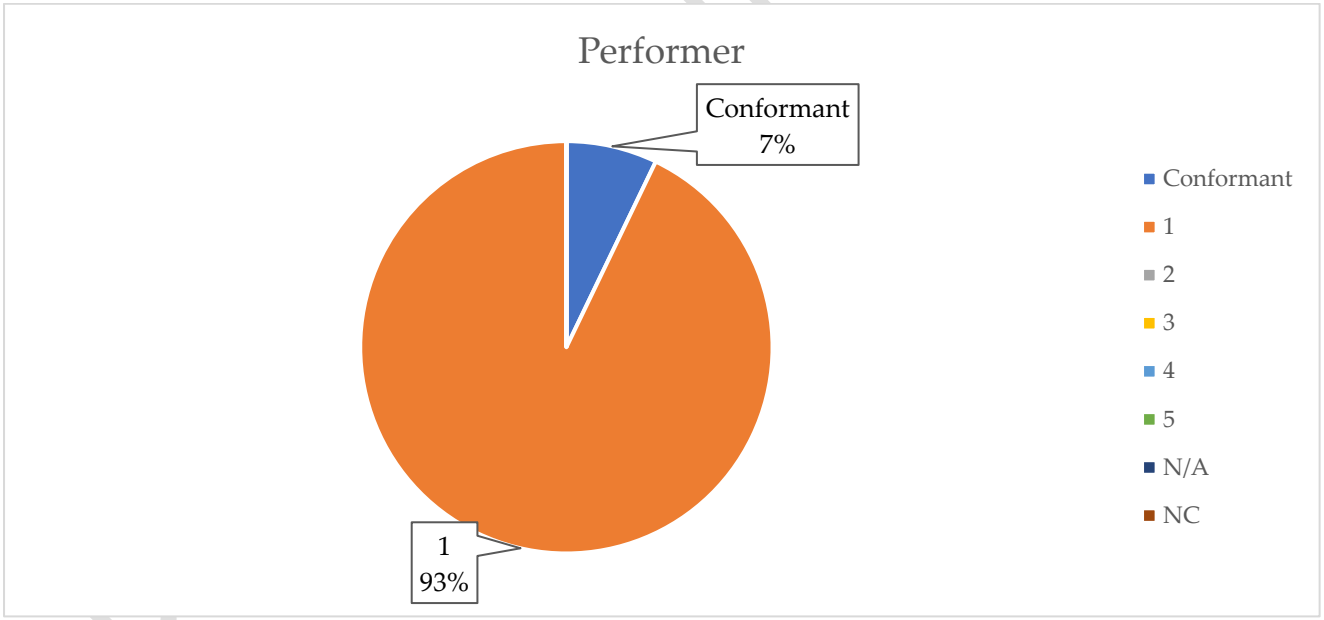
"Observation results" is associated with a conformance rate of 43%. Non-conformance reasons resulted to be as follows: reason n. 1 (43%), reason n. 2 (7%), reason n. 5 (7%).

Observation results



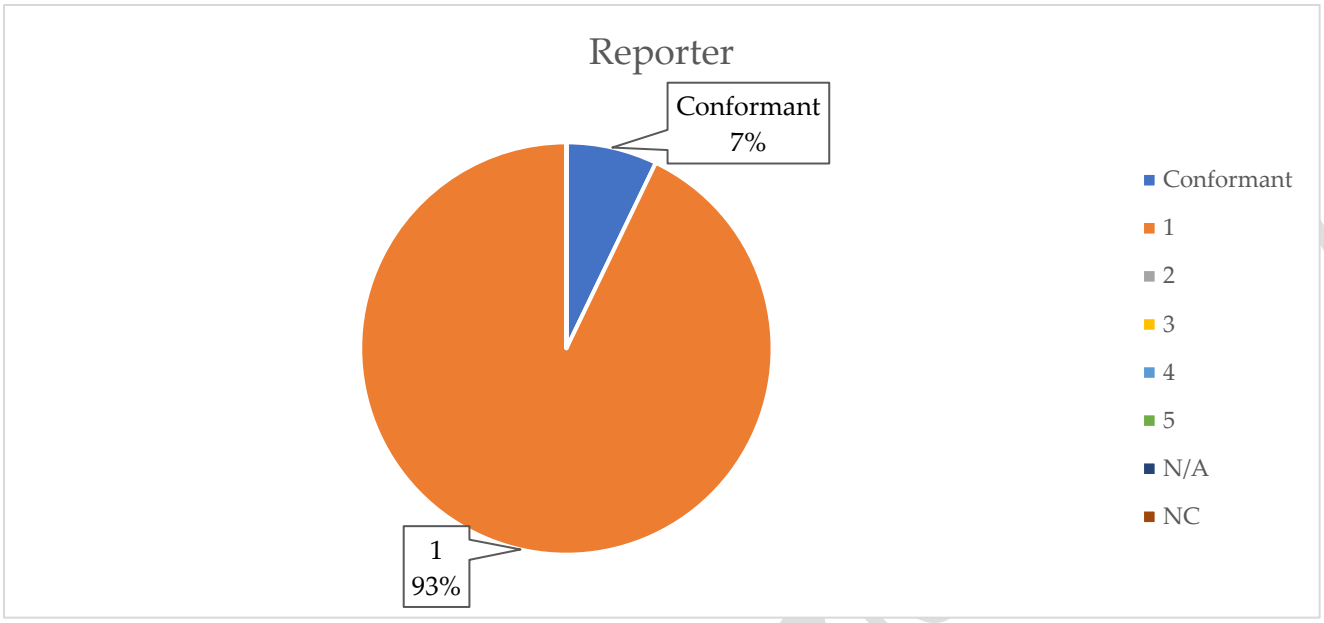
"Performer" is associated with a conformance rate of 7%. Non-conformance reasons resulted to be as follows: reason n. 1 (93%).

Performer



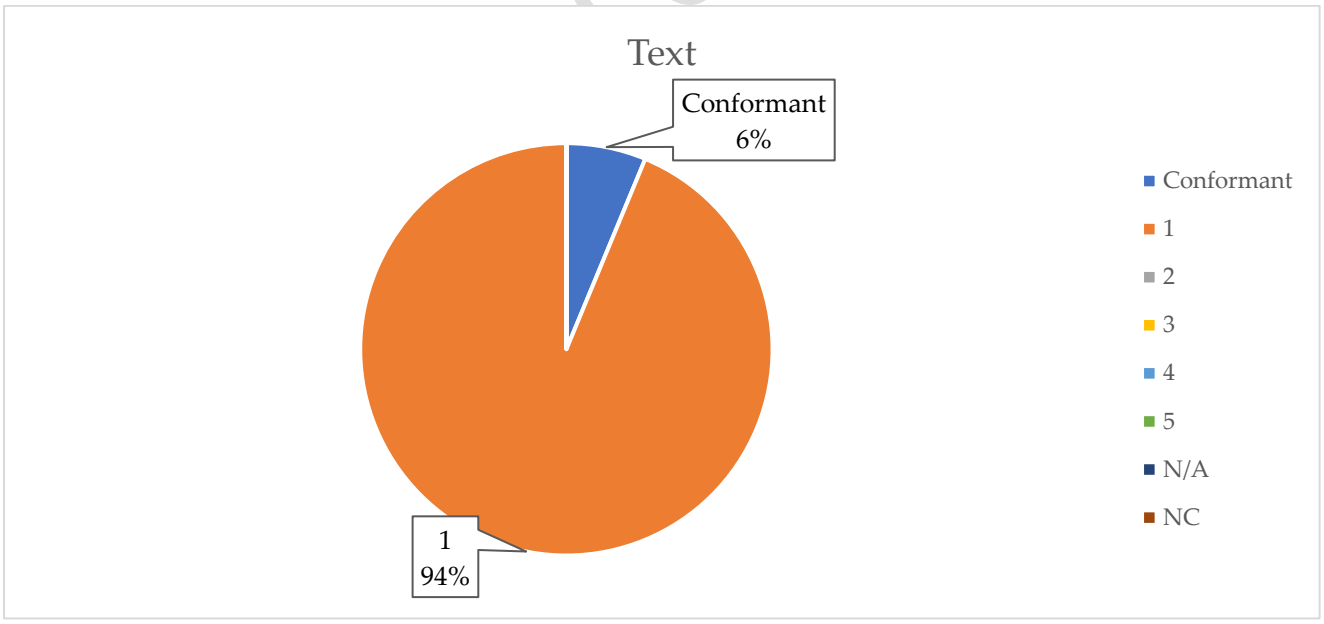
"Reporter" is associated with a conformance rate of 7%. Non-conformance reasons resulted to be as follows: reason n. 1 (93%).

Reporter



The Data Elements "Text" is part of the Extended Section "Therapeutic recommendations" and is associated with a conformance rate of 6%. Non-conformance reasons resulted to be as follows: reason n. 1 (94%).

Text



Other relevant characteristics of Patient Summary

The questionnaire presented also a second section, highlighting other characteristics than the clinical data implementations status described above. The goal of this section is to exchange

information about the used technology, implemented interoperability standards and defined scope of data on the national level promoting the collaboration among the MS to enhance the compliance to the PS. The questions posed were the following:

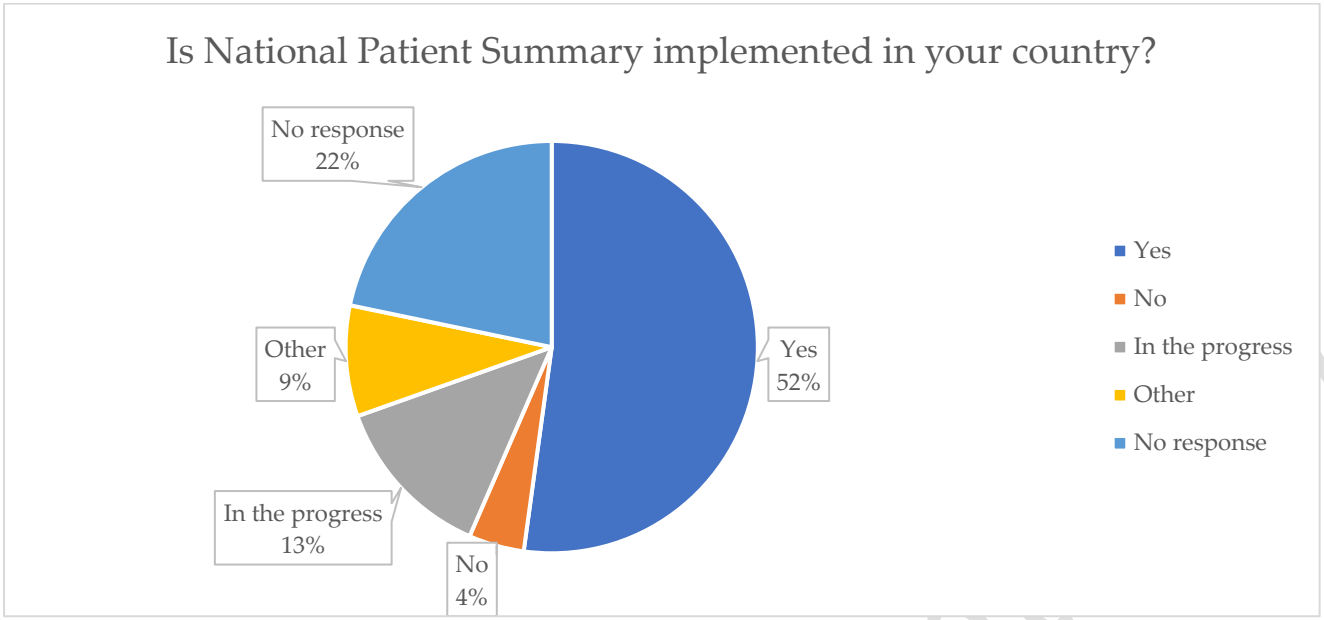
1. Is a national PS implemented in your country?
2. How many of your country's citizen have a patient summary (%)? How many does it represent (number)?
3. What kind of PS is it?
4. What is the coverage of the PS (e.g.: national, regional, other)?
5. Which interoperability standard(s) have been implemented?
6. Is your national PS data scope (sections of the content) the same as cross-border PS (eHDSI)?
7. Does your PS function on the national level or as a regional solution?
8. How are the PS' data collected and stored?
9. How does the updating/changing/actualizing process for the PS looks like?
10. How is the validation of the PS' performed
11. What kind of data are?
12. Can the patient enter data by himself/herself?
13. What kind of PS clinical information sections are in your country?
14. What are the access rules? Who can access PS in your country?

To represent the status of the used technology and interoperability standards across the MSs, which is the goal of this paragraph, in the following pages results deriving from the aggregation of the responses related to the most relevant questions are reported.

Is a National PS implemented in your country?

The majority (53%) of the 23 MSs who took part in the survey responded that National Patient Summary is implemented in their own country. Taking into consideration the missing responses of some MSs, the status of the National PS implementation among the EHDSI countries is represented by the following graphic.

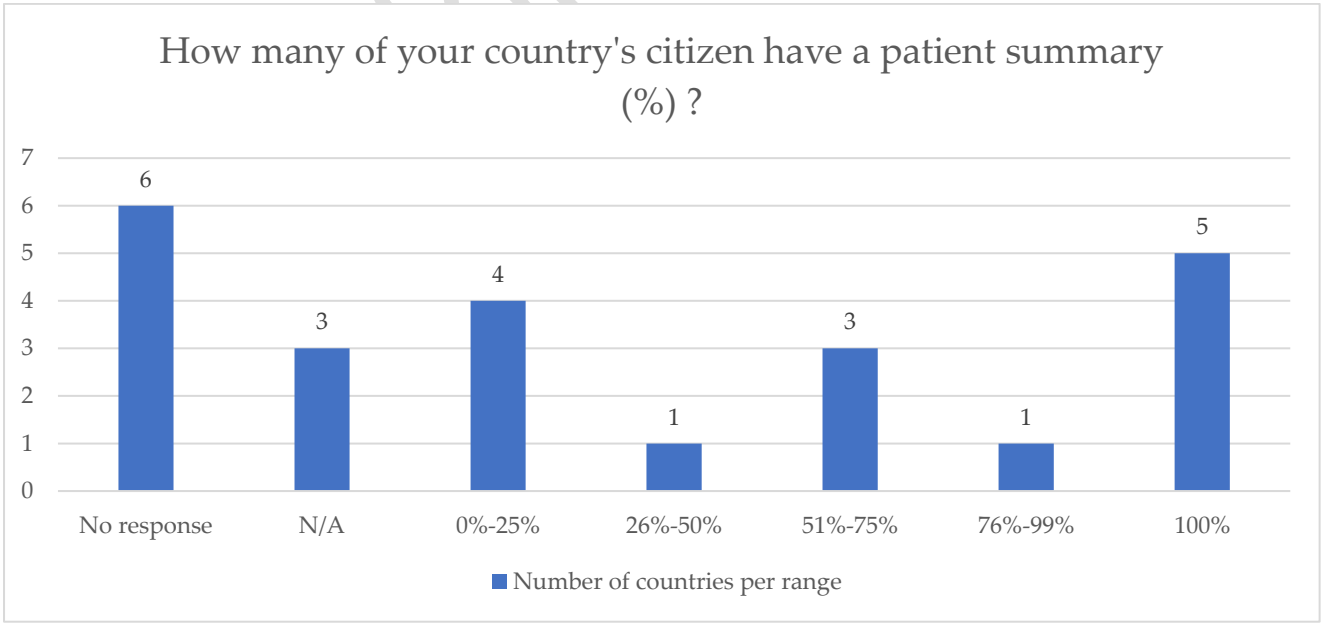
Implementation of PS at national level



How many of your country's citizen have a patient summary (%)? How many does it represent (number)?

Over a total population of more than 410,4 million people considering the 23 countries who took part in the survey, 30% have a patient summary, corresponding to 121,584 million people. The situation varies widely among the MSs as illustrated in the following graphic where countries are grouped in several ranges corresponding to the percentage of people having a patient summary.

Percentage of country's citizen with a PS

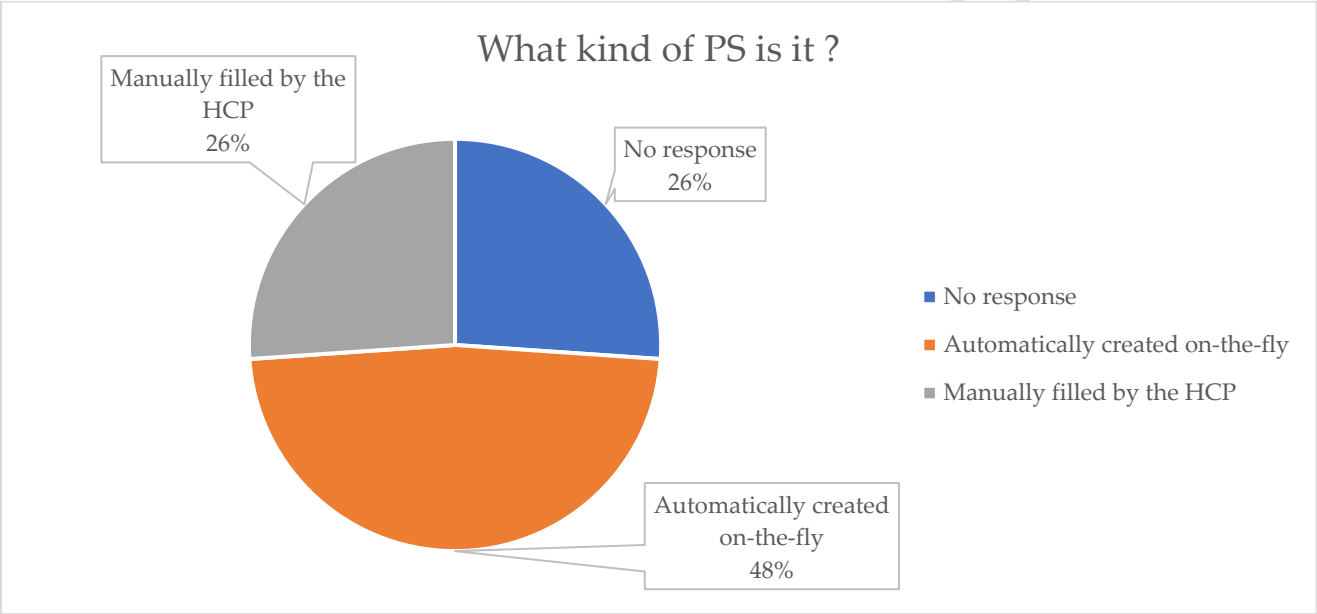


As shown in the graphic above only in 5 countries out of 23 the total population has a patient summary, while on the other side in 4 countries the percentage of population having a patient summary ranges from 0% to 25%, including the only MS in which no one has a patient summary. Overall, there are 9 countries out of 23 in which more than 50% of population has a patient summary.

What kind of PS is it?

This question aims to gather information about the method used at national level to fill in the Patient Summary (manual, filled by the HCP with the patient, automatically created on-the-fly, gathered from different sources). The following graphic shows the present status.

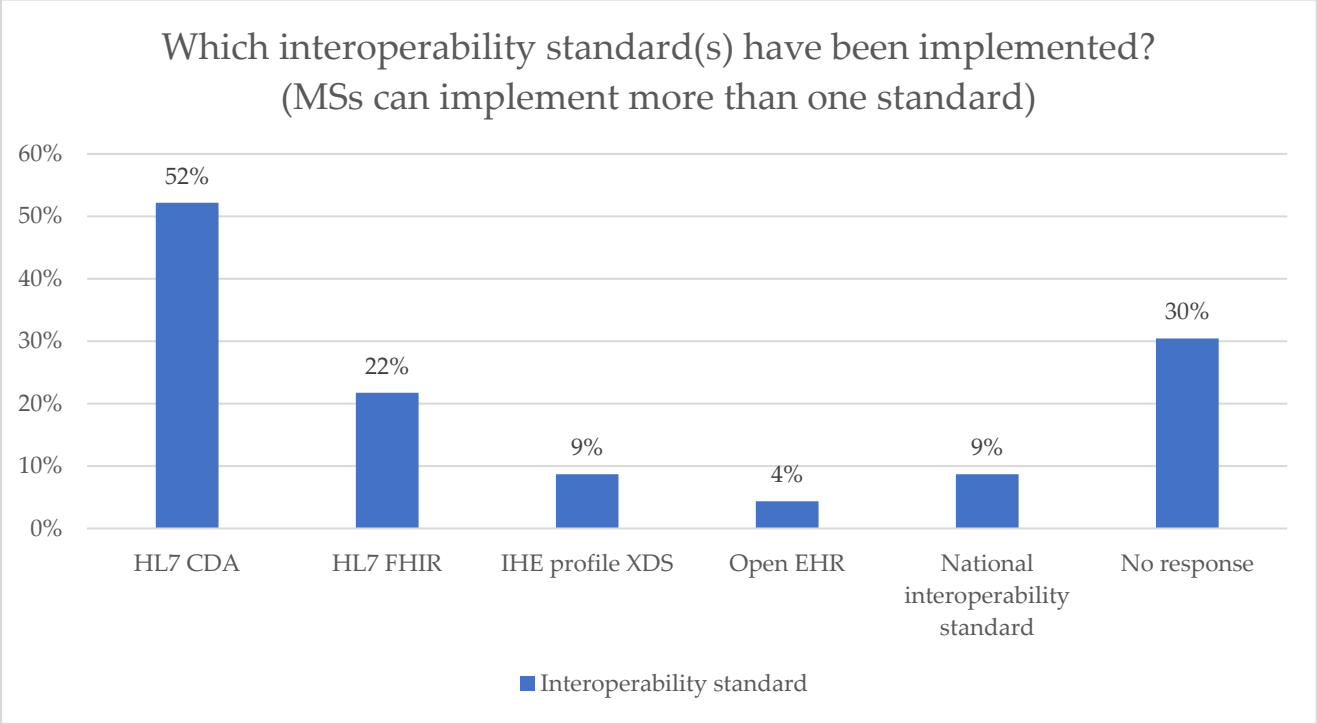
Category of PS



Which interoperability standard(s) have been implemented?

MSs were asked to indicate the kind of interoperability standards implemented within their borders (HL7 CDA, HL7, FHIR, IHE profile XDS, etc.). The following graphic depicts the distribution of the interoperability standards across the MSs. It is important to consider the fact that each MS can implement more than one single interoperability standard.

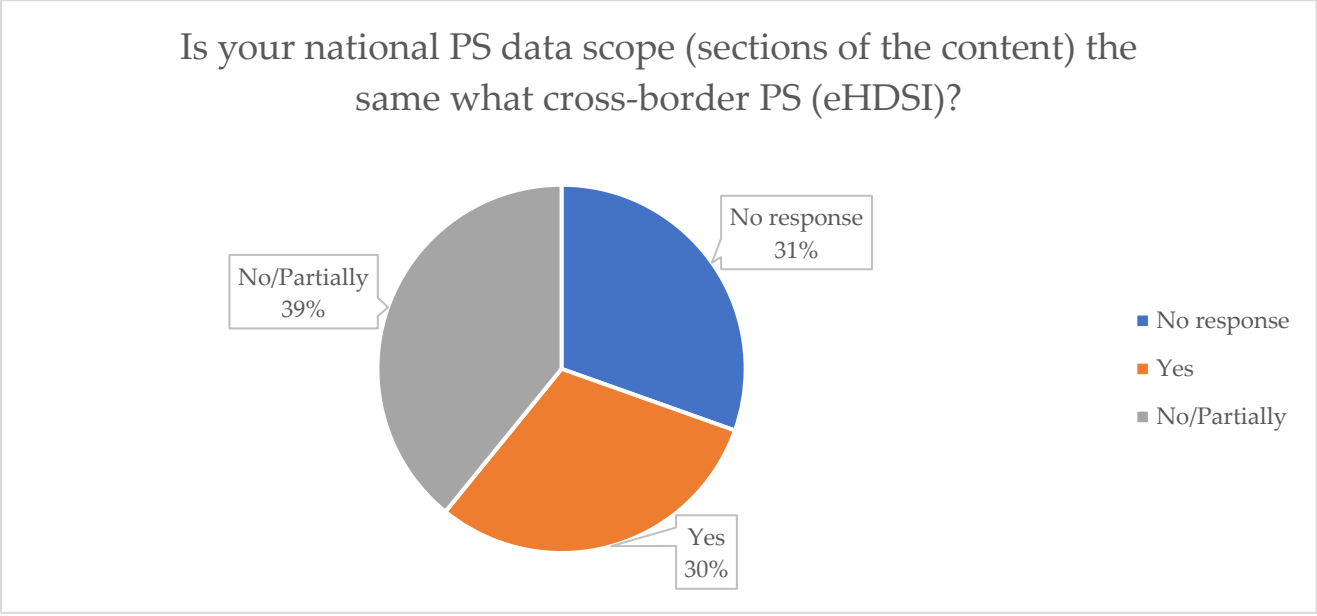
Interoperability standards at national level



Is your national PS data scope (sections of the content) the same as cross-border PS (eHDSI)?

With this question the survey aims to evaluate the level of adherence of national PS contents to the eHDSI Patient Summary. The graphic below shows the responses provided by the MSs categorized in "Yes" or "No/Partially".

Data scope: natoinal PS vs. cross-border PS



10.2.1.6 Healthcare professional's authentication methods

The aim of this section of the PS Questionnaire was to investigate the authentication methods provided to the Healthcare Professionals to permit the access to the Patient Summary. The questions posed were the following:

1. Is there a legal framework linked to the identification and authentication of health professionals? If yes, what scope does it cover?
2. Do you have an identifier for health professional?
3. If you have such an identifier, what's its scope (local/regional or national)?
4. Do you have an electronic registry for health professionals that contains identity attributes to identify them?
5. If you have such a registry, what's its scope (local/regional or national)?
6. Do you handle authentication at the natural person level?
7. Do you handle authentication at the legal person level?
8. What kind of authentication device is used in your country?
9. What is the level of your authentication device: simple (login, password), strong (eg. card + PIN code)?
10. Do you handle multiple authentication level based on some criteria (eg. information accessed, people accessing, functionality...)?
11. Is the authentication device natively recognised by different applications (eg. certificates/PKI, other…)? Or does it need a specific enrolment for each application?

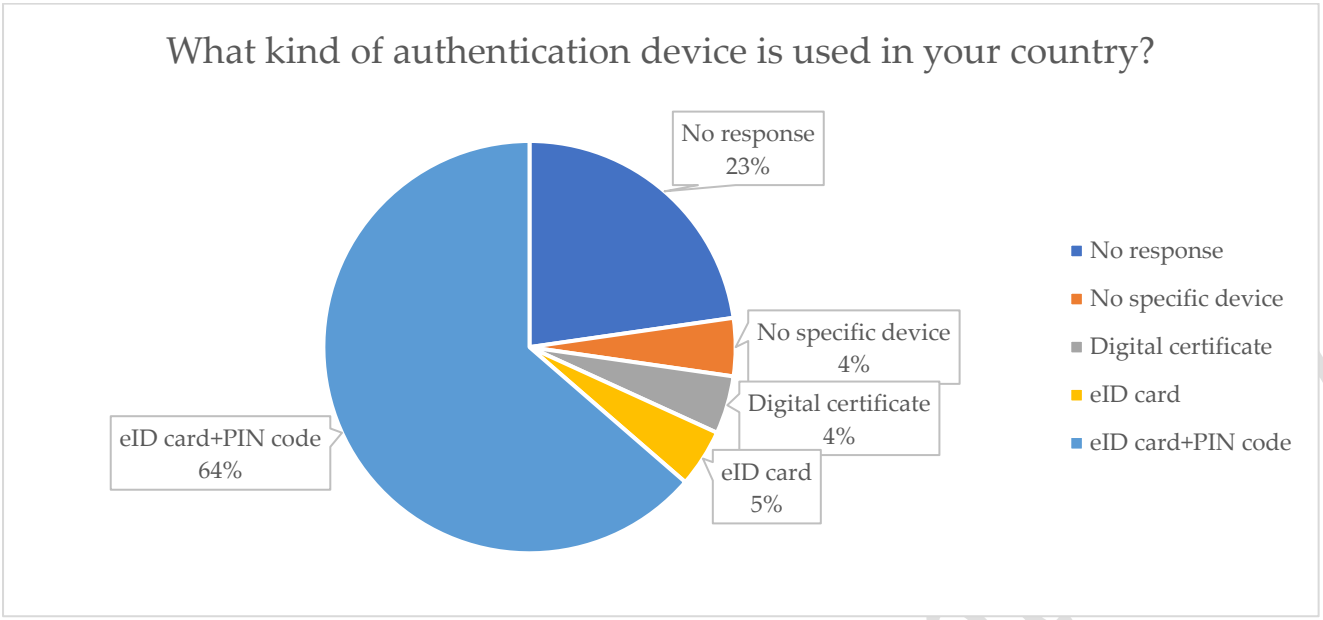
For the scope of the analysis on the PS implementation it is relevant to deepen the responses provided by the MSs to the following questions among those listed above.

What kind of authentication device is used in your country?

The responses provided to this question are relevant to understand the conformity among the MSs in the use of technology provided to the Healthcare professionals to permit them a safe access to the Patient Summary.

The following graphic shows that most of the countries provide to HCP an eID card that allow access in combination with a PIN code.

Authentication device at national level



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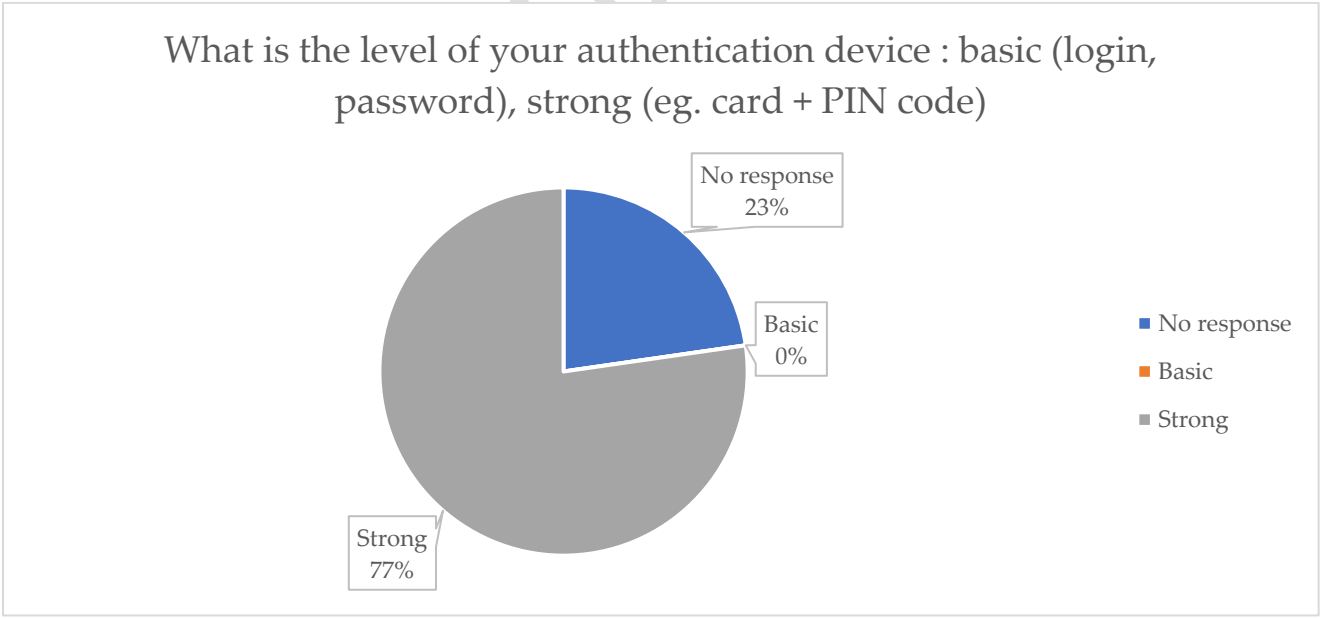
1979 *What is the level of your authentication device: basic (login, password), strong (eg. card + PIN code)?*

1980 Answering to this question the MSs indicated the level of strength of the authentication methods
1981 provided to the HCP to access to the Patient Summary. Responses were classified as "Basic" in the
1982 case the authentication method consist of a single factor authentication, such as entering a
1983 password, and "Strong" in the case the authentication method is based on a two-factor
1984 authentication (e.g. eID card + PIN code).

1985 Level of authentication device



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