



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

04 December 2018
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Information Management

Minutes of the European Union (EU) International Organization for Standardization (ISO) for the identification of medicinal products (IDMP) / Substance, Product, Organisation and Referential data (SPOR) task force meeting

04 December 2018, 9:00 to 12:00

Co-chairs: Isabel Chicharo (EMA), Laurent Desqueper (EuropaBio), Jeffrey Martin (Sweden)

Role	Name
Present	<u>EUNDB:</u> Jeffrey Martin (Sweden), Ana Lopez De La Rica Manjavacas (Spain), Aziz Diop (France), Catherine Russell (United Kingdom), Marko Suvak (Croatia), Georg Neuwirther (Austria), Marta Terron Cuadrado (European Commission), Frits Stulp (Netherlands), Kevin Horan (Ireland), Louise Petersen (Denmark), Peter Bachmann (Germany), Urs Eugster (Switzerland), Christopher Jarvis (EDQM).
	<u>Human Industry Associations representatives:</u> Christoph Kox (AESGP), Andrew Thornley (AESGP), Andreas Franken (AESGP), Nora Weitbrecht (Medicines for Europe), Remco Munnik (Medicines for Europe), Stuart Izod (Medicines for Europe), Patrick Middag (EFPIA), Herve Rique (EBE), Joerg Stueben (EFPIA), Andrea Herrmann (EuropaBio), Laurent Desqueper (EuropaBio), Jean-Michel Cahen (ECI-EEIG), Karl-Heinz Loebel (EUCOPE), Edouard Michoud (Vaccines Europe), Quentin Grignet (Vaccines Europe).
	<u>Veterinary Industry Associations representatives:</u> Patrizia Oelker (AnimalhealthEurope), Pauline Battaglia (AnimalhealthEurope), Jaka Petric (EGGVP).
	<u>Additional experts:</u> Kelly Hnat (K2pharmaconsulting), Gunther Pfeifer (ECHAMP), Malin Jakobsson (WHO).
	<u>Vendors/Software providers:</u> Barry Hammond, Markus Pfahlert, Rune Ringsholm Bergendorff, Susan Metz, Ursula Tschorn.



Role	Name
	<u>EMA</u> : Francisco Penaranda Fernandez, Isabel Chicharo, Agnieszka Laka, Carlos Aicardo, Jaime Gonzalez, Anne-Christine Lantin, Ilaria Del Seppia, John Fisher, Panagiotis Telonis.
Minutes	Inga Angelutsa

1. Welcome

The meeting was opened and participants were welcomed.

Adoption of draft agenda:

The updated Draft Agenda was adopted.

Membership update:

Jeff Martin representing NCAs and Lauren Desqueper representing industry were both presented as new co-chairs of the Task Force.

Louise Petersen representing Denmark and Giovanna Rizzetto replacing Sini Eskola (EFPIA) were introduced as new Task Force members.

2. General updates

Heads of Medicines Agencies (HMA) updates

Georg Neuwirth presented to the SPOR Task Force (SPOR TF) updates from the November HMA meeting held in Vienna. Main discussion points during the HMA meeting were related to:

- Telematics planning for 2019 – 2020, future funding scenarios and Governance;
- Product Management System (PMS) and Target Operating Model (TOM);
- European Substance Database system (EU-SRS).

The outcome of the HMA meeting confirmed for the Telematics strategy to be carried on in 2019 focusing on the most urgent topics, SPOR being one of them. For the funding scenarios, a more elaborated proposal was expected to be presented in the following HMA meeting taking place in Romania. It was highlighted that the mandate of the future Telematics Governance should be empowered and lead to mutual decisions between European Medicines Agency (EMA), National Competent Authorities (NCAs) and the European Commission (EC).

PMS TOM presentation to the HMA focused on benefits and interest of the NCAs within TOM landscape and it was concluded that PMS TOM should also be usable for the Veterinary (VET) legislation. Good data quality was reported to remain a key objective of the PMS. In terms of financing for the PMS, additional investigation on funding is anticipated to take place under the direction of the European Commission.

Updates on the outcome for the EU-SRS presentation and its status followed. During the HMA meeting German national prototype of the new substance database DE-SRS based on G-SRS system of Food and Drug Administration (FDA) was demonstrated. The presentation was highly appreciated as an overview on the future EU-SRS. It was noted that additional meetings with regards to the further implementation of the EU-SRS project in collaboration with BfArM and Medicines Evaluation Board (MEB) have started.

PMS TOM

Georg Newirther updated SPOR TF members on the PMS TOM presentation for the EU Telematics Management Board (EUTMB) meeting held on 8th November 2018.

The PMS TOM concept, timeline, achievements and current challenges were presented to the EUTMB.

The PMS TOM was introduced to the EUTMB as 'a **business process model** to ensure **data quality and consistency** and to optimise the **exchange of application data** between regulators and applicants'.

It was also remarked that interaction between databases for industry, NCA/ EMA and Centralised Databases (Telematics) are envisaged in the future PMS TOM landscape.

In the context of data management and process wise it was mentioned that success of the PMS TOM relies on:

- Grouping data elements in data groups (EU Phase data group, National Phase data group, NCA/EMA data group, Marketing Authorisation Holders (MAH) data group, Additional data group(s));
- Defining a TOM process flow and having a common approach on how to process data fields;
- Integration of the OMS, RMS, SMS and PMS, Union Product DB; also defining ways to create and update medicinal products in PMS and Veterinary (VET) Union Product DB;
- Intensive collaboration amid regulatory bodies and stakeholders also to ensure data consistency among the NCA/EMA and centralised databases.

Georg Newirther highlighted the challenges PMS TOM currently faces and proposed suggestions for improvement as per following:

- To ensure data quality and consistency among the databases: Industry, NCA/EMA and Centralised databases it was suggested:
 - for the resubmission of the updated data to regulators loop across TOM to become mandatory (slide 10 in the attached presentation);
- Introducing consistency and standardisation needed for the Centralised databases could lead to a higher effort to maintain the data. To minimise additional administrative burden in order to keep data synchronised the following suggestions were made:
 - Re-use the same data for regulatory activities and centralised databases (PMS, ...);
 - Abandon separate Article 57 (Art.57) data feeds;
 - Improve electronic data exchange in the network (CTS, national databases, etc.);
- Enable automatisisation of data exchange among the Industry, NCA/EMA and Centralised databases.

It was reported to the EUTMB that TOM process flow is based on current regulatory practices in terms of data submissions. No major changes are foreseen except the proposed mandatory resubmission of updated data expected to happen mainly at the common European phase. It was also highlighted that this model pattern was applicable for all procedure types: NP, CAPs, DCP/MRP for both, human and veterinary products. Additionally, it was mentioned that NCAs and EMA don't have to be fully compliant with ISO IDMP all at the same time.

To support the implementation of the basic principles of the PMS TOM the EUTMB has been asked to endorse the following:

- Re-use of application data (eAF) for regulatory activities and for data feeds into centralised databases (like PMS);
- Make both the update and resubmission of application data (eAF) processes mandatory.

In these regards consultations with scientific committees (CMDv, CMDh, CHMP, CVMP) in order to make these operations mandatory has started. A positive feedback was reported from both the CMDh and CMDv with regards to implementation of the resubmission loop in the regulatory network. No stopper was reported in these regards at that date in time. Subject to further discussions was mentioned to be the clarification of the resubmission frequencies during procedures.

The SPOR TF members were updated on TOM status. TOM working group met in November 2018 to update the TOM process flow and to document requirements for both PMS and CESP development. Further meetings of the TOM group, also additional meetings to present the updated process to the PMS subgroup and the SPOR TF were envisaged for 2019.

It was suggested for the EMA to occasionally participate in upcoming TOM meetings or in specific focus meetings as follow-ups. Additionally, it was proposed to include the European Commission (EC) and/or implementation groups in the future discussions with regards to the integration of the TOM and upcoming veterinary legislation (NVR) requirements.

The need of having high data quality in PMS was pronounced during the November HMA meeting in Vienna. Ongoing discussions to decide on the stepwise implementation of the TOM were mentioned to take place. Few highlights were presented:

- The need to find alignment between the CMDh and CMDv for the regulatory impact was expressed. This impact is subject to be approved by both the regulatory network and scientific committees and it will benefit the endorsement of the TOM concept by the HMA;
- For the technical implementation, it was mentioned that, at that moment in time, the scope of the PMS project didn't cover implementation of TOM. Further steps and responsibilities to take over the technical implementation were still subject to ongoing discussions.

In conclusion Georg Newirther highlighted a major concern to be taken into consideration: 'It is crucial for the PMS project to consider the TOM concept in first instance and not the SPOR timetable for any decision making'.

ACTIONS:

- The question of bringing more clarity on TOM Governance and the integration with SPOR to be raised in the EUNDB forum.



Target Operating
Model for SPOR TF 4

National Competent Authorities (NCA) Data Pilot

Jeffrey Martin briefed the SPOR TF on the NCA Data Pilot status. NCAs conducted the Data Pilot with the goal to understand the ISO IDMP standard and PMS Iteration 1 implications. Meetings were held in

September and November 2018 to address a number of issues gathered during the Data Pilot and to prepare a conclusion before launch of the European Union (EU) Implementation guide (IG) consultation.

The outcome of the meetings was overall positive and a high number of issues were addressed. It was brought to the attention of the SPOR TF that the ISO IDMP standard doesn't have an official interpretation hence the standard related issues were envisaged to be addressed gradually. Nevertheless, the Data Pilot group has gathered more clarity on the ISO IDMP standard and the work was expected to continue aiming for a final conclusion in June 2019.

The Data Pilot group was planning to publish, in an informal manner, a number of issues versus solutions/don't know answer to address more complex areas of the ISO IDMP standard. These areas were expected to include pharmaceutical products, rules to express the composition, marketing authorisation section etc. Published information was anticipated to be included in the EU IG. Subject to further clarification was the confirmation of an official site to publish this information.

European Substance Registration System (EU-SRS)

Frits Stulp presented SPOR TF members updates on the EU-SRS progress, background and project status. It was summarised that the EU-SRS supported by SMS was intended to be part of the SPOR landscape and it's expected to align the substance identifiers (ID) with those from the FDA. The EU-SRS will strongly focus on identification of complete chemical, protein, polymer, multi-substance material and structurally diverse substances. A number of benefits of the substance management system and the intended outcome of the project were brought to the attention of the SPOR TF. Clarifying and understanding connection points between the EU-SRS and the SPOR databases were highlighted as key elements of the EU-SRS project.

It was underlined the function of the substance validation group in the EU-SRS project as playing a key role in the data quality.

Frits Stulp introduced to the SPOR TF members new additions to the EU-SRS project team consisting of two solution architects Pim Aarts (MEB) with Gustavo Rodriguez (EMA) and Annet Rozema (MEB) bringing her support to both Project Management and preparation of the business case.

It was reported that on 25th November 2018, BfArM hosted a meeting in Bonn. Participation of EMA, BfArM and MEB aimed to align intentions on the substance management system. The outcome of the meeting included:

- BfArM decided to use G-SRS as basis to start national substance system in Germany to replace legacy system;
- Demonstration of DE-SRS was given;
- G-SRS was acknowledged as good starting point for substance management;
- This implementation was considered to be a good baseline for the EU-SRS.

Additional discussions were held to ensure a realistic stepwise approach by using BfArM experience as baseline for EU-SRS, also by expanding the EU-SRS project team with BfArM expertise and input.

The SPOR TF was updated on the upcoming meetings for the EU-SRS day 2 and EU-SRS day 3 scheduled for 11th December 2018 and 15th January 2019.

Frits Stulp shared the upcoming steps for the EU-SRS project with the SPOR TF members:

- Agreement of EMA, BfArM and MEB on approach;

- Align the materials on the (more) stepwise approach;
- EU-SRS day(s);
- Continued work on the signature fields;
- Joining all relevant Telematics meetings;
- Communication for further collection of input via the SMS subgroup as soon as review on the SPOR API has been finished;
- Preparation of HMA business case materials and ensure the high quality and revision by all parties.



EU-SRS Project
update to SPOR TF 4

New Veterinary Regulation (NVR)

Anne-Christine Lantin updated the SPOR TF members on the NVR progress providing high-level overview on requirements for IT systems arising from NVR, information on current situation of Telematics IT systems landscape and ongoing work of veterinary expert group.

Two levels of NVR requirements for the IT systems were presented:

- European level for both European Commission (EC) and EMA;
- Member states level.

The EC Maximum Residue Limit (MRL) database is expected to be developed and managed by the EC.

The following databases and information should be developed and provided by the EMA:

- Union product database of veterinary medicinal products;
- Union database on pharmacovigilance of veterinary medicinal products;
- Union database on manufacturing, import, and wholesale distribution;
- Information on sales and use data for antimicrobials.

The above are expected to be established by date of application (DoA) envisaged for the end of 2021, beginning of 2022. Exception was highlighted for the Union Product Database (UPD) which has to be adopted 12 months before the DoA allowing time for the NCAs to submit data by DoA.

In terms of member states requirements, information on online retailers is anticipated to be updated on individual NCA websites before DoA.

It is expected that specific requirements such as formats and technical specifications of the affected IT systems are going to be detailed in Delegated acts, Implementing acts or other provision.

The Union Product Database was presented as the cornerstone of the following veterinary data systems and processes:

- Union Pharmaco-vigilance system;
- Electronic submission;

- Union Database on Manufacturing and Wholesale distribution;
- Sales and use data for antimicrobials;
- Case management.

Anne-Christine Lantin presented the as-is IT Telematics systems landscape from a veterinary perspective and showed how the NVR would impact most of these systems.

The timeline of the SMS and PMS development phases was displayed in parallel with the development timeline of the NVR. It was highlighted that both the SMS and PMS timelines were being updated in line with the relocation plan and the 2019 strategy and budget of EMA. The following points regarding timeline for the NVR were shared:

- The NVR was most likely to be published by the end of 2018;
- The Union Product Database is expected to be adopted by end of 2020, with a potential start of data submission by NCAs;
- NVR DoA is envisaged for the end of 2021.

Following details on NVR were reported. Two types of variations would be distinguished by the NVR:

- **Variations not requiring assessment:** expected to be listed and prepared 12 months before the DoA. An impact on the IT systems is expected, which requires both the UPD to be ready on time and the TOM to be implemented. These variations are anticipated to be directly recorded in the database by the MAHs, subsequently to be approved or rejected by NCAs. Afterwards, the NCAs or EMA are expected to amend the marketing authorisation (MA) and produce a legal document varying the MA.
- **Variation requiring assessment:** expected to comprise all the remaining variations. The process will remain the same as it is now.

Anne-Christine Lantin concluded her presentation providing the SPOR TF with updates on the veterinary expert group. The group has identified a limited number of mandatory fields that will need to be transmitted for all nationally authorised product data into the Union product database.

It was also reported that a 'to-do' leaflet was drafted for the NCAs to help with fulfilling their legal obligations. This document was envisaged to be distributed for consideration to the officially mandated expert group aiming to work on the product data requirements.

Upcoming events were shared with the SPOR TF:

- The NVR final version was presumed to be adopted mid of December 2018;
- EC was expected to organise a meeting with member states to discuss plan for implementation of the NVR. The meeting was anticipated to take place immediately after the sign-off the NVR;
- EC was foreseen to establish the Governance for the UPD and oversee its development until delivery; once the UPD is established it will fall under the EMA's maintenance;
- The roles of HMA, EMA and the mandate of the TF on the coordination of the implementation of the NVR were subject for clarification.

Additional comments regarding the variations not needing assessment were expressed. It was also clarified that data would not be changed directly in PMS in the context of a variation. The Vet Union

product database is a set of components, and PMS is one of them. The need of an additional component to PMS to address the legal requirement of the Union Database was voiced.

It was also assumed that there will be some simplified TOM for variations requiring assessment – still using CESP to make the submission.

It was confirmed that there will be a specific vet session in the TOM group to look at particularities for vet variations.



New Veterinary
Regulations for SPOR

3. Draft EU IG

Ilaria Del Seppia updated the SPOR TF on the EU Implementation Guide content version 1. The EU IG is composed by an introduction and eight chapters.

The introduction of the EU IG constitutes an overview on the ISO IDMP in the scope of SPOR project. Brief descriptions for each chapter were presented:

- Chapter 1 describes pre-registration requirements referring to existing documentation about SPOR access and pre-registration procedure. User privileges and access rights are subject to ongoing discussions for the inclusion in this chapter.
- Chapter 2 explains what data to exchange during initial submission from the business point of view therefore information about data elements, conventions, tools, etc. required for the medicinal product submission is described in this chapter. Additionally, a brief description of the HL7 FHIR message which is part of the Iteration 1 of the PMS implementation is envisaged to be included. It was noted that full description of the HL7 FHIR message will be presented in chapter 6. Chapter 2, at this moment in time, is described as process agnostic considering that TOM is not finalised, it does not describe how to submit the data, simply what data should be submitted. Business process and requirements were mentioned to be included in a later version of the IG.

Suggestions to rename the title of the chapter 2 were made.

- Chapters 3, 4, 5 were presented as being out of scope of the current version 1 of the EU IG. Chapter 5 was initially planned to contain both data access and data export. Subject to ongoing discussions is the clarification for the inclusion of the chapter 5 either in the EU IG or in a user manual.
- Chapter 6 contains technical specifications on structure and format, as well as description of the message for the data exchange of medicinal product. The medicinal product data exchange will be performed using SPOR RESTful Application Programming Interface (API) services. It was mentioned that the SPOR API specifications were circulated among SPOR TF members for consultation.
- Chapter 7 comprises PMS migration guide. It contains an introduction for the data migration and the approach followed by the EMA to enable the transformation and migration of the Art.57 data held in the eXtended EudraVigilance Medicinal Product dictionary (xEVMPD) into the ISO IDMP compliant data format and terminologies which will reside in the PMS hub. Additional sections of this chapter are envisaged to contain details about scope and strategy of the migration,

description of the initial data load, delta data migration, the feedback loop also mapping and migration rules.

- Chapter 8 is anticipated to contain examples on the HL7 FHIR message but is out of the scope of the version 1 of the EU IG. Ilaria Del Seppia highlighted that completion of this chapter will significantly benefit from the output of the NCAs data pilot.

Concerns on post migration data enrichment were expressed. It was mentioned that partial information could be found in chapter 2 and chapter 7; however more details and clarifications expected to be provided under maintenance documentation coming later in time were still subject to discussions.

ACTIONS:

- Revise and rename the title of the chapter 2 to reflect what should be submitted instead of the 'how to be submitted'.
- Organise meeting between the electronic application form eAF and EU IG team to define a way forward for the adaptation of the eAF in line with medicinal product application.

4. S&PMS Progress update

Isabel Chicharo presented SPOR TF members updates on the S&PMS phased implementation plan.

It was highlighted the role of the SPOR API as a connector for systems already interfacing and those going to interface in future with SPOR. It was mentioned that CESP was assumed to be the user interface (UI) for data transmission to the SPOR API. More details on the SPOR API uses were presented.

Consultations on SPOR API were launched end of November 2018. It was reported that NCA representatives and industry stakeholders were nominated for the API consultations. Software vendors were encouraged to contact industry associations regarding their input to the API consultations.

SPOR API implementation is envisaged for the phase 2 planned for end 2019/early 2020. An opportunity to improve the API artefacts for both human and veterinary products is anticipated in phase 3 when TOM is also supposed to be finalised.

The need for data quality assurance was expressed. Ongoing discussions in regards to data quality assurance were reported taking place.

Consultations on the SMS part were reported as finalised and ready for the phase 2. Four webinars in relation to the SMS portal requirements took place. Additional meetings with regards to EU-SRS were planned to start from December 2018 onwards.

On the PMS side, consultations on high level requirements regarding creation, updating, deleting and nullifying medicinal products were reported to have taken place. Discussion on the user management aspects was reported ongoing and expected to be covered in a subsequent EU IG version or separate documents.

The EU IG was mentioned to be in drafting state and being circulated to SPOR TF members for consultation. Webinars for January 2019 to cover the EU IG chapters were envisaged to take place.

In conclusion, it was summarised that the API requirements for both PMS and SMS also the draft for SPOR API specifications were circulated to the SPOR TF members for consultation. The EU IG documentation was anticipated to be shared in January 2019.

5. Programme updates

Agnieszka Laka presented short updates on the SPOR data services for the RMS and OMS. Latest figures on the on boarding users and number of processed change request received since December 2017 were shared with the SPOR TF. It was reported that OMS location ID has been used in 54% of the eAF applications and it was also used in the EudraVigilance user registration. The RMS and OMS data was reported to be consumed by IRIS portal. The SPOR data is envisaged to be used by future applications such as CESP, clinical trials (CT), EudraGMDP and xEVMPD.

Updates on setting up the OMS and RMS key user group (KUG) were presented. It is expected for the KUG to be set up after the Q2 2019. Dedicated webinars to discuss data quality issues encountered by EMA data stewards were proposed to take place from February 2019.

Terms of reference (ToR) for the KUG and the profiles for its members were mentioned being drafted and subject to Telematics approval.

No changes for the SPOR ToR are envisaged for 2019. Face to face SPOR TF meetings were planned to take place on 24th May 2019 and 4th October 2019 in Netherlands.

Inclusion of manufacturers in the OMS was envisaged to take place by the end of the Q2 2019. A document on these regards was developed and it's expected to be published on the public website by the end of December 2018.

6. Other

ISO/TC215 WG6: status/progress & handbook

Panagiotis Telonis briefed SPOR TF on the WG6 activities and in particular the ones related to the ISO IDMP work and related standards. At the ISO meeting held in Paestum Italy last October, the ISO IDMP standards and technical specifications were acknowledged as essential for the pharmaceutical and ehealth domains and eleven WG6 members won the ISO Excellence Award for their achievements during the project. The ISO IDMP project was mentioned being a priority for the WG6 all these years. Cooperation with HL7, ICH and other relevant SDO/liaison organisations was emphasised, as well.

The ISO IDMP was referred to as a project being implemented globally (currently by EMA/EU through SPOR data management services and FDA (USA) on substances through GSRS. Other countries (e.g. Brasil, Korea etc.) are starting relevant initiatives. Other standards and projects directly or indirectly related to ISO IDMP were mentioned either to have started mapping processes for both business rules and definitions in different business areas or synergies/sharing information was acknowledged to achieve global harmonisation and mutual learning (ISO/DTS 23303, ISO/DTS 22990 etc.).

Developments in regard to an updated overview of ISO 11238 for specified substance groups 2 and 4 were presented; additional drafting work for ISO/NP/DTS 23261 (requirements for accessing digital medicinal products information by using the existing data carrier) will be done so that a more mature document be presented in the next WG6 meeting; ISO/TS 16971 (requirements for international machine readable coding of medicinal product package identifiers) will be moved into a DTS ballot rather a standard at this time; The scope of DTS 22703 (requirements for medication safety alerts' became broader, so, harmonisation with IDMP standards, ISO/DTS 22756 and others is needed; The ISO/DTR 14872 technical report 'core principles for maintenance of identifiers and terms' was sent for publication (a high level document at the moment, new annexes will be added in the future and EU network is advised to monitor the activity since it touches our core business).

Also, three new proposals were presented in the ISO meeting:

- a) authoring a handbook for IDMP (guidance to worldwide users of the IDMP-standards from a business point of view, using where possible non-technical descriptions and terminologies);
- b) a new technical specification on examples and logical model for the Identification of Medicinal Products for ISO 11615;
- c) a new technical report for IDMP on Translations and Synonyms.

Regarding (a), TC215 and ISO/CS will investigate the market need and if positive, the process to decide if a Handbook should be developed can be initiated. For point (b), the ISO TC215/WG6 will seek for cooperation with EU IDMP SPOR TF and ICH IPRF. For point (c), a positive agreement was reached with decision to start working on translations of the standard elements.

Furthermore, some initial thoughts for future working items (related to our business) were presented, a proposal for a 'Medicinal Product Lifecycle summary data standard' and a proposal to explore the opportunity to further structure CTD Module 3.

FHIR consultation & process

The full IDMP model (FHIR resources) was entered in FHIR. An overview on SPOR API implementation and the FHIR processes were presented.

In the SPOR API technical specifications two parts of FHIR were used:

- FHIR core consisting from REST API, formats (XML, JSON), shared data types, common infrastructure;
- FHIR resources or data objects with data attributes. Changes to PMS FHIR resources are subject to change control and will ensure backwards compatibility. It was highlighted that all the resources contain by default an attribute called extension intended to increase confidence to implement releases of FHIR.

The notion of FHIR profiles was briefly presented. The FHIR profiles were described as a subset of the ISO IDMP model and it would correlate in the future to the scope of iteration 1. Not all profiles were built yet; some of them requiring guidance and consultation. All the FHIR profiles are envisaged to be published with the implementation of the SPOR API.

Material circulated for SPOR API consultation has been published in the HL7 FHIR with 'maturity level 0'. It was highlighted that the maturity level 0 was achieved by passing several approvals for developed work. Maturity is anticipated to grow over time along with the implementation of SPOR.

Key summary for the SPOR API implementation on the FHIR arena and the sequence of upcoming events were presented. In conclusion, it was highlighted that being FHIR compliant does not oblige implementation of all changes adopted by FHIR community.



SPOR data services -
update to SPOR TF.p