Activities of the *Task-Force on Interoperable Data-sharing in the framework of the operations of ERNs* – 1st year summary and workplan 2017-2018

Contents

Summary of activities in year 1:

This Task-Force (iTF) was established in November 2015 to consolidate interactions between the rare disease (RD) field (i.e. the EUCERD Joint Action and henceforth RD-ACTION) and a number of eHealth initiatives (originally through the EXPAND project). The iTF is framed within WP6 of RD-ACTION, which is the work-package dedicated to Policy and Integration; however, it unites colleagues and partners from *all* RD-ACTION WPs, and its activities complement the broader ERN-related activities of WP6. One of the primary objectives of this synergy was to explore the insights, agreements and resources developed under EC-funded (now largely CEF-funded) eHealth initiatives for sharing data across borders for **unplanned** care, and to assess the potential for these to be 'expanded' to support data-sharing within ERNs.

The TF was established at a crucial moment on the road to ERNs: a new Unit (B3) had just been created in DG SANTE dedicated to Cross-border healthcare and eHealth, and ERN activities were imbedded under this jurisdiction. The first priority for the iTF was therefore to achieve a reasonable degree of 'convergence' between these fields, through stakeholders better understanding the RD/ERN field, on the one hand, and what had been achieved through eHealth initiatives such as epSOS, STORK, EXPAND, Antilope, eSENS, EHR4CR, etc., on the other. This convergence process was achieved through the elaboration of an '*Exploratory Paper on the convergence of rare diseases and eHealth initiatives*', via teleconferences between members of the iTF, and through several face-to-face workshops and meetings over the first year of activity (details of this iTF and its major outputs may be found on the website - http://www.rd-action.eu/ehealth-and-european-reference-networks/)

Summary of Face-to-Face Meetings organised:

- A first convergence workshop was organised to coincide with the final week of EXPAND meetings in Lisbon, Dec 12th 2015. Over 20 experts participated and an internal document on data-sharing scenarios was later generated, to help the iTF establish the applicability and capacity of particular assets connected with the eHealth DSIs to enrich the ERN data-sharing framework.
- A full-day iTF meeting, involving several DG SANTE observers, was held in Brussels on 21st February and generated important discussions on very timely topics, such as: the state of preparedness and timelines for delivery of the ERN IT Platform; possible CEF DSI extensions to support the visibility of RD; the applicability of eID and other CEF Building Blocks for the ERN IT platform, etc. A Report of this Meeting is available on the TF webpage.
- A full-day iTF meeting was organised on 30th June, to coincide with the 2016 eHealth week in Lisbon. The focus was to analyse the recently-published Tender for a SaaS (Scalable software as a solution) for clinical patient management, and to revisit the priorities for the TF in light of this. As the most recent formal meeting, the discussion summary is attached as an Annex to this document, and is also available via the TF webpage.

The aforementioned iTF meeting of 21st February -which involved the majority of the TF members and 8 EC representatives- **identified three different priorities around which to focus the operations of this TF:**

The three Priorities identified in the February TF meeting in Brussels:

Priority 1

ERNs will benefit from an ICT enabled, virtual, integrated healthcare environment, connecting facilities, enabling secure & trustworthy data flow and sharing health care data and expertise virtually. Simultaneously, they must build-up the evidence base to advance care and research in an area of scarce clinical evidence. Enabling such a (patient-centred) environment will require that clinicians can share data and clinical documents across borders in standardized formats, can discover and access such data and information residing in different repositories (e.g. registries) and often in different ERNs, and that they can interpret the content of these documents in a trustworthy and safe way in order to support their clinical decision making. **The contractor developing the IT platform will need some interoperability specifications to implement this effectively, whether in the first instance or at a later point in the timeline.**

Priority 2

There are important issues concerning the legal identification/anonymisation of patients and consent in RD ERNs. An eID framework, including patient consent, compliant to EU Regulations and meeting the requirements of enabling sharing of data within a shared care framework, is needed

Priority 3

Emergency care for Europe's 30 Million RD patients would improve greatly if they could be identified during the unplanned encounter as patients with a specific rare condition, and if decision-making

support and guidance for handover to the appropriate national centre could be provided to the emergency care physician

The months following the February meeting at which these three priorities were agreed saw several developments which affected the feasibility and utility of the above: the current direction of these priorities, at the end of the iTF's first year (i.e. November 2016), are defined below.

Status of the three Priorities as of November 2016

Priority 1

Although the TF (particularly experts from eHN, JASeHN and RD-ACTION WP5) offered support to the EC colleagues in charge of the Tender for an IT platform for ERNs, in terms of defining the interoperability specifications, in the end the Tender was published in June 2016 without direct input from the TF beyond those fruitful the discussions of 21st February. However, concerning delivery of the ERN IT Platform itself, the major goals of this TF were as follows: to support convergence; to convey expert insight regarding ERNs and the future Coordinators' needs from this platform; and to encourage delivery of the Platform significantly earlier than planned. And in fact, these goals were achieved; for instance, the core activities of ERNs were elucidated during the February 2016 meeting, through discussions and demonstrations of the types of data that will need to be captured and shared, and the different data-sharing scenarios (i.e. use cases) HCPs might encounter. Through numerous meetings involving the Applicant Network Coordinators (ANCs) and RD-ACTION WP6 team, the iTF members advocated politically for the delivery of a robust platform in time for the ERNs to begin operations in 2017 (this message was important, as for much of 2016 the ANCs -sceptical that they would receive a shared platform in the next few years- were considering purchasing their own IT solutions, which would have severely hampered interoperability between Networks. RD-ACTION WP6 also collated responses from the ANCs, **to generate a summary of the IT platform requirements**.

During a face-to-face meeting of the iTF on June 30th 2016, the content of the published Tender was discussed, along with the implications for the RD and eHealth fields, and for this TF. The activities the SaaS was intended to provide, as listed in the Descriptive Document,[1] were comprehensive from the 'what' perspective, i.e. in terms of what the platform will need to do: with the exception of training and eLearning, the SaaS addresses important roles regarding consent, storage of data for care and for re-use in research, use of patient identifiers, etc. What was missing, from the eHealth perspective, was the 'how' i.e. detail of how the tenderer should deliver those requirements. For instance, the Tender stipulates that the platform "enforces privacy with role-based user security (patient, health professional, researcher), authentication, identification and authorisation mechanisms to share and store data and information" – but delving deeper, will all ERNs (or each ERN) operate with a single set of roles (and if so, how will this align with role-based access controls that already exist at each HCP?). How will the profile of the consent given by patients be mapped to the profile of users, data and functions that they can each access?

[1] DESCRIPTIVE DOCUMENT for Competitive Dialogue SANTE/2016/A4/013 – accessible via https://etendering.ted.europa.eu/document/archive-download.html?cftId=1594&lngIso=en#

Although the Tender descriptive document included an emphasis on interoperability and eHealth standards,[2] there was no obligation for the ERN IT platform to integrate with the eHealth DSIs (Patient summary and ePrescription tool)[3]. Although there is an explicit requirement to connect to the ECAS service, there is no suggestion in the specifications of a requirement to transfer data over the CEF secure infrastructure (i.e. eDelivery platform) which leaves open the possibility of a self-sustained parallel platform. Some eHealth experts found this unusual, given the eHN emphasis to-date on the legal requirements for cross border health data to be exchanged via a single NCPeH.

Upon reflection, the iTF agreed that the Tender, although less than ideal in some ways, as an outline is generally reflective of the needs of ERNs; furthermore, the fact that it was launched significantly earlier than expected is an important success, which should not be underestimated. It became apparent during the meeting of 30th June that the level of interoperability to CEF infrastructure and eHDSI platform will become clearer in time, once the DSIs are properly implemented and the ERNs are operational – at present, both platforms are arguably still in relative infancy. At some stage, however, what appear at present to be two rather isolated cross-border eHealth environments will need to align, and the iTF remains a very appropriate body to advise on this strategy.

Priority 2

The specifications in the published Tender suggested that ERNs are viewed as a 'special healthcare case' and as such this IT platform may be considered a 'closed' system in the sense that it results from agreements between a defined set of participants. Consequently it appears not to require an eDelivery platform, nor necessarily to conform to the eIDAS regulation. Important discussions are ongoing in the eHN concerning the applicability of eIDAS to healthcare, but in any case it seems that the ERN platform will be exempt from use of the CEF Building Blocks such as eID. If the situation changes or this interpretation is incorrect, the TF may resume work on this issue.

Priority 3

Progress is underway towards the goal of increasing the utility of the ePatient Summary (PS) for rare diseases. Several TF members and colleagues are involved, through the JASeHN, in revising the Generic Guidelines relating to the eHN priorities (which currently include the PS and eP as annexes). Following the meeting on 30th June 2016 in Lisbon, steps have been taken to introduce the Orphacode to these Guidelines, as an optional field. These Guidelines will be reviewed and hopefully adopted by the eHN in November 2016.

[2] Section 2.5.1 'Fixed Requirement' point (ii) states the following requirements: "conforms to European standards and strategies to share health data syntactically and semantically in the eHealth sector, in particular the eHealth Action Plan and international standards, e.g. HL7, CDA (Clinical Document Architecture), CCR (Continuation Care Record), CCD (Continuity of Care Document), C-CDA (Consolidated Clinical Document Architecture). Point (iii) expands on this: "is interoperable and allows the HL7 standard documents described in (ii) to be fetched and retrieved using suitable IHE profiles with system-to-system interface and also allows import/export of similar documents using web browser".

[3] However, section 2.3 'General Objectives' point (v) *does* state that the Tenderer should "take into consideration the horizontal building blocks produced under the Connecting Europe Facility, and the interoperability aspects with the future e-Prescription and Patient Summary".

During the most recent Teleconference of the iTF, the status of the above priorities was discussed and the activities for the following year(s) were agreed as follows:

Current Activities and Next Steps:

- ✓ Pursue the priority to incorporate the OrphaCode to the Patient Summary by preparing a concept paper demonstrating the impact and benefits for MS, should the eHN decide to adopt this proposal. Consolidate links from this work with RD-ACTION WP5.
- ✓ As of November 2016 the successful Tenderer has not been announced – as more details emerge and the ERNs become operational, the iTF will re-evaluate the role it can play in supporting the evolution of a fit-for-purpose ERN IT platform. The expertise of the iTF remains available to the EC and to the Tenderer, to advise on strategies for ensuring the interoperability of this platform with other important initiatives and infrastructures; the iTF has a unique composition, combining eHealth expertise, big data interoperability expertise, and RD expertise (enhanced by the positioning of this TF in WP6 of RD-ACTION, which plays an important role in uniting and supporting the development of ERNs)
- ✓ In the broader RD-ACTION work to define guidance for data collection and sharing[4] in ERNs, alongside promotion of approved standards for RD data such as Orphacode and HPO, it is important to emphasise the importance of FAIR data[5] , which is an increasingly influential concept in big-data generally (for instance, all data uploaded to the European Science Cloud will need to conform to FAIR principles). This Joint Action guidance is designed to guide the Networks, focusing first and foremost on care and standards to optimise this, and advancing to registries – the approach needs to be cautious and supportive.
- ✓ The iTF should seek funding opportunities to enable it to achieve practical progress in helping ERNs to become interoperable within and without their immediate sphere – this could involve interoperability with national eHealth systems, with the NCPeH, etc. It may be possible to focus on a single ERN, as a pilot essentially, and demonstrate how to become 'holistically' interoperable.
- ✓ The TF retains its initial goal to define the contents of a Roadmap (in the mould of the CALLIOPE roadmap) – to do this, the TF members will update its schema of the 'big picture' of the eHealth, big-data, and rare diseases fields, illustrating how and where they interact – and intersect- at present, and most importantly how they should engage in future. In addition to the eHealth platforms and infrastructures, it is important to include RD-specific platforms such as the interoperability platform of RD-Connect and ELIXIR.

[4] The term 'data-sharing' may itself be inappropriate or outdated here, depending upon which activities of the ERNs are intended. 'Physically' uploading or downloading data and sending this somewhere is not ideal (in fact this was not the epSOS approach) and a more achievable goal is often to make the data searchable/queryable, at least on a metadata level. This seems more obviously applicable to the registry-related activities of ERNs, for instance, as opposed to enabling the accessibility of patient information/scans/images etc. for a virtual consultation between numerous experts.

[5] http://www.nature.com/articles/sdata201618

Annex I: Summary of Discussions and Conclusions from 30th June

(PwP presentations from the workshop are available here)

Objective	Comments from the Discussion	Conclusions and Action Points, where relevant
Determine the applicability of CEF Building Blocks for building interoperability around ERNs Assess the current foci of the eHealth Network and its associated projects and, where these may have a bearing on the ERN topic.	Background: the 5 CEF Building Blocks are service offerings – not software or IT tools. Two were highlighted in this meeting: • CEF eID helps public administrations and private online service providers to expand the use of their online services to citizens from other EU Member States. • CEF eDelivery supports the cross-border exchange of documents The aim of e-SENS project is to facilitate the deployment of cross-border digital public services through generic and re-usable technical components. In 2014 a Regulation was passed concerning electronic identification and trust services for electronic transactions in the internal market (eIDAS Regulation). It is designed to ensure legal interoperability by providing a clear regulatory framework to enable secure and seamless electronic interactions between businesses, citizens and public authorities. The CEF eID solution can support compliance with eIDAS Regulation. Neither the CEF BBs nor the e-SENS project are health-specific. The participants discussed the relation of the eIDAS regulation to healthcare, which is a key issue in the eHealth field at present. The eIDAS would logically apply in 'open' IT systems, such as those established for unplanned care, since the environment is entirely open and there are significant 'trust' concerns – after all, patients receiving	Are there BBs or assets relating to translation, for instance, which are useful for WP5 of RD-ACTION? **A key question is, does the eIDAS have any relevance to the ERN framework? It appears not, as the eIDAS will not apply in closed systems resulting from national law**

	emergency care aboard could encounter any health professional from anywhere in Europe, and issues such as who is looking at your data, who is providing your care, and how qualified they are, are important. The differences between the epSOS legacy infrastructures and the ERNs were elucidated - a simplified way of viewing the situation is to consider two different cases relating to cross-border care: on the one hand, the epSOS case where the patient travels, and on the other, the ERN case where the expertise typically travels and the physical movement of patients is handled through formal, pre-planned cross-border arrangements. Different levels of identification and assurance are required in each case, a crucial difference being that in the ERN case, the patients are identified in their own country. Nonetheless, the participants stressed that the ERN platform will still need to be robust, in terms of security and protection from cyber threats.	**or from agreements between a defined set of participants. However, although the ERNs' IT platform will not be an eDelivery platform, there ARE issues around who in each centre will be able to access data in this platform, which need to be considered.**
Revisit the priority regarding the Patient Summary	The context for this priority was summarised: JAseHN performed an evaluation of the two sets of Guidelines (one on the Patient Summary (PS) and the other dedicated to ePrescription.) They combined these into one set of **Generic Guidelines**, with the PS and eP as annexes. Potentially there will be two other annexes, to reflect the other 2 eHN priorities. The aim is to have the GG adopted in November by the eHN so that MS can begin implementing the eHDSIs (i.e. beyond piloting, using real patient data.) Participants were reminded that the eHDSIs are all about the exchange of cross-border health information. The nuts and bolts of this framework are the NCPs for eHealth, which enable the country interoperability gateway (across several Key Interoperability Layers). These NCPeH interact with those of other MS and also interface with National Infrastructures. They are considered Generic Services (i.e. MS based structures connecting to the larger infrastructure). Then you have the Core Services, which operate at	Confirm the status of any plans on the part of the eHN, to add annexes on ERNs and Registries and ascertain any concrete support RD-ACTION might offer.

	the European Level. Every MS that has decided to participate in eHDSI signs up to a Multilateral Legal Agreement. Of course, the purpose of the PS is entirely different to sharing data for a second opinion. Countries generate the PS in different ways: some do it manually, via GPs, whilst others do it by extracting data directly from electronic records. When a PS is requested, the idea is that the MS NCPeH delves into its infrastructure and extracts the PS however it has arranged to. It was agreed at the meeting that attempting to incorporate the OrphaCode to the PS is indeed a priority worth pursuing. Technically, this should not be too difficult to do – the document itself is flexible and adaptable. The logical direction is for MS to adopt the OrphaCode in their Health Information System and then use this in the Patient Record… this use case could therefore be an accelerator to the work of WP5	Raise the necessary awareness of the addition of the OrphaCode, partially via elaboration of a concept paper. determine the next steps necessary here.
Examine the status quo regarding the interoperability needs of ERNs – to what extent does the Tender for a SaaS suggest two cross-border eHealth ecosystems: the ERNs' platform and the open NCPeH-associated eHealth field? Analyse the contents of the IT Platform Tender and how this might evolve – what are the implications for the ERNs and for this ITF	From an eHealth tender perspective, the IT Tender is rather light on detail. The activities defined are quite comprehensive in terms of what the RD community wishes ERNs to do, less so from a procurement perspective. Ideally, the Competitive Dialogue phase will clarify the importance of interoperability with all other platforms, including the DSI platform. eHN may review further, at their discretion, where additional assurance of the congruity of the two ecosystems is deemed necessary	With the understanding that the Tender publication is final, and content cannot now be added, JA will finalise paper 'IT Needs of potential Coordinators'. Relating to the ERN IT Platform, the goal of this iTF was to support convergence discussions and confirm that the Coordinators' needs from this platform are clear, and to urge an urgency in making available the Platform. This has been achieved. The level of interoperability to the other CEF systems and DSI platform will become clearer in time, once the DSis are properly implemented and the ERNs are operational. The iTF will therefore re-

		evaluate the needs in this respect in 2017 (although eHN may choose to focus earlier)
Evaluate any existing legal challenges to data-sharing in ERNs	Petra Wilson outlined the issues raised by the new General Data Protection Regulation of which ERNs will need to take note, e.g.: Consent Data Controllers and Processors Privacy Impact Assessment Right to be forgotten Etc.	Renew these discussions in September RD-ACTION workshop to determine how RD-ACTION can support the EC with the Informed Consent arrangements for ERNs.

Annex II: Glossary

ANC	Applicant Network Coordinator (of an ERN)
ANTILOPE	Advanced eHealth Interoperability
BB	Building Block
CEF	Connecting Europe Facility
DG	Directorate General
DSI	Digital Service Infrastructure
eHN	eHealth Network
eIDAS	electronic identification and trust services for electronic transactions in the internal market
eP	ePrescription tool
epSOS	European Patient Smart Open Services
ERN	European Reference Network
eSENS	Electronic Simple European Networked Services
EXPAND	Expanding Health Data Interoperability Services
JAseHN	Joint Action to Support the eHealth Network
NCPeH	National Contact Point for eHealth
RD-ACTION	Data and Policies for Rare Diseases
PS	Patient Summary
PARENT	Cross-border Patient Registries iNiTiative
SaaS	Scalable software as a solution