

## **Meeting Report: Face-to-Face meeting of the Task-Force on Interoperable data-sharing in the framework of the operations of ERNs**

**30<sup>th</sup> June 2016, 9.30-17:00**

**Venue: Sala 2**, Centro de Reuniões da FIL (Lisbon International Fair) – Rua do Bojador, Parque das Nações – 1998-010 Lisboa (EXPO area).

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**Origins of the Meeting:** this meeting was planned to leverage the fact that Lisbon is hosting a week of eHealth meetings, involving many iTF (<http://www.rd-action.eu/ehealth-and-european-reference-networks/>) members and invited participants from amongst the Applicant Network Coordinators (ANCs) (<http://www.rd-action.eu/european-reference-networks-erns/coordination-of-rare-disease-erns>). The meeting ultimately took place shortly after the publication of the Tender for the ERN IT platform (Scalable software as a solution –SaaS- for a clinical patient management system) and this consequently became a major focus of the agenda.

### **Objectives of this Meeting:**

- 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?

- Assess the current foci of the eHealth Network and its associated projects, where these may have a bearing on the ERN topic
- Determine the applicability of CEF Building Blocks and eHealth DSIs for building interoperability around ERNs
- Evaluate any existing legal challenges to data-sharing in ERNs

## Summary of Discussions and Conclusions

(PwP presentations from the workshop are available [here](#))

Objective	Comments from the Discussion	Conclusions and Action Points, where relevant
<p>Determine the applicability of CEF Building Blocks for building interoperability around ERNs</p> <p>Assess the current foci of the eHealth Network and its associated projects and, where these may have a bearing on the ERN topic.</p>	<p>Background: the <a href="#">5 CEF Building Blocks</a> are service offerings – not software or IT tools. Two were highlighted in this meeting:</p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• CEF eDelivery supports the cross-border exchange of documents</li> </ul> <p>The aim of e-SENS project is to facilitate the deployment of cross-border digital public services through generic and re-usable technical components.</p> <p>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.</p> <p>The CEF eID solution can support compliance with eIDAS Regulation.</p> <p>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.</p> <p>The eIDAS would logically apply in ‘open’ IT systems, such as those established for unplanned care, since the environment is entirely open and</p>	<p>Are there BBs or assets relating to translation, for instance, which are useful for WP5 of RD-ACTION?</p> <p><b>A key question is, does the eIDAS have any relevance to the ERN framework? It</b></p>

	<p>there are significant ‘trust’ concerns – after all, patients receiving emergency care abroad 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.</p> <p>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.</p> <p>Nonetheless, the participants stressed that the ERN platform will still need to be robust, in terms of security and protection from cyber threats.</p>	<p><b>appears not, as the eIDAS will not apply in closed systems resulting from national law 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.</b></p>
<p>Revisit the priority regarding the Patient Summary</p>	<p>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 <b>Generic Guidelines</b>, 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.)</p> <p>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 the European Level. Every MS that has decided to participate in eHDSI signs</p>	<p>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.</p>

	<p>up to a Multilateral Legal Agreement.</p> <p>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</p>	<p>Raise the necessary awareness of the addition of the OrphaCode, partially via elaboration of a concept paper. determine the next steps necessary here.</p>
<p>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?</p> <p>Analyse the contents of the IT Platform Tender and how this might evolve – what are the implications for the ERNs and for this ITF</p>	<p>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</p>	<p>With the understanding that the Tender publication is final, and content cannot now be added, JA will finalise paper 'IT Needs of potential Coordinators'.</p> <p>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.</p> <p>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)</p>

<p>Evaluate any existing legal challenges to data-sharing in ERNs</p>	<p>Petra Wilson outlined the issues raised by the new General Data Protection Regulation of which ERNs will need to take note, e.g.:</p> <ul style="list-style-type: none"> <li>Consent</li> <li>Data Controllers and Processors</li> <li>Privacy Impact Assessment</li> <li>Right to be forgotten</li> <li>Etc.</li> </ul>	<p>Renew these discussions in September RD-ACTION workshop to determine how RD-ACTION can support the EC with the Informed Consent arrangements for ERNs.</p>
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## Annex I: AGENDA

9.30	Welcome: Nature and achievements of the ITF to-date	<b>Presentation</b> V.Hedley
9:50	Status Quo of ERN Proposals, IT needs of the Coordinators and RD-ACTION plans for ERNs over next 2 years	<b>Presentation</b> V. Hedley
10:20	Insights to the plans of Coordinators joining the iTF meeting	<i>Coordinator Introductions</i>
11:00	Coffee Break	
11:30	Overview of EU eHealth policy and strategies (eHealth Network (eHN and eHN Guidelines, walk through the eHealth Interoperability Framework, followed by discussions	<b>Presentation</b> Z.Kolitsi
12:00	Review of the new 'IT platform' Tender Specs: implications for the ERNs and the NCPeH-related eHealth actions	<b>Review of the Tender</b> followed by discussions (moderated by V.Hedley)
13:00	Lunch	(Provided)
13:45	Use Cases relating to ePatient Summary – is there an opportunity to take this forwards?	Incl. <b>a presentation on the ePS (Jeremy Thorp)</b> and how it is used, then discussions on how it could benefit RD field Moderator H. Martins
14:45	Impact of the Data Protection Regulation on the ERN data-sharing framework	<b>Presentation</b> by Petra Wilson, then discussions (moderator Ana Rath)
15:15	Ruling in and ruling out: How might the eHealth DSIs –designed for Cross border, secure Data Exchange - be relevant for ERNs? General Architecture, eHealth services (Patient Summary and ePrescription) and enabling services (eID, terminology, discovery, audit trail services)	<i>Discussion session in which we really assess what is being handled by whom/by which projects, what is needed now, what is 'desirable' for the future, and how we focus TF for remainder of this JA</i>
15:30	Coffee Break	
16:00	DSI discussion continued : Longer-term interoperability vision	Defining contents for a future roadmap in view

		of the specs for the IT Platform
17:00	TF Meeting ends	

<i>17:00-18:30 (off-site)</i>	<i>Discussions with Coordinators regarding next RD-ACTION workshops</i>
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## Annex II: List of Invited Participants

### Participants:

Natalia Allegretti\*

Magdalena Davila

Sofia Douzgou

André Ferreira

Victoria Hedley

Zoi Kolitsi

Dorothee Leroux

Eduardo Lopez

Sevala Malkic (EC)

Licinio Mano\*

Henrique Martins\*

Marcello Melgara

Tapani Piha (EC)\*

Ivan Pristas

Ana Rath

Maurizio Scarpa

Stephan Schug

Patrick Stevens (EC)

Marisa Tejedor Botello

Michelle Thonnet\*

Jeremy Thorp

Joan Lluís Vives Corrons

Petra Wilson

\*Invitee ultimately unable to join the meeting