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What do Coordinators require from an ERN ICT platform?

This information was gathered by the Joint Action in April 2016, as part of a template disseminated to the group of Applicant Network Coordinators (i.e. the individuals preparing at that time to submit proposals to coordinate an ERN).

An important observation is that different ERNs will likely be differently resourced, in terms of eHealth tools, patient registries etc. This is natural, as some of the Thematic Groupings had a longer history of networking (albeit it predominantly on the research side in some cases) than others.
One Applicant Network Coordinator (ANC) effectively summarised the crux of these discussions, as follows: "In order to function properly, the ERNs will require an online platform that can address different needs and is compatible with other tools that might already be in use. Some networks might require a full package of services while others might only need particular additions and relevant add-ons."
Respondents also emphasised the need for an IT platform to be superior to what is in use at present, or to somehow create significant added-value to the field at large: "It will be essential that all IT support will reconcile existing and newly-developed IT elements to ensure we can continue to use what has already been established and only replace this with tools which are better than what we have." The need for interoperable data sharing within each ERN but also between ERNs, to support diagnostics, care and research, was also emphasised.

Responses were received from almost every potential Network, and have been summarised as below, by sub-dividing the very broad term 'ICT Platform' into what appear to be its main constituent parts.

Public-facing Website

The ANCs requested an easy-to-manage public website: The publically-accessible area should include information on the network (scope, thematic areas of expertise, diseases or groups of diseases covered, overall structure and characteristics, as well as information on the steering committees (progress report, contact information). Respondents emphasised the need for this to be available as soon as possible, ideally in Month 1 of each ERN's operations. The site should be continuously updated. The Network Coordinator should be responsible for the content management and the regular activity on this website. The network members should gather and deliver content for the feeds, updates, and articles.

> ***Question:*** *Is the EC planning to provide websites for each ERN, or will it provide a public page for all websites, with the expectation that each ERN hosts and updates its own site? Several would-be ERNs have created their own websites already...*

Internal Communications system

The ANCs requested a web-based tool for project management specifically for international EU networks. "This tool should combine functionalities for central document sharing, progress monitoring, and reporting." It would host all confidential documentation (policies, deliverables, publications, management procedures, strategies, regular reports, minutes, etc.) "The content of the database should be private - secure access control to member representatives."

Application/Platform/System to support virtual case consultation and data collection

All agreed the need for a shared platform through which physicians in different countries can interactively discuss particularly complex or challenging cases.

- Some respondents report use of such applications already, e.g. the virtual tumour board (VTB) application, which has been designed to incorporate IHE interoperability standards.
- In some cases, real-time meetings are preferred, which require audio and visual capabilities.
- Others requested the capacity for locally *and temporally* dissociated interaction between a requesting/referring clinician and specific experts; in other words, there should be a facility to allow the examination of patient cases through the Platform in an expert's own time, including a forum to post comments and discussion.
- Several stressed that this virtual consultation capacity is central to the success of the ERNs, especially for undiagnosed patients.
- "The platform will need to support the sharing of images in high quality, including large data files such as MRI, PET and CT scans. Ideally, the system will be able to 'import' files directly from the systems used routinely by the HCPs, such as PACS, LIS, RIS etc."
- For some networks, this platform will need to allow the provision of a diagnosis and recommendations on care management without patients needing to travel. When physical travelling IS necessary (e.g. when optimal care demands a particular procedure or specific piece of equipment only available in a small number of HCPs), such virtual consultations would ideally be a pre-requisite to determining the need for a patient to travel.

Question: *will the MS authorities recognise such decisions of an ERN in determining when cross-border care is necessary? For ERNs to have an impact and contribute to better use of resources, the recommendations of the ERN resulting from such virtual consultations will need to become influential (i.e. the country of the referring clinician should be open to act upon such advice).*

- The information discussed in virtual consultations will always be sensitive; therefore, ethical and legal requirements must be clarified before the launch of the Networks and henceforth respected. Some stipulated that the encryption and the secure exchange of data is essential for their ERN due to the anatomical nature of the images that need to be shared.

Questions*:*

It is assumed by most that the consultations organised by the ERN to discuss specific patient cases will be considered an extension of the usual national 'care team' one encounters when seeking healthcare at home:

- *Presuming the patient signs an informed consent form to agree to data being shared within the ERN for care (with another 'box'/form relating to research, presumably) - is it then the case that no anonymization of patient information would be necessary for these consultations (i.e. photographs could be shown, names used)?*
- *Or, will patients always need to be de-identified and distinguished using a string of numbers or letters opposed to using names?*

- The cases reviewed by the ERN in collaborative virtual consultations should afterwards be retained in a case record repository of some sort, within or accessible via the IT Platform (would this need to be anonymised i.e. would the patient names be removed and replaced with a pseudonym/identifier?). This would be important in allowing the ERNs to develop and monitor performance indicators

Question: The power of data in RD increases proportionally to its volume in RD: the more (high quality and comparable) data one can aggregate, the greater the potential for knowledge generation (which in turn can translate to best practice guidelines, research opportunities and improved provision of care to patients). Therefore, when contemplating the storage and re-use of anonymised patient data, are we thinking only of data from those patients referred for shared care within the ERN (i.e. via a virtual/MDT review) or of all the patients with a particular condition who visit the HCPs within a given ERN (assuming appropriate consenting is in place, of course)

Registry functionality/interoperability

Many ANC respondents emphasised the importance of the ERN IT platform supporting registration of rare disease patients, and highlighted the multiple benefits of rare disease registries, in terms of research but also for the improvement of healthcare e.g. by supporting epidemiology (the study of the cause and impact of disease on a given population) which in turn can streamline the provision of services and improve both quality and economic efficiency for health systems; by elucidating the natural history of the disease; by enabling the planning and execution of efficient clinical trials, and supporting post-marketing-surveillance, all of which ultimately leads to better therapeutic options for patients). Comments included the following:

- Registries should support research, and this includes, where relevant, the correlation of genotype & phenotype data: “A European-wide registry able to capture a patient’s phenotype, genotype, diagnostic tests and standard outcome measures would be required.” Such a registry will “enable benchmarking between centres to recognize best practices and upskill, and will support essential scientific research, for instance regarding the genetic background of rare diseases.”
- Even more so than with the sharing of data for virtual consultations, the pooling of data via a registry poses major challenges: “privacy regulations hamper the exchange of certain data at present and workable solutions with respect of privacy should be sought”. Another participant emphasised the need to “be mindful of the absence of resource at the HCP level to undertake complex databasing, and data governance issues.”
- Most fields have a complex array of relevant rare disease registries already, whether operating at the regional, national or international level – how to make use of these/ make these interoperable in the ERN landscape is a key question. “Several units/HCPs in my field already have national databases specific to my focal disease area, which could be made available to the other centres.”
- Others seemed to propose a better solution is to begin anew, once the ERN is approved: “We need a prospective care registry for all rare disorders in our ERN (data structure: minimal phenotype dataset fit for all of our patients, Available biomaterial, Phenotypic and genetic diagnosis, Natural history scales, Care metrics)”

- If a new registry were to be provided for each ERN, for many Networks there would be an urgent need to consider how to populate this with legacy data and/or interact with the patchwork of existing registries: "we need a registration system for patients that will be able to communicate with existing registries".

> ***Questions**: Are there any areas which really have no major registries at present and could benefit from an entirely new registry established by the ERN and somehow embedded in the ERN IT Platform to be set-up? At what level is there added value in pooling data via a registry; for instance, do coordinators desire an ERN-wide registry, addressing all diseases under their Thematic Grouping, or would a more specific, sub-domain level be more meaningful?*

- For the majority of ERNs, it seems, some attempt will need to be made to deal with existing registries relevant to the Thematic Grouping, in order to maximize the value of this precious data. Several respondents therefore stressed the value of receiving a tool-kit of sorts, especially interoperability tools, to make existing separate connections searchable/queryable: "'A Registry toolbox is required, including software for setting-up new registries at minimal expense (open source software) and supporting material for data protection issues, patient informed consent, ethics approval, etc." Similarly "Interoperability software is necessary to allow common data analysis for new and existing registries and interoperability at European level (the European Platform for Rare Disease patient registration, JRC, should be instrumental here)"

> ***Question**: What can the EU Platform for Rare Disease Registration provide for the ERNs? Will it provide an interoperability toolkit to enable the Networks to make existing disease-relevant registries queryable/searchable? Will it provide software for Networks which wish to establish new registries? Will it collect any data for surveillance and epidemiology from the ERNs?*

Training and Education

An important role of the ERN IT platform, as identified by the potential Coordinators, is to support distance education and training. Several respondents requested that "Training and education programmes should be delivered via an eLearning programme" made available as part of the Platform of IT-related tools. Some Applicant Networks already use such tools, it seems, and attest their importance to the ERNs: "an e-Learning platform is a useful tool for initial and continuing medical education in this field, offering a complete panel of training tools to the registered participants and contributing to lowering inequalities in knowledge accessibility throughout Europe". An "e-learning platform should support training in secondary Centres, and should also host video tutorials for patients and associations".

In the domains requiring highly specialised *surgical* techniques, a 'training-via-video' capability was hailed as particularly important, and in some cases would require special tools; for instance, a respondent requested the "capacity for live video conferencing from the operating theatre, to enable teaching and education of highly specialised surgical techniques. We would also like to record these operations and again be able to securely share the files with other HCPs for education and training purposes. (This also requires a special head mounted video camera which the surgeon

wears during the operation or is installed in the operation theatre lights as well as a separately installed camera)."

Patient Portal/ Patient Access to data

Several respondents attested the value of the ERNs' IT platform being able to support direct patient input via a patient portal or some sort. ANCs requested a common web-based tool to capture details from patients on their conditions and quality-of-life related information. Patient reported outcomes are known to enrich the data contained in registries, for instance, and in fact registries are often designed to enable both clinician-entered data and also patient-entered information, to gain a greater volume of data than might be collected in a normal consultation (whilst also conveying invaluable insight from an expert who lives with a condition 24/7).

In a world of increasingly sophisticated eHealth and mHealth solutions, some respondents emphasised the benefits of being able to integrate data from applications to collect, for instance, "functional bladder information that is easy for the patient to manage e.g. currently under development is an app for smart phones for patients to collect functional bladder data and share it with their clinician (enables a more accurate diagnosis)".

> ***Question***: *What opportunities will there be for patients to access their own data in the Platform: access in terms of viewing it and also contributing data on daily life, for instance? Will there be any functionality to see who has viewed a patient's information? Could a dynamic consent be envisaged via this platform?*

Research-supporting tools

- Some respondents emphasised the scope for ERNs to support the process of cross-border genetic testing (and indeed, this is highlighted as a key function of ERNs in the *CEGRD Recommendations on Cross-Border Genetic Testing of RD*)
- The value of stimulating research through the improved use of biobanks was also highlighted "Tools for biological sample exchange are required, along with support with legal issues (European and national permits of cross border biological sample exchange).' ANCs reported that in relation to biobanking, they expect to "follow the BBMRI structure and tools where possible".
- The importance of being able to "use existing research platform for OMICS data (RD-CONNECT)" was emphasised.
- It was noted that "a platform for clinical trial management would be very useful"

How does the information collected via this template correlate with the Fixed Requirements published in June 2016 for the 'IT Platform for ERNs'

In the Annex below, the key points outlined by the Applicant Network Coordinators (ANCs) in the sections above are 'mapped' against the Fixed Requirements published in the Descriptive Document for **SANTE/2016/A4/013** ***Scalable Software as a Service (SaaS) for a clinical patient management system to support European Reference Networks in the diagnosis and treatment of rare or low prevalence complex diseases or conditions across national borders***

Conclusions:

- Many of the 'needs' above highlighted by the Applicant Network Coordinators have in fact been addressed by/incorporated to the Fixed Specifications published in relation to the SaaS for a clinical patient management system:
    - There is good acknowledgement of the need for legal and ethical robustness and protection to be built-in to the system.
    - The description of the types of data that will need to be shareable via this SaaS seem to accord with those highlighted by the coordinators (the inclusion of genetic and phenotypic data is important).
    - Crucially, there is explicit acknowledgement that the SaaS will need to ensure that data shared within the ERN can be encrypted, stored and made available for reuse, which was a key requirement highlighted by the ANCs.

Of course, not all of the requirements outlined above were explicitly mentioned in the Fixed Requirements for the SaaS, and in some cases this likely relates to the scope of the SaaS in the published documents: what the ERN community has referred to very generally as an 'ICT platform for ERNs' is hereby termed far more specifically as a 'SaaS for a clinical patient management system'. Therefore, if explicit details on the creation of registries/interoperability of registries, for instance, are absent – as seems to be the case- this should not be particularly surprising.

One notable requirement which came across strongly in the ANC responses but appears to be absent from the Fixed Requirements for the SaaS is a tool/platform to support eLearning. As many ANCs are counting on the ERN IT platform to enable training and education activities – essential for eroding inequalities in access to care by raising standards across Europe- it is important that this need is addressed somehow.

ANNEX – Mapping Requirements to the Requirements of the published **SANTE/2016/A4/013** ***Scalable Software as a Service (SaaS) for a clinical patient management system to support European Reference Networks in the diagnosis and treatment of rare or low prevalence complex diseases or conditions across national borders***

This table is a non-exhaustive illustration of how some of the Fixed Requirements published in section 2.5 of the Descriptive Document above correspond with the key needs as identified by the Applicant Network Coordinators

Virtual Consultation system, data sharing & and data repository	*Some respondents report use of such applications already, e.g. the virtual tumour board (VTB) application, which has been designed to incorporate IHE interoperability standards*	**(ii) conforms to European standards and strategies to share health data syntactically and semantically in the eHealth sector, in particular the eHealth13 Action Plan14 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);** **(iii) 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;**
	The information discussed in virtual consultations will always be sensitive; therefore, ethical and legal requirements must be clarified before the launch of the Networks and henceforth respected.	**(vii) respects European and national legal requirements for data protection and security for health information exchange;** **(viii) registers patient consent for storing and sharing data for treatment (consent form based on a template to be provided by the Commission);** **(ix) registers consent for storing and sharing data for research (consent form based on a template to be provided by the Commission);** **(xi) enforces privacy with role-based user security (patient, health professional, researcher), authentication, identification and authorisation mechanisms to share and store data and information;**

	Cont.	**(x) implements and maintains secure infrastructure and system-wide security and monitoring;** **(xii) provides a moderated user-management console with different rights to create and or share and or view data within a single Network or between Networks (e.g. for patients with multiple conditions);**
	The platform will need to support the sharing of images in high quality, including large data files such as MRI, PET and CT scans.	**(xiii) collects the following multilingual information securely (using browser, file upload, ftp):** **– structured patient general information (e.g. name, date of birth, gender), clinical data (e.g. allergies, current medical problems, medical implants, major surgical procedures during the last six months) and a list of current medication (including prescribed medicines);** **– upload of digital medical images through Picture Archive and Communication Systems (PACS) in multiple formats for ultrasound (US), magnetic resonance (MR), nuclear medicine imaging, positron emission tomography (PET), computed tomography (CT), endoscopy (ES), mammograms (MG), digital radiography (DR), computed radiography (CR), histopathology;** **– anatomical pathology ('biobank') data (macroscopic, microscopic, biochemical, immunologic and molecular examination of organs and tissues);** **– genetic phenotypes;** **(xviii) provides visualisation of high-resolution images through a web-interface (e.g. DICOM viewer or microscope tools**

	The cases reviewed by the ERN in collaborative virtual consultations should afterwards be retained in a case record repository within or accessible via the IT Platform	**(xiv) encrypts and stores the data;** **(xv) pseudonymises patient data for sharing, use in clinical decision making tools, protocols, guidelines, case library or research;** **(xvi) hosts the data storage within EU borders and ensures that the hosting is single-tenant with stable, fast and easy data storage and retrieval, back-up and recovery;** **(xvii) ensures that hosting is redundant at both the database and application server level;**
Training & Education	*Training and education programmes should be delivered via an eLearning programme" made available as part of the Platform of IT-related tools.*	**? No apparent reference to training, education and eLearning. This came across as a really important component of an ideal ERN ICT platform, in view of the potential for disseminating good practices and reducing inequalities in access to high quality care.**
Patient Portals	*Many respondents attested the value of the ERNs' IT platform being able to support direct patient input via patient portal*	**No specific mention of patient *portals* etc, however it seems there is a goal to enable multi-user usage of the platform and patients are listed as users** **(xx) uses solutions proven in telemedicine, teledermatology, teleradiology, telepathology etc. to suit the needs of specific Networks** **(xi) enforces privacy with role-based user security (patient, health professional, researcher), authentication, identification and authorisation mechanisms to share and store data and information;** **(xii) provides a moderated user-management console with different rights to create and or share and or view data within a single Network or between Networks (e.g. for patients with multiple conditions);**

Registries	*We need a prospective care registry for all rare disorders in our ERN (data structure: minimal phenotype dataset fit for all of our patients, Available biomaterial, Phenotypic and genetic diagnosis, Natural history scales, Care metrics)*	**(Some of the following will *presumably* have relevance to registries, though not explicitly stated – it depends on whether some of the data mentioned below is envisaged to feed into a registry at some stage)** **(xiii) collects the following multilingual information securely (using browser, file upload, ftp):** **– structured patient general information (e.g. name, date of birth, gender), clinical data (e.g. allergies, current medical problems, medical implants, major surgical procedures during the last six months) and a list of current medication (including prescribed medicines);** **– upload of digital medical images through Picture Archive and Communication Systems (PACS) in multiple formats for ultrasound (US), magnetic resonance (MR), nuclear medicine imaging, positron emission tomography (PET), computed tomography (CT), endoscopy (ES), mammograms (MG), digital radiography (DR), computed radiography (CR), histopathology;** **– anatomical pathology ('biobank') data (macroscopic, microscopic, biochemical, immunologic and molecular examination of organs and tissues);** **– genetic phenotypes;** **(xiv) encrypts and stores the data;** **(xv) pseudonymises patient data for sharing, use in clinical decision making tools, protocols, guidelines, case library or research;** **(xvi) hosts the data storage within EU borders and ensures that the hosting is single-tenant with stable, fast and easy data storage and retrieval, back-up and recovery;** **(xvii) ensures that hosting is redundant at both the database and application server level;**

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