Co-funded by the Health Programme of the European Union

03 October 2014

Minutes ExPO-r-Net 2nd biannual ExeCom Meeting

Venue: Hospital Universitari i Politècnic La Fe, Torre A
Avinguda de Fernando Abril Martorell, nº 106. 46026. Valencia, Spain

Session 1, CHAIR Kathy Prichard-Jones 9:00-10:15	
Introduction and objectives of the meeting by Ruth Ladenstein, Children´s Cancer Research Institute (CCRI), ***see presentation 1_Ladenstein_Welcome.pdf***	09:00-09:10
Ruth Ladenstein welcomes all participants, briefly explains the agenda and upcoming tasks which have to be discussed in this meeting.	
WP 1 – Project coordination: o QUAP, process coordination o To do´s for the first reporting to CHAFEA **Barbara Brunmair,** , Children´s Cancer Research Institute (CCRI)	09:10-09:25
Barbara Brunmair first summarizes the milestones (M) and deliverables in work package (WP) 1 and what has been achieved until the meeting: - M1, the kick-off meeting in Luxembourg was already finalized - M2, the Quality Assurance Plan (QUAP) was also finalized and approved by the ExPO-r-Net partners as well as the funding organisation. Barbara briefly points out the changes in the QUAP as recommended by ExPO-r-Net partners which were an adaption of the organisational structure with detailed clarification of the project management team as well as the structure of the ExPO-r-Net general assembly and the advisory support by ECRC, PPAC and EAC. - M3, the organization of biannual ExeCom meetings is an ongoing process. Barbara shows the meeting schedule as displayed in the QUAP with examples of recent and following meetings: o Next general assembly (major meeting) →ExPO-r-Net session at the SIOP congress in Toronto Oct 2014 o Current ExeCom meeting (medium meeting) →Valencia o PMT meetings (small meeting) →face to face meetings embedded in ENCCA or SIOPE o PMT integrating with Leukaemia and Tumour groups ITCC, TYA (working meetings/dissemination activities) →Wilms tumour group meeting, TYA meeting, ENCCA long term sustainability meeting o PMT or WP leaders (small meetings and teleconferences) →Project updates July 2014 Barbara also reminds of the communication in ExPO-r-Net, where all information between the funding organisation and partners should be processed through the coordinator. She then explains the upcoming first interim report which has to be delivered within 60 days after the first 12 months. It should contain a technical progress report, a financial report on the amount of the previous pre-financing instalment used and a payment request for the next pre-payment. The preparations for the report will start in Jan. 2015. The associated partners should provide their technical and financial information until 31.03.2014. ***See presentation ExPO-r-Net WP 1-Brunmair.pdf***	
WP2 - Project dissemination**:** o Extranet webpage o Intranet platform (update by AIT) o Brochure and bookmark o E-blast o ExPO-r-Net meeting in Toronto	09:25-09:55

Giulia Petrarulo, European Society for Paediatric Oncology SIOP Europe (SIOPE) **Günter Schreier**, Austrian Institute of Technology GmbH (AIT)	

Giulia Petrarulo informs about dissemination action in the first 6 months of ExPO-r-Net:

- Logo symbolizing Europe, the network and links between centres. The colours of the logo are coherent with all ExPO-r-Net communication tools.
- Brochure, firstly disseminated at the SIOPE-ENCCA conference in Sept. 2014
- Bookmark to be distributed at the SIOP-congress in Toronto in Oct. 2014
- E-Blast in coherence with all SIOPE-related communication outlets including important news for all partners like deadlines, meetings, publications etc.
- Dedicated section in the SIOPE newsletter (wide reach out to ExPO-r-Net target audiences)
- Online tool extranet www.expornet.eu with key information about the project (background, activities, work packages, partners etc.). The extranet is a work in progress with different sections similar to the ENCCA-website. The partners will be contacted for feeding/updating the news sections
- Intranet (presented by Günter Schreier)
- Social media (twitter)

She then tells the audience when ExPO-r-Net was disseminated at events:

- Kick-off meeting →article in SIOPE newsletter, pictures on SIOPE website
- ExPO-r-Net was present at the ERN conference 2014 →organized by DG SANCO to bring together healthcare providers, experts, national authorities, decision-makers and independent bodies
- SIOPE-ENCCA conference 2014 (multi-stakeholder event) →ExPO-r-Net was presented
- SIOP-congress Toronto 2014 →ExPO-r-Net session on Friday, 24th Oct. 2014

See presentation ExPO-r-Net WP 2_Petrarulo.pdf

Günter Schreier then goes into detail about the planned ExPO-r-Net intranet. Office 365 will be the collaboration platform for ExPO-r-Net. It offers useful features like document management, event calendar, task management, announcements, content of the work package sites and meeting sites. One communication element will be the Lync videoconference tool for web meetings with people inside and outside ExPO-r-Net. Günter presents the structure of the intranet which will be similar to the ENCCA intranet but with improvement suggestions by Günter like taking advantage of Sharpoint 2013 from the beginning and others to be discussed in detail. The URL/Domain could be the SIOPE portal (https://siopeportal.sharepoint.com/sites/expo-r-net) which keeps the external costs low. The users could have accounts like guenter.schreier@expo-r-net.eu. He expects the external costs to be low

See presentation ExPO-r-Net WP 2_Schreier Intranet.pdf

WP3 - Project evaluation: o Development and commence of an internal evaluation plan until Feb. 2015 o Questionnaire for ExPO-r-Net WP-leaders o Gather information on the migration of patients in paediatric oncology in Europe **Pam Kearns**, University of Birmingham (UOB)	09:55-10:15

One of the milestones of WP3 is the determination of an internal evaluation plan. Pam Kearns explains that this plan used elements of the QUAP. The QUAP as well as WP documents were given to the Institute of Cancer Policy Review Board (ICPRB) for independent Review. The minutes and progress reports from the WPs are utilized for internal evaluation (review and feedback). Pam also intends to develop a questionnaire for the WP leaders to assess progress satisfaction and expectations.

M2 of WP3 is the commence of the internal evaluation plan, i.e. review of the WP documents and feedback. As examples Pam mentions:

- the interim review of the WP4 questionnaire to identify needs of rare childhood and young people cancer types and entity subgroups
- Minutes of the WP TCs as well as the TC with Enrique Terol are currently under review

The ICPRB review will be done for WP6, where a 1st draft of principles of accreditation process for paediatric oncology/haematology is developed.

The determination of an external evaluation plan should be finished in March 2015, Pam anticipates a first draft at the end of November 2014. The external evaluation report should then be available in December 2016.

Finally, Pam puts under discussion the following issues:

- Need for base-line information on the migration of patients in paediatric oncology in Europe
- Clarity in ExPO-r-Net purpose
    - Differentiation between defining standard of care patient pathways/best practice and referral routes for clinical trials
    - Definition of expert reference centres and standards for all EU paediatric oncology centres

See presentation ExPO-r-Net WP3_Kearns.pdf

Discussion:

The need for information on the **migration of paediatric oncology patients**[TO DO] is discussed. Ruth asks if there is a hands-on tool available, ideally a map of migration. Pam answers that Richard Sullivan investigated this but did not find suitable information. David Walker informs that his institute gathers information on the place of residence and place of treatment, which could be a standard procedure in institutions.

Pam wonders how in such cases success and improvement can be shown. Kathy Prichard-Jones says that this can only be done by surveying the centres, but is it worth the effort? Do health service organisations keep the record? What happens, if the patient comes with charity money, which is not displayed anywhere official? To solve this issue Kathy suggests to first define conditions and then ask the reference centres how many treatments are done for other centres (own country or other country). This limits the number of variables.

Marisa de Rosa informs that Italy can at least provide information on the national level since many patients travel from the south to the north for treatment. She thinks that also the survivorship passport can be informative in the future. However, immediate baseline information cannot yet be given.

When Dominique Valteau-Couanet asks why ExPO-r-Net needs this information Pam answers that it would serve as a measure that ExPO-r-Net makes a difference, is sufficient.

David is sure that the information how many patients are going abroad is somewhere stored in the countries. Richard is still following this up and trying to find information.

Ruth summarizes that the task of ExPO-r-Net is to streamline qualified referrals which is not structured yet. This needs to become transparent and equal over Europe. How is Europe monitoring these patients? How many patients went from one member state to another? This will not be found in the centres. Does the commission know?

Enrique Terol answers that there is a big database where such things are monitored but it does not give information on the disease and is not easily available due to social security regulations. Every 3-5 years there are **regular reports about cross-border healthcare**[TO DO], the next one will be available in 2015, including reimbursement etc.. Enrique further emphasizes that ExPO-r-Net has to clearly define how this should work to give public authorities clear guidelines.

Ruth hopes that the EU will provide help via Enrique in giving access to necessary data and answering requests for specific information.

Stefan Bielack and Pam discuss that this information will only be necessary from EU-member states.

José Sanchez de Toledo thinks that a first step should be the definition of reference centres. He is convinced that then the information on patient migration follows automatically.

Ruth makes aware that defining reference centres might trigger sensitivities. It is not the purpose of ExPO-r-Net to state that one centre is better than the other. Instead we want to recommend specific centres for patients with unique/special therapeutic needs. This has to be clarified with the clinical chairs. ExPO-r-Net intends to assure that there is an expertise level inside the country and instead of moving the patient, information should be moved. Local expertise should not be undermined but supported by (virtual) tumour boards.

David suggests finding accurate terms for description and what defines a cross border tool.

In summary, Pam will make a draft of the next steps and will liaise with Enrique and Richard for further information.
Coffee break

Session 2, Chair Adela Cañete

10:30-12:30

WP 8 - Integrating children with very rare tumours in a ERN: o Preparation of a document defining the expert meetings for very rare tumours (M1) o Document summarizing the needs for a very rare tumour website o Establishment of a website for very rare tumours (M2) o Questionnaire on very rare tumours for the European National Society Chairs o Building a network of people dealing with very rare tumours **Gianni Bisogno**, Azienda Ospedaliera di Padova (AOPD)	10:30-11:10

WP8 intends to integrate very rare tumours (VRT) and soft tissue sarcomas (STS) into the future PO-ERN. This means:

- identification and connection of Paediatric Oncology Centres and Cooperative Groups with the necessary expertise
- provide accurate diagnosis and evidence-based treatment to children with VRT in Europe (and worldwide)

Gianni Bisogno informs that his WP was discussed in the EpSSG board meeting in May 2014, in TCs with SIOPE and associated partner and in an ExPO-r-Net WP8/Expert meeting in Milan in Sept 2014. The following steps to achieve the deliverable "standard of care guidelines for VRT and very rare STS are taken:

- Identification of national Cooperative Groups via a VRT questionnaire (survey monkey)*
- Discussion and comparison of the different treatment used for VRT in EXPeRT meetings*
- Definition of a VRT priority list in EXPeRT and EpSSG meetings*
- Data sharing among the different Groups and analysis to create a common scientific background by EXPeRT and EpSSG analysis*
- Creating new scientific evidence*
- Definition of guidelines via EXPeRT and EpSSG guidelines*
- Optional: methodology review*

Remark: To Do´s for follow up

The milestone "**establishment of VRT network tumour board and working group on rare STS in collaboration with EpSSG**[TO DO]" will be discussed in November 2014. The board has been established during the ExPO-r-Net WP8 meeting in September 2014 and a document describing the working procedure has been written. An advisory desk has opened in 1st October 2014. But this must be a flexible and always ongoing process. Gianni emphasizes that a European tumour board on very rare tumours will need legal advice and the effectiveness and quality of the system is strictly related with the available resources.

The milestone "**establishment of a website dedicated to inform families and the public**[TO DO]" will be ready in March 2015. This will be done in cooperation with SIOPE. As for ExPO-r-Net, the website will be part of the SIOPE website which saves costs. In this context Gianni explains that although there is a link between the needs of this Work Package and the needs of the ExPERT clinical study group the two initiatives are separate, and shouldn't be confounded. The final structure of the website is not fully defined yet. Gianni puts up for discussion that it could be i) either a platform where patients can ask questions about very rare tumours and exchange clinical data/images with clinical experts. ii) or as an informative page for patients, where the standard procedure of diagnosis/referral/participation in clinical trials of patients with very rare tumours is explained in detail. Option 2 is more feasible for SIOPE. Another milestone of WP8 is a European meeting to reach consensus on guidelines for VRTs and rare STS.

The priority list is i) pleuropulmonary blastoma (Bisogno), ii) pancreatoblastoma (Bien, Ferrari), iii) Sertoly-Leydig Tumors (Schneider, Cecchetto) and probably infantile fibrosarcoma (Orbach, Ferrari) and embryonic sarcoma of the liver (Bisogno). Finally, Gianni announces the next biannual ExPO-r-Net meeting which he will host in Padova on the 6th of March 2015.

See presentation ExPO-r-Net WP 8-Bisogno.pdf

The second part of this WP is presented by Dominik Schneider, who informs in more detail about the **establishment of an interdisciplinary virtual tumour board for VRT and STS**[TO DO] as a means of quality assurance together with the EXPeRT Consultation Network. A concept paper was developed including aims. It should enable the physicians to:

- Draw on experiences from their own patients
- Discuss with worldwide experts and multidisciplinary experts
- Explore various therapeutic/diagnostic options, even if they are not available in the centre caring for the patient, and
- Continuously expand and refine knowledge

It should enable the patients/parents to:

- benefit from the collective international experience of several specialists
- have access to modern treatments
- receive treatment locally but with international supervision
- be referred to a different centre if particular treatment is needed and not available locally
- avoid extensive search and travels to find the “right” person and the “best” centre

The number of VRT and STS diagnoses is high and according to the EXPeRT consensus, a **minimal data set**[TO DO] should include i) age and sex of patient, ii) diagnosis: pathology, inclusion of reference centres, staging and associated disorders, iii) previous treatment, iv) questions. In a minimal follow up of 3 months it will be asked how helpful the EXPeRT board´s recommendation was, if the consultation had an impact on the management (for example change of strategy) and if further advice is required. After 12, 24, 36 months the status of the patient will be inquired and, again, if further advice is needed.

The active management of the tumour board will include:

- Preparation of consultation, request, consent, data etc.
- Management of tele-conferences
- Management of follow-up
- Coordination in Dortmund (D. Schneider)

As telecommunication technology tools email, ftp-server, video conferences etc. will be used. For the specific diseases specific experts will be allocated. Finally, Dominik shows examples how the request form for the virtual tumor board could look like.

See presentation ExPO-r-Net WP 8-Schneider.pdf

Discussion:

Since it is planned to **establish a compensations system**[TO DO] on the long term, Ruth Ladenstein recommends capturing also the time needed for the advice. Dominik agrees that in particular a videoconference takes time including the filling of the form. He also stresses that they will give only advices without responsibilities. David Walker adds that in the UK given advice has no authority in the local centre to avoid legal problems. Stefan Bielack informs that in the osteosarcoma group it is stated very clearly that it is only an advice and re-compensation is done by a formal system*. Centres which cannot afford that will not make a request. In this context Ruth and Dominik interject that not the patient or the hospital should “pay the bill” but the respective national health system. Stefan explains that Germany has national regulations where patients with specific needs are allowed to come whereas others are not. The centres have certain requirements and with those you have to go to the insurance companies and negotiate. The insurance company makes an estimate on how many consultations where made and for those you will get re-compensation. This is done on an annual basis.

**Remark*: *ExPO-r-Net has to get information on the wording of such a document (from Forgo/SSFP?)*

WP7 - Cross border dimension of long term follow up**:** o Questionnaire on the prerequisites and technical aspects of a tumour board o Cooperation with the tumour board from Münster o Summary of the results from Günter Schreier's meeting with the ITH **Riccardo Haupt,** Istituto Giannina Gaslini (IGG)	11:10-11:50

Riccardo Haupt informs the audience that the **translation of both the survivorship passport and the survivorship guidelines**[TO DO] have started, Italian is almost done, other languages are still to complete. He briefly explains with a figure the structure of the passport including the numerous variables per worksheet. The WP also includes the translation of recommendations and brochures i) from professional English to lay English and ii) from lay English to other languages **with the help of professional volunteers** (i.a. by application to the United Nations Volunteers, UNV). He shows as an example the multiple translation of "primary ovarian insufficiency follow up-screening" from professional English to lay English and Italian. Informative lay brochures explaining details of human body functions will be used as attachments. As decided within the ExPO-r-Net TC in July 2014 the first language priority list will be the big languages English, French, Spanish, German, Polish, Italian and a random selection of the lesser spoken languages Hungarian, Portuguese and Greek. Other languages will follow. It is planned to include a selection of network partners who have supported translations of the European Standards of Care and patients organisations in Greece, Romania and Austria.

For the WP7 milestone "Identification of experts for the virtual late effects centre" it is planned to obtain a preliminary list of names with as many countries represented as possible in the next PanCare meeting in Lucerne Oct. 2015. At the end of his presentation Riccardo recommends to coordinate ExPO-r-Net with other EC-funded projects like ENCCA, PanCareSurFup, PanCareLIFE and stakeholders like SIOPE, ICCCPO and PanCare for project dissemination and to share experience/methodology for identification of experts.

See presentation ExPO-r-Net WP 7_Haupt.pdf

Discussion:

The question arises who should become active with the application to the United Nations Volunteers. Ruth Ladenstein suggests choosing SIOPE for this process, since they present the whole community which gives their request more strength than a request from ExPO-r-Net, which is agreed upon by all participants.

Dominik Schneider asks where the information on the passports is centralized, who the owner of the registry is, and how it will be used in the future (research?). Riccardo answers that the prototype was developed by CINECA who made a follow-up database. Data sharing between survivors would be possible, the ownership of the data belongs to the survivors and data providers. Eugenia Rinaldi explains that CINECA has a security certificate for the database and they are able to always track data/patient movement. If preferred, it would also be possible to not centralize the data and instead keep them in local centres but this option is more complicated and therefore less favourable. According to Dominik the survivorship passport will result in an immense database for research. Riccardo agrees that there is an intention to use the database for this purpose in the future with consent from the survivors. Ruth summarizes that the survivorship passport was developed in ENCCA and that the ownership will stay with the survivors but it will be an open and moving process for cross border use in the future. It will empower the patient to provide all necessary information about his status at any time after adulthood, which should result in the best possible advice from the latest knowledge given. A patient with a headache should be able to give his physician relevant information about his brain tumour background. Therefore this is an extremely important concept with high future potential. First effects are already visible, for example: the survivorship passport became an official part of the recently published Austrian cancer plan. Riccardo agrees that the passport is an excellent tool to empower patients to have the best follow-up possible and the exact details to be drawn from the passport on the research level are not decided yet. He also makes aware that feeding the passport with information is very time-consuming and efforts are made that data could be automatically transferred from other databases. In principal it is possible and CINECA is working on it.

WP5 - PO tumor board ERN based on EHealth concepts: o Questionnaire on the prerequisites and technical aspects of a tumour board o Cooperation with the tumour board from Münster o Summary of the results from Günter Schreier's meeting with the ITH **Adela Cañete**, Hospital Universitario la Fe de la Communidad Valencia (HULAFE) **Günter Schreier**, Austrian Institute of Technology GmbH (AIT)	11:50-12:30

Adela Cañete informs that WP5 is to develop a strategy to build ExPO-r-Net Tumour boards as tools for providing access to expert care to all European children with cancer in a cross-border setting. In this context it is intended to seek mechanism to facilitate movement of information and expertise rather than patients, which is the extension of tumour board culture. This requires common standards and an ICT system that warrants data interoperability, efficient data management and confidentiality and leads to the following tasks:

- Knowing the state of the art: identify currently functioning TB in Europe and abroad.
- Analyse the methodology used through a questionnaire (clinical and IT elements).
- Specify conceptual models and standardize IT languages.
- Define Standard Operating Procedures (SOPs) and roadmaps to implement ExPO-r-NeT TB as soon as e-Health IT platforms currently in development in Europe are launched.
- Develop a coherent ICT strategy and devise interoperability architecture for ExPO-r-NeT.

The evaluation of current existing tumour boards through a questionnaire containing clinical and technical (IT) questions has started already on a national level in Spain as presented in detail in the previous day´s tumour board workshop (see minutes TBW). **The questionnaire will be adapted for European use[TO DO].**
Adela also identified **tools used for virtual tumour boards*[TO DO]**: France, Institute Gustave Roussy, the platform Curekids, St. Jude Children´s Research Hospital use the web conferencing platform Adobe connect, Germany, Münster uses Vidyo and others communicate via skype. Adela then explains the most common Adobe Connect system in detail:

- It provides a secure website for conference participants in order to ensure patient confidentiality
- The conference can be viewed only by invited guests. The URL for the meeting is sent to participants through secure e-mail
- Participants must download the software to the computer they plan to use before the scheduled conference (Adobe Flash Player, Adobe Connect Meeting Add-in)
- The conference participants have to click on the URL link provided to access the conference.

Therefore Participants only need telephone access and internet connection to participate, which are readily available at their place of work.
Finally, Adela put under discussion the following identified problems: i) confidentiality, ii) data protection (security), iii) costs. Will an informed consent by the patient legally justify any virtual tumour board action? Different levels have to be considered: i) data transfer, ii) case presentation, iii) communication. ExPO-r-net will also face different complexity levels according to local/national development.
**Choice for recommendation*
See presentation WP 5_Canyete.pdf
After Adela Günter Schreier takes over to describe the technical part of WP5. He first explains the participation of the AIT in WP2 where an intranet will be prepared similar to the ENCCA-intranet. Günters notions his involvement also in WP4 and that a clear idea of the core requirements for ERN in general and ExPO-r-Net in particular has to be developed. What are the i) administrative, ii) patient related and iii) science related requirements?
In WP5 AIT focusses on the development of an ICT strategy and interoperability architecture for ExPO-r-Net. For this Günter already participated in several meetings like the ERN-expert panel in Brussels, 2014, the HL7 FHIR workshop and the IHE day in Vienna as well as 2 meetings with ITH icoserve technology for healthcare GmbH in Innsbruck. It is important to link the already existing ICT landscape with the network including:

- Institutional IT systems
- Interoperability initiatives like IHE (Integrating the Healthcare Enterprise), LOINC, eHealth EIF

- Health information exchange systems like ELGA, epsos
- National and international regulations (summary documents)

In this context an important issue is the standardisation process which may take years. In case of IHE the workflow is already specified and IHE profiles available*. They could be adopted for ExPO-r-Net to define all players and adapted to the paediatric need. This will save time and effort.
Günter finally shows an example how the ERN proposed ICT architecture could look like. Some parts may be in the cloud, some elements will be institution extracts from interfaces where the physician gives information hosted by institutions. Later we may directly link with patients who may be questioned about their health status for example once a year.
The next open tasks will be to foster partnerships with industry, IHE Europe and to jointly develop a solution architecture comprising managing ERN and patient treatment and creating dissemination and knowledge. This will result in an ERN reference architecture and a productive ERN ICT platform which goes beyond the lifetime of ExPO-r-Net and needs further funding.
**Identify concretely what needs to be done*
Discussion:
Pam Kearns asks if IT tumour software examples are already developed and how to deal with confidentiality if information is exchanged between institutions. Günter answers that there is a cross enterprise tumour board workflow definition available and that several layers of software are needed (for the upload of information, for communication etc.). The basic method for the exchange of information is the written consent of the patient and a secure system.
Gianni Bisogno interjects that in the tumour board workshop 3 systems for virtual tumour boards have been presented: Adobe Connect, Vidyo and the CINECA-system* and he wonders which system he should use for his purposes. Günter answers that presently ExPO-r-Net will not restrict to one single system for videoconferencing. What is more important is the provision of a clear process for an interface at the hospitals that allows/facilitates networking. A lot of money was already invested ins such systems therefore a specified systems analysis is important.
For example, the transition from paediatric services to adult services requires multidisciplinary meetings and a feasible system which is already the case with brain tumours. Also the UK has the ICT for health project, where ExPO-r-Net can learn. In the end we need a European interoperability and ExPO-r-Net will develop its own IHE profile tailored to our needs.
Oskar Pastors recommends that ExPO-r-Net has to assure from the beginning of the project that the same interoperability system is used to avoid problems already within the project, not to mention whole Europe. Günter agrees and informs that a standardized definition on clinical documents is needed. We are already highly standardized but some issues are still open like terminology, language. We will need highly structured documents but physicians also need sections for free text.
Enrique Terol informs that there are already 6-7 systems available with many modifications. To solve the issue of communication and the national approach, the commission intends to develop an agreement covering all member states. The exchange of patient summaries is already agreed upon.
**We need a comparison of the 3 systems*

Lunch

After the lunch break, the group picture was taken in the lunch area.

Session 3, Chair Ruth Ladenstein 10:30-12:30	
Crucial actions for ExPO-r-Net in the next 12-18 months **Enrique Terol**, DG SANCO, European Commission	13:15-13:35
Enrique Terol informs that there are now 2 legal acts on ERN:	

- **Commission delegated decision** setting out criteria and conditions that reference networks and healthcare providers wishing to join a ERN must fulfil
- **Commission implementing decision** setting out criteria for establishing and evaluating ERN and their members and for facilitating the exchange of information and expertise on establishing and evaluating such networks

The commission will establish criteria which are: i) 6 sets of criteria for networks, ii) 5 sets of general criteria for members and iii) 2 sets of specific criteria for members.
The general criteria will be as follows:

- patients empowerment and centred care
- organisational, management and business continuity
- research and training capacity
- exchange of expertise, information systems and e-health tools
- expertise, good practice, quality, patients safety and evaluation

The member´s specific criteria (based on evidence and consensus of community) will be:

- documented competence, experience and activity
- provide evidence of good clinical care and outcomes
- characteristics of human resources
- organisation and functioning: multidisciplinary healthcare team
- specific equipment within the centre or easily accessible
- communication/interaction at a distance capacity

Chronologically, there will be a call for networks followed by an eligibility check and technical assessment of all proposals. If approved, the ERN member will be allowed to use the ERN Logo.
Timeline:

- Preparatory conference; September-October 2015: workshops and practical information, space for encounters (ExPO-r-Net)
- Call: November 2015, deadline: February 2016
- Assessment of proposals: March -May 2016.
- Approval of positive proposals by board of member states (MS): June – July 2016

It is not a competitive call with funding. Any network fulfilling the criteria will be approved. The member states will have a key role in it because they are responsible for endorsement, approval, recognition of centres on a national level and building the board of MS. In this context Enrique invites the audience to approach national authorities to increase the awareness of the MS.
To achieve these goals it has to be decided with colleagues and the commission which IT general and specific criteria have to be fulfilled. Enrique suggests holding a teleconference on this with ExPO-r-Net members and the commission. As well, an IT platform has to be established and fed with inputs from pilot network experience. The following elements should be explored: **needs, list of IT tools and solutions, main outstanding issues like data protection, technical capacity, budget etc. and feasibility of the setup of a comprehensive IT platform**[TO DO]. The EC intends to contract an external independent body to make an ability study and develop a pilot tool in 2015/2016. There are networking elements, communication and eHealth solutions needed for tele-medicine, remote monitoring and follow up, secure exchange of patient information, remote training, remote guidance and diagnosis and virtual clinical/tumour boards. Clinical tumour boards are recognized as essential component of excellence in cancer care and complex diseases, which bring together medical disciplines for the best care of patients using eHealth and telemedicine technology. As examples Enrique mentions the well-established teledermatology in rare skin diseases, teleradiology, telesurgery, teleconsultation and telecardiology.
Assessment and approval of the networks will be done with an assessment manual and tools based on the criteria established[TO DO] in the legal acts by external and independent institutions (assessment bodies) with experience and knowledge on healthcare systems and the capacity to conduct and carry out assessment and evaluation of the networks and healthcare providers. The contractor (assessment body) will contact and review current state of the art with national authorities, accreditation bodies and

stakeholders (ExPO-r-Net) starting in February 2015. The specific criteria will not address the concrete disease but how to evaluate the quality of the proposed criteria (evidence based, consensus, support of international societies, etc...). The call for assessment bodies will start in December 2014.
Enrique also recommends connecting with other expert groups on rare diseases and cancer e.g. orphanet.
He considers as challenges to:

- Approve and attract the right Networks and Centres
- Establish efficient organisational network models
- Avoid fragmentation/duplication of efforts
- Develop/use standardised tools (CG, registries, p. pathways, IT interoperability..)
- Increase the capacity of healthcare providers by the "real" exchange of knowledge and cooperation (virtual tumour boards, etc..)
- Ensure sustainability with stronger engagement of MS
- Strengthen the "partnership" between experts, scientific societies, national authorities and EU institutions

So far there is no concrete financial framework or mandate in the directive to financially support networks. Possible sources of support and financing at EU-level are

- Funding the process of ERN establishment (formal establishment of networks, IT platform, conferences, workshops)
- funding of the networks by project grants (annual calls)
- Other sources and competitive calls (horizon 2020, structural funds, social funds etc.)
- Reimbursement of services (referrals and telemedicine)
- Digital plan new commission
- Industry and other interested stakeholders

From ExPO-r-Net he expects the following[TO DO:]

- Business model of the network/organisational model
- Group of diseases to group in the network (rare, low prevalence, complex)
- Definition of services – concepts
- IT experience and needs; virtual communication models
- Specific rare cancer criteria (not general accreditation model) to feed the assessment and networks proposal
- Pathways models, referral criteria
- Information system/balance scoreboard/info about cross border referrals/network activities
- Integration of other players
- Collaboration/participation in ERN activities

See presentation ExPO-r-Net Terol.pdf

Discussion:

To the question of Pam Kearns if the MS are informed, Enrique answers that a communication campaign will start soon as well as publications (e.g. Lancet) with information on the different bodies, pilot networks, board of MS etc..
Kathy Prichard-Jones mentions the Joint Action on Comprehensive Cancer Control (CANCON) and wonders if this is relevant in the context. Enrique informs that they are not a network of healthcare but to produce guidelines of healthcare.
Kathy also wants to know how the outcome for centres will be measured. Ruth Ladenstein asks if it will be patient outcome, case volume, participation in clinical trials or something else. Enrique admits that the measurement of outcome will be a complicated issue and that something meaningful and very clear has to be developed. Kathy informs that the UK made a comparison of individual centres against total UK-outcome, but the numbers were very small and not very informative. Dominik Schneider says that interpretations are difficult for different patients and treatments. Ruth comments that the clinical trial groups made a survey on the comparison of small vs. big centres and some results were that in small centres you often come down to too small numbers and large fluctuation. Therefore instead of measuring

something like survival outcome, activity parameters could be measured, but this is open for future discussion. Enrique mentions that the idea is to propose something for which there is evidence and which can show a quality improvement process. This shall be decided together with the centres. The assessment bodies will then check if there is agreement and information has to be synchronized. All proposed ERN centres should fulfil the same criteria. National networks should show hubs of expertise and national authorities should be included in the process (but should not determine centres).
Günter Schreier asks if the EC considers a patient registry also as a natural part of such a network which Enrique agrees.
Ruth summarizes that the next goal of ExPO-r-Net would be a **proposal in early 2015 for possible reference sites**[TO DO], which shall be formalised for the ERN call in December 2015. It will be a first "pilot" ERN that will grow over time in a multi-layered fashion.

WP6 - Defining criteria to identify and certify PO expert centres**:** o Definition of terminology used for the accreditation process (glossary, to be evaluated by WP3) o Identification of centres of excellence: draft of ideas on what would qualify a reference centre **Jerzy Kowalczyk,** Medical University of Lublin (MUL)	13:35-14:15

The objectives of Jerzy Kowalczyk´s WP are to build a paediatric oncology ERN-roadmap and to define the criteria for identification and recognition of centres. This leads to the tasks i) define the terminology and definitions used for the recognition process, ii) describe quality certification system, iii) prepare a checklist enabling self-assessment by treatment centres and iv) set up a working committee to assess and to monitor the certification process in paediatric oncology units. The milestone "Definition of terminology used for the certification process" (glossary) is already structured and will be finished in December 2014.
In view of Enrique Terol´s presentation Jerzy Kowalczyk realizes that parts of his work package have to be executed in a faster pace than expected, e.g. the description of a quality certification system to ensure that procedures are being carried out in line with agreed standards. He names 7 steps as principles of the quality certification process:

- Application of a POH (paediatric haemato-oncology) centre in the programme
- Self-assessment
- Go / no go decision
- Peer review visit and designation check (not as originally suggested by SIOPE but according to Enrique Terol by assessment bodies contracted by the EC)
- Reporting
- Formulate improvement plan
- SIOPE Certificate*

**This is more likely to be done by accreditation bodies*
Jerzy suggests to distinguish between 4 different types of POH centres:

- POH Unit (simple standardized therapy)
- (Specialised) Clinical POH Centre (diagnostics and treatment)
- POH Research Centre (normal clinical treatment plus research and diagnostic work)
- Comprehensive POH Centre (highly specialized services and good research)

The quality certification/evaluation process will include a **self-assessment questionnaire**[TO DO] which Jerzy is currently developing. It will include a glossary of terms and definitions, a qualitative (general standards, management, research innovations etc.) and a quantitative part (numbers related to infrastructure).
Jerzy also asked 18 chairs of European tumour study groups if they have a system to recognize POH centres fulfilling all necessary requirements like special hospital facilities, centre size, access to specific diagnostics and more. The questionnaire will help him to prepare a checklist enabling self-assessment by the centres of their compliance with European standards. The expected date for this checklist was march 2015. This would be followed by self-assessment by the centres until March 2017. However, Jerzy thinks about speeding up the process because of the expected DG SANCO ERN-Call in late 2015.

At the end of his presentation Jerzy points out that his definitions of the glossary and the types of POH units are open for discussion and adaptions if needed. The entities responsible for the quality certification process will be the EC/contracted assessment bodies. His talk is immediately followed by Ruth Ladenstein´s presentation of WP4 because they are closely related and could be discussed together.
Remark: Accreditation processes in Europe, what is already established?
See presentation ExPO-r-Net WP 6_Kowalczyk.pdf

WP4 - Needs and Challenges of cross boarder healthcare: o Questionnaire on specific diagnostic and therapeutic needs distributed within ExPO-r-Net and to ECRC members **Ruth Ladenstein**, Children´s Cancer Research Institute (CCRI)	14:15-14:55

This WP should identify the special (unique) therapeutic needs of young people with cancer (e.g. special surgery, proton therapy) by a questionnaire to be answered by the ECTG (ECRC) chairs. It should also address the concomitant challenges like costs, resources, psychological burden and ethical aspects. The goal would be to identify institutions/centres offering top level of expertise and ready to engage as reference centres by establishing a/o rolling out tumour boards. Therefore a **report on specific needs of particular paediatric oncology patients*TO DO** has to be delivered as well as a roadmap identifying reference centres and tumour boards. The identification of specific needs is investigated via a questionnaire which was developed by Ruth Ladenstein in close cooperation with the European tumour and leukaemia groups and revised by Pam Kearns. As suggested by Martin Schrappe, the questionnaire (survey monkey) is split in 2 separate versions: i) frontline and ii) relapse. It was circulated within the ECTG committees and a first analysis of the results was already performed by Giulia Petrarulo. Milestone 3 of WP4, the identification of reference sites eligible and willing to be part of ExPO-r-Net via the ECRC has to be adapted to the timeline for ERN from the EC/DG SANCO. Ruth proposes to establish a phase 1 core PO-ERN for 2015.

**Include specification of further special needs by tumour groups*

She reviewed associated and collaborating partners of ExPO-r-Net and suggests the following potential first well known PO-ERN sites as possibility to act quickly :

- SAK (St. Anna Kinderspital) / Vienna – AT
- La FE (Fundaciòn para la Investigaciòn Hospital Universitario La Fe)/ Valencia – ES
- IGR (Institut Gustave-Roussy)/ Villejuif – France
- MUL (Medical University Lublin) / Lublin – PO
- ULUND (Lund University) / Lund- Sweden
- AOPD (Azienda Ospedaliera di Padova)/ Padova- IT
- IGG (Instituto Giannina Gaslini) / Genua- IT
- CAU (Christian Albrecht University Kiel)/ Kiel - Germany
- INT (Instituto Nazionale dei Tumori) / Milan- IT
- KlinikumDo (Klinikum Dortmund)/ Dortmund- Germany
- UOB (University of Birmingham) / Birmingham - UK
- UCL (University College London) / London – UK
- Charité (Universitätsmedizin Berlin:Charité) Berlin – Germany

Those centres could at least be proposed to work for/contribute to the assessment process.
Remark: i) evaluate if criteria for comprehensive PO-centre fulfilled, ii) additional plan to identify the centres of clinical trial group chairs , France and the UK should be asked for their formal processes.
After official recognition by the EC as a PO-ERN, phase 1 will be followed by phase 2 with the roll-out of the identification process for PO-ERN throughout Europe, i.e. an expansion of the initial network with additional partners. Besides the easily identifiable established centres there will be several other clusters of expertise that should not be discriminated, maybe specialized on one specific need. Such additional centres will be identified by WP6, Jerzy Kowalczyk. The final result of WP4 should then be a clear roadmap of centres for health care providers and patients.

See presentation ExPO-r-Net WP4_Ladenstein.pdf

Discussion:

The questionnaire is briefly discussed. Jerzy Kowalczyk wonders if the part related to clinical trials should be duplicated or more to enable filling up several trials from one group. Ruth informs that this was discussed with Martin Schrappe who wants to approach his sub-leaders individually.

For the selection of centres Jerzy emphasizes that the lowest common level of centres have to be found. Upcoming new centres then have to adjust to this level. Ruth follows this idea but mentions that the existing expert centres already have a very high level of expertise which new centres might not be able to follow. Therefore a brainstorming process on the criteria should take place. Stefan Bielack says that Germany already has national and supernational reference networks in place and there are **national guidelines for PO-centres*TO DO** (GPOH infrastructure, disease specific trial groups, accreditation rules for PO centres). He is afraid that ExPO-r-Net could conflict with such systems and wonders how they fit together. Dominik Schneider mentions that there is legislation on PO-centres in Germany but it does not show the specific levels of expertise. He agrees with Stefan that an interference with national law could be problematic. He is not convinced by the 3 levels of centres but rather suggests basic criteria for all centres. David Walker informs that similar and complex arrangements exist in the UK for self-assessment, to support and run trials and definition of national standards. Pam agrees that national standards are well defined but counters that this is not the purpose of ExPO-r-Net. ExPO-r-Net identifies expert reference centres to make their knowledge technically available across member states. This needs uniform multinational standards. ExPO-r-Net will identify what special areas are not be delivered, when patients need additional special advice, input or movement. The “special” has to be defined. Who can deliver the “special”? This in not necessarily the actual centre. We therefore define expert reference networks for different needs.

Dominik and David, however, still share the concern that different levels of expert centres might not be perceived well.

The participants also identify the issue of intellectual knowledge, if a person moves from one place to another (the expertise goes with the expert). Therefore there should be assessment not only of expertise, but also of technology, access to drugs, unique therapeutic interventions etc.. This will be identified with the help of the clinical trial groups, parent groups, NaPHOS and others. Currently patients from Romania and Bulgaria rather go abroad than use local well equipped centres. In the future best local treatment could be guided with tumor boards, i. e. movement of information, not patients. ExPO-r-Net should be able to show such countries pathways to information. Additionally, ExPO-r-Net will identify centres which offer unique therapeutic interventions like proton therapy. These two aspects should not be mingled.

**GPOH guidelines*

Discussion between Associated Partners:	14:55-15:55
Necessary first steps to become an established PO-ERN in Q2-2015 *PHASE 1 (until Q2 2015)* o Do qualify institutes/hospitals of Associated Partners as a European Reference Center? o Common brainstorming on qualifying criteria and application process *PHASE 2 (Q3 2015 until project end)* o Consideration of additional sites based on the ECRC (Leukemia/Tumor Groups) feedback o Internal ExPO-r-Net ERN evaluation process and coordination of application	

Ruth Ladenstein invites to a brainstorming on the identification of already existing expert sites for a first PO-ERN. Such sites could be institutions from associated or collaborating partners providing:

- specific services,
- have a history of multidisciplinary approach/teamwork,
- are visible on a national and international level,
- coordinate at least one major clinical trial,
- have tumor board expertise

- etc.

Dominique Valteau-Couanet informs in this context that IGR has linked 4 centres with tumor boards where the types of tumours are shared (bone, lung, head and neck, neurology phase 1/2 studies). The tumour specific meetings have different frequencies depending on the tumours (weekly, monthly…). First they had time-consuming face-to-face meetings which were then changed into videoconferences to spare travel time (see also minutes Tumour Board Workshop, 02.10.2014).

Pam Kearns suggests Birmingham and Nottingham as qualified centres, with high level care, high dose therapy, transplant radiotherapy but no proton therapy. Birmingham has specific expertise in osteosarcoma and bone marrow transplantation. She suggests **defining needs for easier identification of centres**[TO DO] first. David Walker offers the following needs: i) multiple tumour boards, critical mass for special advice, surgery and more. He is positive that centres able to trigger treatment changes are expert centres.

Stefan Bielack announces that hubs of expertise might differ for different carriers of expertise. Some are experts for one field, others for many different fields, sometimes the expertise comes from a network, virtual tumour boards. Stefan´s group has high expertise in radiotherapy, surgery, chemotherapy advice.

Ruth suggests re-discussion as soon as the questionnaire is analysed, because the ECRC chairs direct the concert in their field. In a second wave hubs of expertise will be identified on the basis of feedback from the questionnaires.

Summary and closing remarks, by Ruth Ladenstein, Children´s Cancer Research Institute (CCRI)	15:55-16:00
End of Meeting	