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06 March 2015

Minutes ExPO-r-Net 3rd biannual ExeCom Meeting

Venue: Piazza Cavour, 27/ Via VIII Febbraio, 20/24, 35122 Padova
Host: Azienda Ospedaliera di Padova (AOPD), Padova, Italy

Session 1: Horizontal Work Packages

Chair: Gianni Bisogno
8:30-10:00

Introduction and objectives of the meeting **Ruth Ladenstein**, Children´s Cancer Research Institute (CCRI)	08:30-09:00

After Gianni Bisogno welcomes the participants and gives a shot introduction on the meeting venue, Ruth Ladenstein briefly introduces the project to the new collaborative partners. The overall aim of ExPO-rNet is to reduce inequalities in paediatric cancer patient survival across Europe The main objectives of the project are the identification of hubs of coordination which are willing to deliver cross border advice or care and concomitant integration of necessary IT-technologies. She also shows a list of all ExPO-r-Net associated and collaborating partners and briefly explains the ExPO-r-Net work packages which are going to be presented in this meeting. The most immediate need for ExPO-r-Net is to identify a common process for the building of European Paediatric Oncology Reference Networks (PO-ERN), which will the current standards of care on the next level. Therefore a specific interactive meeting session is dedicated to this topic.

see presentation ExPO-r-Net 3 Ladenstein_Welcome.pdf

Discussion.

After the request from the audience for more detailed information on ERNs and their financing, Enrique Terol explains that there will be many networks which are going to apply for the upcoming ERN-call in late 2015, traditional ones as well as specialized ones and that the EU did not foresee full financing of certified ERNs. However, there are (not yet fully secured) co-financing sources. For example, IT elements will be funded. The final financing possibilities are not fully clarified yet.

WP 1 – Project coordination: o 1st interim report, technical progress report, financial report, payment request o Upcoming meetings **Barbara Brunmair,** , Children´s Cancer Research Institute (CCRI)	09:00-09:15

Since the first report is due until end of April 2015, Barbara Brunmair explains the reporting strategy:

- The associated partners have received templates and information on the first financial report which have to be filled in until 31.03.2015
- After the meeting, the WP-leaders will receive templates for the technical/scientific reporting to be filled in together with the partners involved in the WP until 31.03.2015

- In parallel, Barbara and Ruth will work on the general chapters of the reporting documents
- The templates for WP2 and WP3 will include additional dissemination and evaluation questions
- After the feedback from the partners Barbara and Ruth will merge the input from all partners into one document which will be sent out to all associated partners for approval at 17.04.2015.
- Pam Kearns will only be able to finalize her report on WP3, evaluation after the WP-leaders have provided their reports on the core WP
- Planned submission of the 1st interim report on 27.04.2015.

She briefly shows the financial cycle of ExPO-r-Net and where the project stands followed by a brief presentation of the templates on the financial and technical/scientific reporting.

Next, she announces the next biannual meeting which, according to plan, is supposed to take place in Lublin, Poland. Potential dates for this next meeting could be calendar week 37 (10.-11.09.2015) and Calendar week 38 (17.-18.09.2015). An overlap with the ECCO, SIOP, PANCARESURFUP and ERN meetings should be avoided.

See presentation ExPO-r-Net 3 WP 1-Brunmair.pdf

Discussion:

The audience preferred the first suggested date, 10.-11.09.2015 and made 2 suggestions:

1) To choose meeting locations which are as easily reachable as possible. Already Valencia and Padova were not easily reachable and Lublin only has a small airport with few direct connections as well. Warsaw, the next big airport is a 2h drive to Lublin. It is noted that meeting locations which are difficult to reach cost a lot of travel time, which might prevent people from coming.
2) To attach the ExPO-r-Net meeting to the upcoming ECCO meeting in Vienna (25.-29.09.2015) because it can be assumed that many ExPO-r-Net partners will attend the ECCO meeting and would therefore already be on site.

***Remark**: According to these suggestions the meeting venue for the 4th ExPO-r-Net biannual ExeCom meeting will be shifted to Vienna. A doodle was sent out to see if people prefer the 10.-11.09.2015 or the 29.-30.09.2015 (immediately after ECCO) as meeting date. Further planned meeting venues may also be reconsidered.*

WP2 - Project dissemination**:** o New dissemination tools and events o Intranet platform update (by AIT) **Olga Kozhaeva,** European Society for Paediatric Oncology SIOP Europe (SIOPE) **Günter Schreier**, Austrian Institute of Technology GmBH (AIT)	09:15-09:30

Dissemination:

Olga Kozhaeva presents the objectives of WP2 and starts with the consistent visual identity of the project.

She briefly informs about the progress of WP2 with promotional/distribution material (bookmark, flyer, roll-up banner) presented at several dissemination channels (conferences etc.) to the respective target audience. The project bulletin includes quarterly project eBlasts and features in the SIOPE newsletter. The target audience is also addressed via social media (twitter). Concerning broad external dissemination Olga shows the conferences where ExPO-r-Net was presented in the past and a plan where it should be present in the upcoming year:

- Rare Cancers: Exploiting the Potential of ERNs: 24 March (BE)
- CCI Meeting of European Member Groups: 8-10 May (SE)
- UK Childhood Cancer Conference 2015: 15 May (UK)
- Eurordis Membership Meeting: 29-30 May (ES)
- FLIMS Workshop: 20-26 June
- European Cancer Congress: 25-29 Sept. 2015 (AT)
- 2nd ERN Conference of the European Commission: TBC
- SIOP International Congress 2015: 8-11 Oct. (South Africa)
- ENCCA Closing Conference: Dec. 2015 (BE)

Finally, Olga presents the ExPO-r-Net website (www.ExPOrNet.eu), which was updated and filled with new content and a project intranet is currently under development (see below).

See presentation ExPO-r-Net 3 WP 2_Kozhaeva.pdf

Discussion:

Martin Schrappe asks who is mostly going to use the website, and how it will be promoted. Olga informs that a google analysis would be possible about the amount of users and that Enrique Terol kindly made it possible that the website was highlighted at the European Commission. The presentations from this meeting will be made available to the partners via Dropbox, later the intranet and some selected summary presentations will also be available in the extranet.

Intranet:

Günter Schreier explains that the intranet will be implemented based on Office 365 and will include tools for document management, a calendar and the contact list. The communication element will be Lync Online for web meetings. The intranet is almost finished and will be launched at the 20th March 2015. The reason for the early launch is the first interim report. It should already be possible to upload reporting documents until end of March. He demonstrates how the respective sections in the intranet are assembled and can be used by the individual partner. He also briefly repeats the structure of the intranet, which should be kept as simple as possible because of the limited budget available.

He informs that the intranet users will receive an email with the account details and a description how to sign in. The accounts to sign in to EXPO-r-Net Intranet will be like: firstname.lastname@expornet.eu

See presentation ExPO-r-Net 3 WP 2_Schreier Intranet.pdf

WP3 - Project evaluation: o Internal evaluation plan and external review by ICPRB o Questionnaire for ExPO-r-Net WP-leaders o Results on the migration of patients in paediatric oncology in Europe **Pam Kearns**, University of Birmingham (UOB)	09:30-09:45

The idea of this WP is to stay on target. In the first 12 month the project partners mostly elaborated on what they need to achieve. The real work starts from now on. The evaluation WP consists of an internal evaluation plan based on the quality assurance plan where the minutes, progress reports and documents from the WPs are reviewed as well as ongoing direct review by Pam Kearns via email, teleconferences. Furthermore, the ICPRB will also review and give feedback. So far, Pam reviewed and gave feedback to minutes and documents from WP4 and WP6. A specific feedback teleconference on WP4 and 6 was held on the 26th January 2015. Currently under review are the minutes from recent TCs on WP5, 7 and 8. From WP8 Pam also received the VRT-VTB project document which she is going to evaluate.

Further milestones of this WP are the determination of an external evaluation plan, which was anticipated for March 2015 but is delayed and expected to be available in May 2015. In December 2016 an external evaluation report on the ExPO-r-Net project should be available. Pam expects that in the following year the processes will start to be more formalized giving her more input to be reviewed.

Finally, Pam points out that ExPO-r-Net is not meant to solve every PO issue but the project should i) focus on the delivery of an EU accessible VTB platform and ii) focus on ERN for diseases/therapies where there is a need.

See presentation ExPO-r-Net 3 WP3_Kearns.pdf

Discussion:

Francois Doz asks if there is a medical economist in the project because it will be important to know about the costs for virtual tumour board advice and hourly personnel costs, how to be dealt with financial differences between countries. Of course it will cost less than cross-border treatment of paediatric patients but it will still be expensive. Pam explain that there will be advice from the Kings College but there is no specific medical economy package in the project. She agrees that ExPO-r-Net has to identify the costs for people´s time and infrastructure, which should not be too complicated.

However, it will be almost impossible to prove a health economic benefit. Nevertheless, soft data on advice and management will be collected and analysed. Martin Schrappe agrees that the health economic impact is hard to prove, however, it should be possible to show an impact on care. Dominique Valteau-

Couanet suggests asking if the patients have access to shared expertise between care providers inside the countries. Since some countries have 20% less survival than other it could be possible to see a change. Pam agrees but mentions that this would be a new project and is not in the scope of ExPO-r-Net. Ruth Ladenstein summarizes that the project partners have to first concentrate on what ExPO-r-Net has to be. It is much too early to show a difference in outcome, which takes 5-10 years. ExPO-r-Net should first provide the network and accessibility. Of course we hope that there will be a follow up with outcome measures but this is another project and should not be mixed.

Welcome and acknowledgement of ExPO-r-Net by Giorgio Perilongo, SIOP president	09:50-10:00
Coffee break	

Session 2a: Integrated Actions of WP 4, 6 & 8 to establish the ExPO-r-Net pilot reference network (PO-ERN)

Focus on the 3 Rare Tumors - Retinoblastoma, Hepatoblastoma, Wilms tumor; Common Principles

Chair: Ruth Ladenstein

10:30-13:00

WP 4- Needs and Challenges of cross boarder healthcare, Suggestions and guidance towards the pilot ERN in 2015 **Ruth Ladenstein**, Children´s Cancer Research Institute (CCRI)	10:30-10:45

Because of the tight schedule and the delay Ruth Ladenstein quickly explains the goals of session 2a. The scope of the project has to be clearly defined, streamlined and understood. ExPO-r-Net is basically a healthcare project, though with scientific aspects. It is about transferals for highly specialized interventions and is supported by the EU. It is not in the scope of the project to establish a European wide accreditation for each centre. Our next and central task is the building of a first ERN in 2015 with the help of the very rare tumour (VRT) groups, which can be enlarged later. For this reason we invited VRT collaborating partners to share their expertise about their VRT network. Since neither Kathy Prichard-Jones nor Norbert Graf could attend the ExPO-r-Net meeting, the Wilms Tumour group will be replaced by Gabriele Calaminus, who will present germ cell tumours.

WP 6- Defining criteria to identify PO expert centres Suggestions and guidance towards the pilot ERN in 2015 **Jerzy Kowalczyk**, Medical University of Lublin (MUL)	10:45-11:00

Jerzy Kowalczyk explains that together with Ruth Ladenstein and Pam Kearns it was decided to run a 2-way strategy:

- Top down identification of hubs of coordination on very rare tumours for a first pilot PO-ERN
- Together with NaPHOS identification of centres with standards of care in Eastern European (EE) countries which may interact in the future with hubs of coordination.

WP6 will mainly focus on strategy 2. The identified centres in EE countries should be able to do at least baseline healthcare with advice from virtual tumour boards. This would enable frontline treatment at place in national centres and the patients should only go abroad when they have specific needs.
Jerzy has discovered 16 EE countries who are involved in SIOPE activities, of those 11 are EU-members, and 5 future candidate members. This includes a total of 32.5 Mio children and adolescents with 4.700 new paediatric cancer patients per year. Jerzy also compared the health expenditures: In 2012 Western European countries spent more than $ 3.000,- per capita, in EE countries it is on average $ 500-2.000,-. Jerzy differentiated the EE countries depending on their annual health expenditure per capita with less than $ 1.000,- in Romania (EU-member), Belarus, Bosnia-Herzegovina, Ukraine and Macedonia. With the help of the NaPHOS Jerzy identified 90 centres in EE countries. Of those, he estimates that 35-38 could potentially fulfil the standards of care criteria and may cooperate with hubs of coordination. 25 centres are located in EE EU-member states. However, certain requirements have to be fulfilled to become a reference PO-units like qualified staff, links with other specialized units, professional multi-disciplinary care team (and back up team), inpatient, day ward and outpatient facilities, residential facilities for family, regular update of treatment protocol recommendations, monitoring of late outcome, psychological and palliative care, social support etc..
To ensure that the organization of the services and the spatial distribution of the necessary equipment in the respective centres are implemented in a manner that caters for high quality and in accordance with the European Standards of Care for Children with Cancer, Jerzy has prepared a self-assessment questionnaire. It consists of a qualitative and a quantitative part and will be evaluated by Pam Kearns and Ruth Ladenstein before distribution. However, any certification-process is not the responsibility of ExPO-r-Net. The questionnaire may be of help to certify centres, but this will be done on a national level.

See presentation ExPO-r-Net 3 WP6-Guidance-ERN_Kowalczyk.pdf

Discussion:

Ruth compliments Jerzy for his very important work to make EE centres visible. Since in the VRT-meeting the day before many EE centres with good standards were already introduced, she is sure that in each EE country at least one centre can be found, which is able to become a national hub of coordination including cross-border healthcare tasks. She also says that it is very important to find out which accreditation processes are already in place (Germany, France, UK..). They may be adopted in countries which do not have such systems yet. Ruth hopes that in the next meeting in 6 months we do already have back the first questionnaires, which enables better understanding of the EE landscape.
Martin Schrappe and Jerzy discuss the differences of the incidence of cancers per population between the EE countries. The numbers were annual data provided by the NaPHOS chairs. Martin also wants to know

how parent organisations are going to be involved and Jerzy points out that parent involvement is guaranteed via the glossary, which he presented already in the last meeting. Apostolis Pourtsidis wonders why Jerzy did not include countries like Albania and Jerzy explains that he only presented countries working together with SIOPE and the ECRC. Gianni Bisogno asks if site visits are planned. Ruth repeats that ExPO-r-Net is not going to certify but site visits could be taken into account. Martin suggests that SIOPE could be a regulatory body or, as it is done in Germany, health insurance companies.

Ruth reminds once more that Jerzy will only evaluate, the final accreditation/certification will be done by the EU/member states. Enrique agrees that the EU will be responsible for assessment and establishment of approvals including audits and so on. Jerzy´s questionnaire, however, will show what is already there and what is missing, which will help the authorities. Anita Kienesberger underlines the importance to involve parents. She gives as an example an insufficient survey in which parents were not involved, representing in part the wrong centres. The involvement of parents later gave a much broader and more detailed picture. Jerzy agrees and intends to additionally develop specific questions for parents.

Bruce Morland asks how it will be dealt with Western European countries. Jerzy comments that his major task is to improve the healthcare level in poorer countries. At least one standard of care centre per country should be available. It should have internationally approved treatment protocols and collaborate in clinical trials. For Western European countries a different (top down) approach will be needed. Bruce further asks how it will be dealt with patients going cross-border. Ruth explains that ExPO-r-Net will of course also address cross-border healthcare but this is a topic in another WP. Pam Kearns agrees that a minimum standard of care should be available and national accreditation systems should be put on board. She again emphasizes that ExPO-r-Net will not be able to solve all problems within the next 2 years and should not be distracted. She explains that Bruce´s questions were already discussed in several meetings before and it was decided to clearly separate the tasks i) identification of centres with standards of care in EE countries, ii) top-down identification of hubs of coordination (able to perform cross border healthcare and give cross border advice via virtual tumour boards) in Western European countries. Dominique Valteau-Couanet makes aware that some countries are very small with a very low number of patients, therefore the number of patients should be asked as well to avoid problems. David Walker suggests a careful naming of the centres, for example “ExPO-r-Net centres” instead of expert centres. This avoids confusion. The consortium is already well aware about potential sensitivities and the best naming will be carefully considered. Ruth repeats once more that the identification of centres with standards of care in EE countries and the identification of hubs of coordination in Western European countries is a two-fold process that should not be mixed. She also explains that it is not the intention of ExPO-r-Net to immediately identify hundreds of centres to apply for an ERN but instead first concentrate on VRT centres.

In parallel, a standard-of care model for EE countries will be developed by Jerzy which enables the patients to stay at home for treatment except for very specific needs.

*Remark: **TO DO**: gather information about already existing accreditation processes, which may be used for ExPO-r-Net/adopted by countries without certification processes.*

WP 8- Integrating children with very rare tumors in an ERN Practical aspects and suggestions considering the creation of a pilot ERN in 2015 based on the 3 Tumor Groups experience - **Retinoblastoma - François Doz,** Institute Curie, France - **Hepatoblastoma - Bruce Morland/Piotr Czauderna**, Birmingham Children´s Hospital, UK/ The Medical University of Gdansk, Poland - **Germ Cell Tumour – Gabriele Calaminus**, University Childrens Hopsital Münster, Germany	11:00-12:00

Gianni Bisogno briefly introduces the 3 very rare tumors, which will be presented in this meeting: retinoblastoma, hepatoblastoma and germ cell tumour. He differentiates between the identification of centres, which is done by ExPO-r-Net and the identification of networks, which is done by EXPeRT (European Cooperative Study Group for Paediatric Rare Tumours). Today´s session will discuss single tumours and should help elucidate if such a single-tumour model is suitable or other models have to be considered.

Retinoblastoma (RB).

Francois Doz presents the RB network. The international retinoblastoma group is no SIOPE tumour group because the children are first diagnosed by the ophthalmologist, who then consults the paediatric oncologist. So far, no prospective international studies with this tumour are available, but guidelines for imaging RB as well pathology guidelines are available and the survival is very good. Francois identified the following areas of special needs: i) staging, ii) grouping, iii) histopathological risk criteria/MRD, iv) conservative treatment, v) extra-ocular disease and vi) secondary cancer. He explains that concerning extra-ocular disease there is a difference in outcome between low income countries where children die because of this and high income countries. In general, in case of RB high emphasis is put on preserving the eye. However, the first task is to preserve life and second the eye. Francois presents a flow chart about conservative treatment approaches in RB. To avoid extra-ocular spreading, the therapy techniques used like interstitial radiation therapy and intra-arterial chemotherapy need highly specialized expert experience and are not available in every centre. In case of RB all pre-existing hubs of expertise and their current role within the tumour group are very well known. A survey on RB illustrated that from 22 centres only a minority have significant patient numbers Centres in small countries or where more than one or two centers are available would have <10 cases/year. Large centres tend to concentrate academic production. Many practices are done at different institutions and only few centres have significant

experience in intra-arterial chemotherapy. In many areas of EE countries there is a lack of data and cooperative protocols are needed to generate valid data. To tackle the problems the EURbG was founded with the general objective to to improve the medical care received by patients with RB and their families by fostering the cooperation among highly specialized centres and the community by means of the creation of a network (EURbG) connecting professionals from multiple specialties, affected families, parental associations and institutions for treatment and support. Francois could identify the following RB hubs of coordination and their current role:

- Conservative therapy (Lausanne)
- Non-conservative therapy (Paris)
- Late effects (Amsterdam)
- Mutation diagnosis and biobanking (Essen)
- Parental groups (Paris, Berlin, UK)
- Web resources and communication (UK)
- Outreach (Brno-Istanbul)
- Coordination (Barcelona)

EURbG is currently working on the inclusion of parent groups and invitation of other groups and develops a draft protocol for salvage conservative therapy. It also intended to update the staging system and to develop a protocol using neoadjuvant CT before enucleation in case of initial ON involvement on imaging (or buphthalmia). MRD is also considered as well as second malignancies screening.

Francois finally summarizes that in case of RB there are referring centres available for highly specialized conservative treatments i) brachytherapy, ii) intra-arterial chemotherapy and iii) intra-vitreous chemotherapy offering cross border advice. A tumour board is established for initial therapeutic decision using image transmission (RETCAM, US/OCT, MRI) and selective indication for referring patients in highly specialized centres. However, children with RB do travel across countries but, currently, without a structured network. This will need the inclusion of parent organizations. The expected special challenge will be the harmonization of processes: evaluation, grouping, staging, treatments and the network for referral: indications, pathway. In short, the RB group is in principal ready for a European collaboration as foreseen in ExPO-r-Net. He hopes that ExPO-r-Net will help to structure and organize such collaboration and also clarifies the issue of additional costs for tumour boards.

See presentation ExPO-r-Net 3 Retinoblastoma_Doz.pdf

Discussion:

Ruth Ladenstein is very positive that the very advanced RB group could be an easily implementable example network for ExPO-r-Net. ExPO-r-Net can make the group more visible and may help

parents/patients finding their way to the specific group. Pam Kearns agrees that they have already a very good starting point and asks Francois if they would be willing to work as pilots including the investments that need to be taken to establish a virtual tumour board. She asks Francois, if he would be able to calculate the costs. Francois thinks that it would be mainly time and IT. Such a cost calculation should be shown to the European Commission.

Gianni Bisogno makes aware that RB has a different history compared with other diseases. Therefore his model might not fit for others tumour types. For examples, Gianni cannot provide such a concentration of patients in selected centres, instead they only have 1-2 centres in some countries. Ruth agrees that for specific entities there are specific ways of functioning which can differ completely. This includes a variation in cost models. Francois says that in case of RB they distinguish between the two concepts localized treatment and, more prominently, conservative approach. In bone tumours and liver tumours localized treatment is much more important for the success of the treatment. In case of RB the final goal is to avoid death at all, however, some children still die because it is tried to save the eye. This needs rethinking. David Walker informs that brain tumours are tightly linked to the surgeons and their opinion/decisions (which are not always made based on objective criteria but on personal judgement).

*Remark: **TO DO**: Calculate the costs to establish and maintain a tumour specific virtual tumour board. Aim to establish a RB-ERN. Formally tell September 2015*

Hepatoblastoma (HB).

Bruce Morland presents SIOPEL. Reflecting on the presentation of Francois Doz, there are many similarities. They also have established a network of liver tumours but in case of HB special expert experience is needed from the surgeons, whereas chemotherapy is standard. SIOPEL as an expert reference group on liver tumours is not restricted to Europe but a global network (probably the only one). It consists of 211 corresponding members from all over the world and has developed therapy guidelines and a web based consultation platform developed by CINECA. This platform is monitored by a moderator who summarizes the discussion and is responsible for the feedback, a drop-down menu and the possibility to upload images.

Piotr Czauderna then presents the flexible virtual consultation platform in detail: a consortium was founded (Children´s Hepatic Tumour International Consortium, CHIC) to build an international dataset for HB based on the data selected by SIOPEL from several multicentre trials with a total of 1.605 patients. He introduces the consultation systems which consists of several functionalities (interface for the administrator, conference call feature, email alerting system, diagnostic image web-viewer for pathology and radiology images and a storage system = database). The images are currently pre-uploaded in an

anonymized form and the experts can either download it and watch it locally or view it directly on the web. The requesting clinician will get an advice (conclusion of the web discussion) from the moderator, as soon as the full procedure is run through (after 1 week). Currently, the system has 2 moderators and 4 expert panels. All panellists (surgery, oncology, pathology and radiology) are appointed by major liver study groups. The following disclaimers have to be accepted to use the system:

- Clinician must actively attest to patient being ineligible for existing cooperative group trial
- Clinician must actively attest to having obtained consent / assent from patient / guardians
- Clinician must acknowledge that opinion does not constitute a formal consultation prior to receiving case review and that ultimate responsibility remains with treating clinician

Piotr finally presents a typical case flow over 1 week. He thinks that the system represents global experience and can be very useful.

Bruce concludes with a detailed presentation of the next trial (PHITT, Paediatric Hepatic International Tumour Trial) and expected challenges for SIOPEL, as there are:

- Patients need to be expertly assigned to correct risk groups (PRETEXT assignment is not always easy, tumour extension/vascular involvement often lacks consensus even among “experts”, real time radiological review)
- Surgical expertise within most centres is limited (is there ever such a thing as a “simple” liver resection?, should all liver surgery be centralised?, transplant referral needs to happen at diagnosis for all high risk cases, transplant availability across Europe is patchy)
- Chemotherapy for HB/HCC is not a major challenge (chemoembolisation)
- Other issues (management of relapse, experimental therapies)

The “low hanging fruits” would be the use of the consultation platform, the available surgical expertise (a questionnaire clarifying access to transplantation, plans for centralization will be finalized in the next SIOPEL meeting in April 2015), to make use of the PHITT trial and to define patients benefiting from cross border referral.

Bruce assumes that a virtual consultation system addresses most issues relating to rare tumours and has advantages over a “simple” tumour board. He agrees that for some tumours there will be a need to identify centres which are able to accept cross border referrals but he wonders i) how these are going to be selected, ii) how to ensure standards are excellent and maintained, iii) how clinicians are persuaded to refer, iv) how travel will be facilitated for the families and v) who is going to pay for this. He finishes with the announcement not to reinvent the wheel but include already available examples.

See presentation ExPO-r-Net 3 Hepatoblastoma_Morland_Czauderna.pdf

Discussion:

Anita Kienseberger informs that in HB parents were not yet involved which made differences with FB visible. She and Francois Doz suggest involving parents also in HB, which is agreed by Bruce. Dominik Schneider asks if a specific software is needed to use the CINECA consultation tool and Piotr explains that you need a laptop, a regular web browser and for large files the big-file software, nothing else. Regarding costs Marisa de Rosa explains that the CINECA consultation tool so far is financed by ENCCA, the future maintenance costs will depend on the number of imaging and other factors.

Germ Cell Tumour (GCT).

Gabriele Calaminus explains that in case of GCT the first telepathological conference took place in 2009. To improve pathological diagnosis the clinicians had to work together and to overcome long distances (in particular in Russia) they communicated via teleconference. At that time the equipment was very simple. All that was needed was a stable connection, the exchange of ppt-slides, a microscope, a videocamera and a headset. The cases are prepared in advance and the pathologist shows the slides. Only those cases are discussed which are questionable. During the discussion all information is already available. In general in GCT there is a very close cooperation with many patients per year and referral centres. When cases are discussed (skype conference with fixed documentation structure) there is always a protocol which is distributed to the participants and stored on a database. The teleconference always has to conclude with a consensus. In addition, the GCT-group has a weekly based clinical advice system. Now the system can already be used to create evidence. There were 680 consultations including multiple conferences on one case and 220 Russian hospitals are registered. According to an analysis GBT has now an overall survival (OS) of 65%. Before there was very little information and an OS of less than 20%. The system was expanded for training and now it also includes national workshops. Gabriele is sure that the founding of virtual tumour boards will help in particular countries with large geographical dimensions.

See presentation ExPO-r-Net 3 GermCellTumour_Calaminus.pdf

Discussion:

Before the specific discussion starts Ruth Ladenstein announces that there are two perspectives:

- The consultation platform scenario and
- The healthcare scenario

Both scenarios serve different tasks and should not be mixed. We have to be very clear in this. She asks Gabriele if she could name coordinating centres for ExPO-r-Net which Gabriele agrees.

Gianni Bisogno wonders if, by using a simple teleconferencing tool, there could be a danger to be overflown with questions. Gabriele explains that this could indeed happen at the beginning of the establishment of such a tool, but very soon the complicated cases will assert themselves and only those will be discussed.

Latest news from Enrique Terol (DG SANCO), update on ERN-related European activities and **ERN IT platform by Markus Kalliola** (DG SANCO) **Common discussion** building the first PO-ERN and practical steps ahead	12:00-13:00

Enrique Terol is pleased that with the three tumour examples presented before he got a good view of the different perspectives. He informs that the commission will help to learn from the experiences by approaching the consortium with questions. Since the structure and scope of an ERN was already explained by Ruth, he does not go again into detail on that. He informs that there were 2 legal acts on ERN (Commission delegated decision and Commission implementing decision, both in March 2014). These decisions build the legal basis for the European Union healthcare approach. Now the system has to be built with the help of pilot networks. He informs that the following activities are currently ongoing:

- ✓ Board of Member States
- ✓ Assessment manual and toolbox
- ✓ Assessment bodies
- ✓ ERN service study
- ✓ ERN IT platform (described below)
- ✓ ERN Conference 2015
- ✓ Awareness activities
- ✓ Other players and areas of expertise
- ✓ Preparatory steps: priorities for the Networks

He also points out that the member states (Board of members) will have a key role in the process, therefore the centres have to be recognized on the national level. He recommends working closely with the individual member states (talking with national authorities) because they have the capacity to endorse ERN-applicants. Enrique will provide the respective contacts.

The call for networks will be launched in December 2015 with the deadline in March 2016. After application there will be an eligibility check. If approved there will be a technical assessment. The respective criteria will be transformed to operational criteria (accreditation). The EU will name the centres of expertise who have to be members of the network. If the assessment is positive, the logo will be awarded.

The assessment manual and toolbox was decided in December 2014, the contractors were Consortium Accreditation Canada; EURORDYS; HOPE. There are several key deliverables for the assessment manual (see presentation) which will be also provided by Enrique in detail. There are 6 sets of Criteria for Networks, 5 sets of general criteria for members and 2 sets of specific criteria for members to be evaluated via self-assessment. The EC will provide a tool for the assessment of 6 sets of Criteria for

Networks, however, Enrique recommends to start immediately, if own tools are already available because the availability of EC-tool could be delayed. The specific criteria for members are heavily discussed in the ExPO-r-Net consortium. The set of specific criteria and conditions may vary depending on the scope of the concrete area of expertise. Enrique explains that for specific criteria ExPO-r-Net has to provide the organisation and functioning, the EC will check, if the ExPO-r-Net criteria are credible and useful. Therefore the criteria should be based on evidence, consensus or similar. If there is no basis for a specific criterion available, it has at to be at least discussed/jsutified. ExPO-r-Net has to develop a bottom up proposal. He informs that UK, Denmark, Portugal and France already have systems in place. In Spain they are currently setting up the criteria.

Selected assessment bodies will check if the application is well done (call for assessment bodies in April 2015, it is intended to identify 10-12 experienced agencies like HIS in France).

Other upcoming actions are the ERN services study (tender in December 2014) and the development of an ERN IT platform, which will be presented by the colleague of Enrique, Markus Kalliola.

Markus defines that tumour Boards are recognized as an essential component of excellence in cancer care and complex diseases. They bring together a range of medical disciplines for discussions on how to best care for the patient. Using eHealth & telemedicine technology, teams of specialists of the Members of the future NETWORKS across the EU would meet in videoconferences called "Virtual Clinical or Tumour Boards" to share medical information and agree on treatment options. The ERN IT platform will consist of several building blocks (see presentation): i) public ERN web, ii) DG SANTE web and iii) call and assessment of ERN website. A secure IT ERN platform will provide a shared intranet for all ERNs and a specific intranet for each ERN. Broadband communication should enable the exchange of clinical information and patient data. It should also contain clinical decision making tools, communication and conferencing tools, an information system, training and e-learning tools as well as research tools. At the Moment, Markus and others are working on the communication and conferencing tool. He learned in this meeting, that ExPO-r-Net has very specific needs. It may therefore be that the EC tool might not be compatible for all but to add value they provide something which can be used by as many as possible. It is planned to ask the members of pilot networks to participate in the development, give feedback and interact with the EC.

At this point, Enrique takes over again and announces the Second Conference ERN in Lisbon 8-9 October 2015. Approximately 400 participants are expected including the commissioner and the ministers of health from Portugal and Luxembourg. It will contain a plenary season (lesson learned from the pilot experiences), a workshop (setting a network) and a showroom with space for informational material and small stand for ExPO-r-Net.

Enrique finishes with a list of “homework” (preparatory and strategic activities) for ExPO-r-Net:

- ✓ Strengthening your network
  - o Identification of possible Members
  - o Self assessment exercise (Network and members): decision of participation as members or as Associated National Centres
  - o Business/organisational model
- ✓ Liaise with your MS authorities (contact with your ERN board representative and discuss)
- ✓ Define your services – concepts (participate ERN service study)
- ✓ Fine tuning of your IT needs and how to accomplish the IT/communication criteria. (cooperate with the ERN IT platform)
- ✓ Agree on the specific pediatric rare cancer criteria (not general accreditation model)
- ✓ Define Pathways models, referral criteria, clinical decision tools
- ✓ Information system/indicators
- ✓ Discuss with other players from adult rare cancers, the rare disease community and others

The timeline for the call for networks proposals will be:

- Preparatory conference; Lisbon September-October 2015 : workshops and practical information, space for encounters
- Call: December 2015
- Assessment of proposals March -May 2016.
- Approval of + proposals by Board of MS June – July 2016

See presentation ExPO-r-Net 3 ERN activities_Terol_Kalliola.pdf

Discussion:

Bruce Morland wants to know the benefit in terms of financing when becoming an ERN. Enrique answers that the legislators did not include financing in the first instance and are now struggling to find money. However, the assessment process will be financed as well as the IT platform, which will be free of charge for the networks. They have money to fund pilot projects from approved networks and in Horizon 2020 there will be specific network calls. He is also confident that additional money will be raised for network infrastructure and eHealth. To get money and distribute it to the networks the support of the member states is needed. The idea was proposed to them last year and was positively recognized, the final decision will be made in mid-2016.

Gianni Bisogno asks if the number of networks has to be limited since different tumour groups have very different networks and numbers of centres. What if there are 30 centres in one country but only 1-2 are in an ERN, as representatives of the others. Enrique explains that there are no specific rules yet. As a minimum there should be at least 10 centres from 8 different member states. There should be capacity

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and balance. It is up to the network to define how it can be done. Enrique understands that paediatric oncology has different networks with different tools but the final goal is to establish one paediatric oncology European reference network (PO-ERN). It is also not necessary to have a physical centre but it can be a consortium. This is, for example, already the case in the Netherlands, where small centres build one consortium. This could be a solution for small countries. Ruth Ladenstein and Francois Doz discuss RB. There are 22 centres, but not all are special care points.

Even if it is not immediately connected with financing, Ruth highly recommends applying for an ERN because of the expected later benefits and the accreditation process is for free. She also wonders if and how the EC would finance communication tools like the presented consultation platform. Would the EC finance the database, legal background etc.? So far it is not fully clear how to cooperate and benefit best.

Martin Schrappe mentions that they are currently defining cancer via molecular genetics, which will be highly relevant in the future for personalized medicine. Will this be taken into account?

Enrique answers that as Ruth already mentioned the EC is now in the process of development and definition. It is still under discussion in which way to support best, therefore the EC needs help and feedback from the networks. If you can already provide clear ideas they can be taken into consideration.

Concerning prevalence and incidence: we understand that old fashioned criteria are not feasible for rare diseases but we need low prevalence, therefore incidence has to be discussed. Martin Schrappe agrees and mentions that due to molecular genetics there are now subgroups in Leukaemia which were not known before and can be considered rare diseases.

Bruce Morland says that paediatric oncology has a small number of key opinion leaders with networks below for the respective diseases. Gianni agrees with Bruce that a strategic decisions should be made how the future ERN should be built. Should there be a leading group involving all diseases, should there be networks for each disease, or should it be a network of coordinating centres independent of disease and opinion leaders? This would reduce the number of centres in Europe to 10-15 with the smaller centres as cooperation partners.

Enrique answers that whatever is feasible should be done. ExPO-r-Net should present a mature model which is to the liking of the authorities and for which they want to pay. Each year there can be a call for members, where new members can be added. It is up to ExPO-r-Net how it can be done. He thinks that a bottom up process might be too difficult in the moment and recommends working top down. The national authorities may not want all centres included and would only endorse hubs of coordination.

After the discussion, Ruth announces that due to the delay the WP progress reports will be postponed after lunch and will be kept as short as possible.

Lunch

After the lunch break, the group picture was taken in front of the Caffé Pedrocchi.

Session 3, Core Work Packages ***Chair Ruth Ladenstein*** 14:00-16:30	
WP 4- Last period short progress report **Ruth Ladenstein**, Children´s Cancer Research Institute	14:20-14:30
Ruth very briefly informs that her questionnaire was analysed in detail and there will be a differentiation in i) frontline setting and ii) relapse setting. The results from the questionnaire will help to develop roadmap of European hubs of coordination and expertise within the study groups who are eligible to treat highly complex high-risk cases in a cross-border healthcare setting and can function as tumour boards for national and/or cross border advice. ***See presentation ExPO-r-Net 3 WP4_Ladenstein.pdf***	
WP 5- PO tumour board ERN based on eHealth concepts, progress update and action points o Results on the European questionnaire on the prerequisites and technical aspects of a tumour board o First structures for the definition of SOPs and roadmaps on tumour boards o Update on cooperation with ITH icoserve, platforms, server capacities o IHE profiles to be integrated in the ICT architecture of ExPO-r-Net **Adela Canyete & Günter Schreier,** Fundacion Para La Investigacion del Hospital Universitario la Fe de la Communidad Valencia & Austrian Institute of Technology	14:30-15:30
Adela Cañete informs that deliverable 1 of WP5 is a report identifying European Tumour Boards (TB) of ECTGs providing ICT logistics within 24 months. For this currently functioning TB in Europe and abroad are identified with the help of a questionnaire (clinical and IT elements). The last task would then be to define Standard Operating Procedures (SOPs) and a TB-roadmap to be implemented in ExPO-r-NeT as soon as IT-eHealth is ready. The questionnaire should evaluate current existing TB (SWOT ANALYSIS). It was already sent to Spanish centres as extensively discussed in the last ExPO-r-Net meeting in Valenica and was already sent/will be sent to the clinical trial groups (CTG) for RB, HB and VRT. The answers from Gianni Bisogno (TREP), Dominik Schneider (STEP) and Daniel Orbach (FRACTURE) were already analysed: - VRT: 3 countries answered because there is no formal ECTG yet. - Retinoblastoma: network, not a ECTG yet. - SIOPEL: does not coordinate referrals and has a web-based consultation platform as presented earlier today. Mostly the clinicians contact the experts by email and there is no formal SOP for consultations, therefore it was not possible to evaluate the workload yet. Adela points out that 80% of the consultations are done on a national level (pilot the SOPs in different scenarios). For example Valenica has everything necessary to run the network. When Valencia is asked for a consultation, the expert panel will get a summary of the	

request which will be staged and included in the system together with the images. Then the experts review the case and afterwards a conference call is initiated. The requesting centre presents the case and it is discussed in real time. Finally, the expert panel makes a recommendation. It can already be seen as a kind of a cross border setting since Spain has several different counties. The whole process started in October 2014 and since then they had several consultations. So far, it was very satisfactory for all parts (clinical solving and educative for everybody including young doctors attending) but some issues are difficult to organize:

- Firewalls
- need to have an IT-person available in both places,
- weekly Adobe connect updates,
- lack of "familiarity" and "confidence " of medical community with IT-systems= need of education
- data confidentiality, IC (not specifically done but the family was informed about the TB)

The following issues have to be clarified for 20% consultations on an European level (pilot SOPs in different scenarios):

- CTG centre: La Fe. We are preparing SOPs for second consultations within the group.
- IT-Partner: AIT.
- Well-established web: SIOPEN-r-net where clinical and biological data is uploaded. An improvement of the existing imaging uploading system is currently under development.
- SIOPEN sub committees' expertise.
- Will we need to study the compensation/cost?
- Who is responsible? Institution? The sponsor? SIOPEN?

Adela therefore proposes to complete the questionnaire for national groups and CTG:

- Modify the questionnaire with suggestions (i.e. cost calculation).
- Expand to other groups with SIOPE help.
- Describe how the different groups are (or aren´t) organized for 2nd consultations. Retrospective vs prospective evaluation (VRT initiative would be excellent).
- To know the current situation of institutional-based TB in paediatric oncology (PO) in Europe.
- Set up the "standards for institutional TB " in PO (link with WP 4).

Finally Adela informs that she had a videoconference on ExPO-r-Net with the Spanish ministry of health. She summarizes that there are a lot of efforts and work on second consultations that are not visible for policy makers and consumers. We need to structure cross border 2nd consultations in order to increase our visibility, facilitate our tasks as hubs of coordination and therefore impact on improving our way of

delivering excellent multidisciplinary cross-border care in parallel to excellent national care (SOPs).

See presentation ExPO-r-Net 3 WP5_Canete.pdf

Günter Schreier presents the work of AIT in ExPO-r-Net, which is basically involved in 3 WP, namely WP2 (dissemination), where AIT has taken over responsibility for the intranet as described earlier, WP4 and WP5. In WP4 AIT needs to develop a clear idea of the core requirements/processes/use cases of European Reference Networks in general and ExPO-r-Net in particular.

The core requirements/processes could be:

- Administrative
  - a new centre applies for membership (WP6)
  - …
- Patient related
  - Schedule a virtual tumour board to decide on the treatment (WP5)
  - Create, retrieve, amend … a survivorship passport document (WP7)
  - …
- Science related
  - A registry study for very rate tumours opens for recruitment (WP8)
  - …

For WP5 AIT develops the interoperability architecture. The initial ideas were presented in a teleconference with the EC on European Reference Networks IT aspects in October 2014. AIT liaised with IHE Europe and ITH icoserve. The next steps will be to enhance the partnership with ITH, liaise with the Austrian Ministry of Health (Dr. Auer, eHealth Network chair person), refine solution architecture, add elements to manage ERNs and link to research. Beyond designing the solution architecture for ExPO-r-Net the goal would be a productive ERN ICT platform for PO ERN and a generalised ERN reference architecture (needs further funding).

See presentation ExPO-r-Net 3 WP5_Schreier.pdf

Günter then introduces his colleague Michael Nitzlnader who later presents a generalized, standardized interoperable solution architecture to be potentially used by the ExPO-r-Net, based on IHE Interoperability.

Günter introduces and clarifies the different terms. Sending images and case consultations alone are not a defined standard clinical tumour board. He also thanks Enrique that the EC offered cooperation to find a common solution. It is important for ExPO-r-Net to be interoperable, since in a healthcare setting the institutional ICT systems should be able to be linked. This has to be done institution wide. The regulatory aspects have to be taken into account as well. What IHE basically does, is to select standards in order to

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facilitate interoperability for particular use cases, called “Integration Profiles” in IHE terms. The vision for eHealth in the EU interoperability framework consists of several levels, where IHE undoubtedly provides the ground technical level. Basically, there are 2 possibilities to facilitate IT system communication: i) integration via a mediator, ii) standard interface solutions. For ExPO-r-Net the latter is the only sustainable solution. IHE already provides specific profiles, which are very important for ExPO-r-Net. IHE profiles are defined by a dialogue of users (clinicians) and IT developers (vendors). Günter emphasizes that the IHE concept is somehow like LEGO, you choose the elements (IHE Profiles) that you need and build the house (application) you finally want. For example the XDS profile was developed for Cross-Enterprise Document Sharing, but there are also others that very good address the needs of ExPO-r-Net.

Günter hands over to Michael who points out that the hospitals need to be interfaced with the TB tool, i.e. the so called “consumer systems” should also be interfaced using IHE profiles. He explains in detail the already developed “Cross-Enterprise Tumour Board Workflow Definition (XTB-WD)” profile, which was specifically designed for the typical clinical workflow involved in organising, preparing, conducting and managing TBs. First a request has to be sent with basic information including documents/images. The request is assigned to a specific TB. Then the TB is prepared, experts review the case in advance (this is the case consultation phase of the TB). This is followed by the process of holding the meeting (audio and videoconferencing) and a final conclusion for the ongoing treatment. The workflow is defined and all documents are securely stored.

This is the state of the art method on how it can be done based on IHE interoperability.

Michael presents screen shots of a fully web-based application currently developed by ITH icoserve which is based on the IHE XTB-WD profile. He shows what the user interface looks like and how a case is initiated in the system. The IHE based tumour board approach is based on ITH icoserve’s IHE core system which is already used in many European countries.

Günter takes over again and informs that the source of documents can be electronic health record documents or directly from the hospital. All kinds of documents can be used. He repeats that first and foremost ExPO-r-Net needs solutions for a healthcare approach, nevertheless, there will also be a secondary use for research based on the ENCCA model (research concept IHE repository and registry, EUPID and research). He finally clarifies that ERNs will need a tailored ICT architecture, infrastructure and interoperability strategy. For this reason AIT came up with the proposed architecture including a solution for clinical conferences, which is the general term for Tumour Boards. This is important from the perspective that other ERNs, not dealing with tumours, will also need such systems. The whole IT system can be linked to existing tools which are already available, in case they provide some basic IHE interoperability.

Discussion:

Bruce Morland wonders why not using already existing systems like the CINECA system instead of "reinventing the wheel". Günter replies that according to Adela for virtual tumour boards there are a lot of such tools available which have several flaws. AIT's task in the project clearly is to come up with a solution architecture that is fully fit for healthcare (not a research tool for a single defined disease community) and must be based on interoperability. This was the reason why AIT introduced the standardized clinical conferences tool from ITH. Bruce makes also aware that the IHE based system might be expensive compared with other tools. Günter agrees that money is an issue. Healthcare IT systems do cost money, but these are the solutions Enrique is looking for to provide IT tools across diseases, indications and in particular also outside the PO world.

However, according to his assessment, only IHE based solutions will have a realistic chance to get funded by the CEF (Connecting Europe Facility) which Enrique mentioned in his presentation on the EC's approach to ERN IT infrastructures.

Piotr Czauderna has the opinion that the IHE virtual tumour board tool is only a more sophisticated version of the regular teleconferencing tool, while the CINECA case consultation system is something different, based on a different philosophy. He also makes aware that national languages are an issue in case on the IHE virtual tumour board, because the system cannot automatically draw the data from patients' electronic health records, if they are issued in a different language. This requires manual translation of patient´s data in case of transnational tumour boards, which is a sort of limitation. He also says that a tumour board and a case consultation system are two different approaches. The SIOPEL preferred case consultation system due to the involvement of a large number of specialists representing several institutions and various time zones.

Since time is tight, Ruth interrupts the discussion and summarizes that, depending on the different scenarios, different systems like the CINECA system can be used within the PO-communities and one does not exclude the other. She summarizes that what Günter presented today was a suggestion for an interoperable IT solution for healthcare that can be a basis for ERNs in Europe. It is not intended to question the CINECA system but there should also be other solutions which are ready to work with European structures.

Bruce thinks that everything can also be done by CINECA and wonders if ExPO-r-Net will choose one of the suggested solutions to be proposed to the EC. Ruth informs that decisions are not made yet.

Interoperability will be a key for the future and the system presented by Günter is interoperable. Then there is the CINECA system, which is more disease tailored, since it allows for automated data capture using electronic Case Report Forms (eCRFs) and registry creation from consulted patients, and finally we

have Adobe Connect for advisory functions. In the end the commission will propose one solution which you may use or you can keep a system that you are already working with. Günter reiterates that AIT´s responsibility in ExPO-r-Net is to suggest interoperable IT solutions. Markus Kalliola interjects that when ExPO-r-Net is going to propose something it is important to know how many hospitals are ready to use such a solution and how many hospitals are IHE compatible. Günter repeats that the IHE system is a general clinical conferences system, which is not restricted to oncology. He also informs that to get funding for IT we need to get member states on board. For Expo-r-Net that means Ruth needs to talk to Dr. Auer, who usually points out very clearly the importance of interoperability.

In this context Marisa de Rosa informs that the CINECA consultation system, though specifically developed for liver tumour, is fully standardized and applicable for any other disease. Eugenia adds that the IHE Cross-enterprise Tumor Board Workflow Definition (XTB-WD) has been integrated into the CINECA system.

WP 7- Cross border dimension of long term follow up, progress update and action points o Translation of the survivorship passport and guidelines o Identification of experts for virtual late effects centers o Joint activities with other stakeholders **Lars Hjort and Riccardo Haupt,** Lund University & Istituto Giannina Gaslini	15:30-16:00

Lars Hjort informs briefly about the background of WP7:

- Continuing work done and on-going in current FP7 projects ENCCA and PanCareSurFup as well as in the International Guidelines Harmonisation Group (IGHG)
- Providing first-hand survivor and parent input in the work through Partner #18 ÖKKH with Anita Kienesberger et al.
- Maintaining the on-going work with CINECA (Partner #11)
- Utilizing the PanCare Network and SIOP-Europe (Partner #2) and their partnerships

The objectives are to build a virtual paediatric oncology expert reference network for late effects after treatment for cancer in childhood and adolescence and to translate the survivorship passport (SP) and relevant Guidelines into multiple European languages. The translation of the SP and its Guidelines has already started and they have begun to identify experts for the virtual late effects centre. The following things need to be discussed and clarified:

- Identification of experts, methodology could be shared with WP6, 8 and possibly 5.

At what level is an expert opinion needed, i) by hospital/region/country/international, ii) by rarity of the event, or iii) by severity of the event?

- Using the correct term, e. g. centres of consultation may be less provocative than “expert

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centres"

- Translations: i) priority list of languages, big vs. less common, ii) selection of partners to work with (networks, patient organizations, United Nations Volunteers)

Riccardo Haupt takes over with the objectives of WP7 (translate the SP into European languages, provide homogeneous layout and define IT solution for data storage and transfer). He briefly presents the SP structure and guidelines. Currently they have identified volunteers for translations from several countries but are still looking for more, for example in radiotherapy fields. The layout is developed together with SIOPE, who also prepared brochures and flyer for late effects based on former examples like breast cancer surveillance recommendations.

Furthermore, they developed a strategy how the virtual late effects centre can be deployed:

The SaaS model (Software-as-a-Service), which is presented by Marisa de Rosa from CINECA, allows the SP to be a cloud application available across countries/hospitals by any device in internet through secure protocol and user profile. Different databases from each country are put together in a global database, followed by a passport generator for the different countries. The advantages of the SaaS model are: i) centralized platform for cross-border availability, ii) real time data availability (24h worldwide), iii) sharing procedures and information, iv) data standardization, v) sustainability (no local IT infrastructure costs for hardware, maintenance and software upgrade) and vi) quality and security certifications provided by the hosting data centre. The model also allows a daily data transfer to and from the central database to and from a local site (database mirroring, 2 copies, local and central), in detail, historical data could be imported from a local database to the central database and by data mirroring the central database from the SP exports the data back to the local database. Riccardo explains that with this model a country personalized SP application can be developed and installed into a local IT infrastructure and share all or a subset of the data via cloud for across countries/hospitals.

See presentation ExPO-r-Net 3 WP7_Hjort_Haupt.pdf

Discussion:

Ruth Ladenstein informs that the SP is included in the Austrian Cancer Plan and it is important to clarify how it can be nourished with data from clinical trials. Martin Schrappe wants to know how the data from hospitals are fed into the SP since hospitals use different systems. Marisa explains that this is currently under development. With data mapping it will be checked which information needed for the passport is already available and can be translated. After data standardisation a new database will be created. From this standardized database information can be transferred into any form. The difficult parts will be data mapping and standardisation. Riccardo informs that the system is currently tested in La Fe hospital Valencia together with Adela Cañete. As was shown in the presentation the data needed for the SP are

marked in green and transferred to the SP.

Gianni Bisogno says that this is a huge database with very ambitious goals and it is likely that a dedicated person per hospital has to work at least 1h per patient on that. He recommends also cooperating with the tumour groups who have information available ready to be used for the SP. Riccardo explains that collecting data from clinical trials is too complicated and the SP should already be available as soon as a patient enters a trial. He thinks that going through the clinical record would be the best way and estimates that it would take about 1 week and 1 IT expert per hospital for data mapping. As soon as the SP is brought out, consent is needed. If data are collected from clinical trials they could go automatically to the passport. Lars finalizes by pointing out that ExPO-r-Net as well as ENCCA are pilots therefore we create prototypes that might not necessarily be perfect but it is the intention to make them a s good as possible.

WP 6- Last period short progress report **Jerzy Kowalczyk**, Medical University of Lublin	16:00-16:15

Jerzy Kowalzyk informs that some of the tasks of WP6 have already been discussed in the morning. One milestone which was not presented in detail is the definition of terminology used for the certification process (Glossary), which was developed until December 2014. It was sent to Pam Kearns for evaluation and will be distributed to the partners afterwards. The lesson learned was that several terms have different meanings in different countries and they were merged to produce the clearest possible picture. The glossary can also be used for other SIOPE activities. It is displayed on a website and can be looked at by all interested ExPO-r-Net partners. So far there are 106 terms and definitions, new terms can be added whenever needed. Also a document was developed about the definition of terminology used for the certification process, which is currently under evaluation by Pam. Jerzy hopes that until the end of March the self-assessment questionnaire for Eastern European countries will be ready for distribution and at the end of June it could be given to the NaPHOS to select centres which are eligible.

See presentation ExPO-r-Net 3 WP6_Kowalczyk.pdf

Summary and closing remarks, by Ruth Ladenstein, Children´s Cancer Research Institute (CCRI)	16:15-16:30
End of Meeting	