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Minutes ExPO-r-Net Kick-off Meeting

Date: 21 March 2014
Venue: EUROFORUM room 001,
10, rue Robert Stumper, L-2557 Luxembourg

Session 1 WELCOME AND INTRODUCTION TO THE PROJECT

9:00-10:10
Chair: Gilles Vassal

Welcome by the SIOPE president, Gilles Vassal, SIOP Europe **Welcome by the coordinator** with agenda presentation and objectives of the meeting, Ruth Ladenstein, Children´s Cancer Research Institute (CCRI), ***see presentation 1_Ladenstein_Welcome.pdf***	
EC welcome and introduction, European reference networks, DG SANCO Enrique Terol, Policy Officer DG SANCO, European Commission	09:10-09:40

Enrique Terol introduced the Directive 2011/24/EU of patients´ rights in cross border healthcare, which entered into force at the national level in October 2013. This directive includes the support of the development of European Reference Networks (ERN) to improve access to highly specialised healthcare for patients suffering of diseases and conditions which i) have a low prevalence, ii) are complex and cost intensive and iii) require a particular concentration of expertise. He described the milestones and timeline for the implementation of ERN, as well as the objectives of the directive. He gave an explanation, which criteria and conditions are desired for the networks as well as the health care providers. He outlined the governance, coordination and implementation of the networks and underlined it by a scheme for an ERN scenario with the help of a specific example (network rare neuromuscular diseases). The benefits and incentives for healthcare providers in ERN would be i) improved experience, knowledge and capacity, ii) international recognition and visual identity, iii) leadership in their area of expertise and iv) better capacity and stronger position to participate in other alternatives (grants etc.). He gave as examples for pilot networks of cooperation under the Directive 2011/24/EU ExPO-r-Net (2014-2017) and E-Pilepsy (2014-2017). Enrique also pointed to the challenges for ERN, which are:

- To engage, attract, identify and designate the right Networks and Healthcare providers (the added value)
- To establish a network model with useful platforms and tools
- To have an stronger engagement of MS to ensure sustainability
- To avoid fragmentation / duplication of efforts (too many networks addressing similar conditions)
- To develop and use standardised tools (Clinical Guidelines, registries, patient pathways, interoperability of IT systems, ..)
- To increase the capacity of healthcare providers by the "real" exchange of knowledge and cooperation (virtual tumour boards, etc..)
- To strength the "partnership" between Experts, Scientific Societies, National authorities and EU institutions

In the last slide he summarized the contributions from and questions to ExPO-r-Net, which are:

- To explore and develop the criteria and conditions for Networks in the concrete case of pediatric cancer
- To define and agree the specific criteria for the Members of a Paediatric Oncology Network
- To test and develop a networking organizational model based in multidisciplinarity and cooperation between among the members of the network and with external providers
- To agree and implement clinical guidelines / protocols and patient pathways (referral criteria included)
- To implement and analyse the feasibility of the use at EU level of networking tools and IT

solutions (virtual boards, transfer of images, e-learning etc..)

See presentation 2_Terol.pdf

Discussion: Enrique Terol highlighted that the most important issues are finding money to support the list of activities and to convince the member states to adapt the rules accordingly. This will be a long process of several years but is feasible.
All partners discussed that giving expert opinion is time consuming and costly. From the EU point of view a legal status is foreseen for crossborder healthcare, but concepts for ERN, billings systems, teleconsultation rules etc. are lacking. ExPO-r-Net could contribute to defining costs for expert consultation. The type of service and costs has to be conceptualized. The partners agreed that they are already in a situation where they give expert advice and support and adequate rules have to be defined.

Introduction to the Project, project objectives, project identity set Ruth Ladenstein, CCRI, ExPO-r-Net Coordinator	09:40-10:10

After displaying the ExPO-r-Net project identity set (logo, comments on templates to be used, inclusion of the funding organisation etc.), Ruth Ladenstein first summarized the history of the project including details on the call under the directive 2011/24/EU. In particular, the call objective was to implement and further develop the European standards of care for children with cancer in a pilot network of cooperation between paediatric oncology centres. This action should be based on work already carried out by following projects: ENCCA, PANCARESURFUP, EUROSARC, INTERALL and ASSET. She presented key figures about ExPO-r-Net like project duration, funding modalities, the consortium etc. and listed the work packages (3 Horizontal and 5 Core WPs) including specific objectives.
Finally, she outlined the project goals to build a Paediatric Oncology (PO)-ERN providing paramount requirements for Cross-border healthcare which are:

- Provision of healthcare to children and young people with cancer in a Member State other than the Member State of affiliation.
- Identification of the target groups, i.e. children with special diagnostic and therapeutic needs with conditions requiring a particular concentration of resources or expertise, especially when the expertise with certain cancer conditions is rare and case volume low.
- Reduction of current inequalities in childhood cancer survival and healthcare capabilities in different member states.
- Establish a PO-ERN linking pre-existing reference centres with tumour boards to provide cross border expertise. The latter is inherent to the Cooperative PO- Clinical Trial tumour and Leukaemia Groups which may contribute high-level diagnostic and medical expertise to rare childhood cancer populations.
- Improving access to high-quality health care for children with cancer whose conditions require specialised resources or expertise not widely available due to low case volumes and lack of local resource.

Ruth Ladenstein expects the project to have the following impact: i) will identify and specify the cross-border health needs based on the large experience of European Leukaemia and Tumour Groups based on integrative work with the ECRC (European Clinical Research Council of Paediatric Haemato-Oncology), ii) incorporate the expertise from right across Europe and collate existing information to help patients get access to the best possible information, treatment and care, i) improve standards of care for children and young people with cancer.
ExPO-r-Net will provide a clear roadmap to approved expert referral sites and tumour advisory boards for healthcare providers and will foster eHealth solutions based on interoperability and standardisation for better exchange of information.

See presentation 3_Ladenstein_Introduction ExPO-r-Net.pdf

Coffee break

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Session 2 HORIZONTAL WORK PACKAGES 1-3

10:25-12:30

Chair: Lars Hjort

WP1-Project Coordination	10:25-11:40
Global management structure Ruth Ladenstein, CCRI, ExPO-r-Net Coordinator	
Deliverables: • Interim, technical progress and financial progress reports	• **Month 36**
Milestones: • Kick off meeting in the Executive Agency's premises in Luxembourg • Quality Assurance Plan • Biannual Consortium Meetings (every 6 months)	• **Month 1** • **Month 3** • **Month 36**

In this talk, Ruth Ladenstein presented the global management structure of ExPO-r-Net, including a detailed outline of the Consortium of 18 Associated and 42 Collaborating Partners and the 3 horizontal and 5 core WPs. She presented the obligations of the coordinator to ensure that the project is carried out properly (e.g. monitoring project execution and dissemination, ensuring that contractual provisions are respected by all partners, communication with the EC, provision of all data requested by the EC etc.). She also outlined the roles and responsibilities of the WP leaders, which are: i) to control the progress of the work within the WPs, ii) to assess the quality of outputs of the respective WP deliverables and milestones, iii) to initiate und participate in necessary meetings including provision of minutes, iv) to refer to the project management team (PTM) in case of major issues affecting the work foreseen, v) to meet on a 2 monthly basis (at least via telephone conference calls) to follow the work in progress. The work flow for reporting should be from task leader to WP leader, project manager, project coordinator and PMT to the funding organisation. In the next slide, the composition of the proposed management bodies was presented. The PMT should consist of the project manager, coordinator, dissemination manager and the respective SIOPE president (active, incoming and one past SIOPE president). The executive committee (ExeCom) of the project comprises all associated partners and the general assembly also includes the collaborating partners, European leukemia and tumor groups, ITCC &TYA consortium and PANCARE.
In the next slides, details on the PMT including its obligations to assist the project coordinator, on the responsibilities of the ExeCom and the role of the general assembly (GA) in the project were given. To ensure a successful execution of ExPO-r-Net, a quality assurance plan will be developed within the first 3 months of the project.
Ruth Ladenstein also pointed out the importance of a representation of ExPO-r-Net within the ECRC (European Clinical Research Council in Pediatric and Adolescent Oncology) to integrate pre-existing major European Paediatric Haemato-Oncology (PO) tumor and leukemia therapeutic networks, integrate knowledge across different cancer entities, identify clinical trial centers for specific entities as pre-existing hubs for future tumor boards and to better integrate and represent local expertise and infrastructure by inviting chairs of the European national paediatric oncology societies (NAPHOS). The ECRC meets at least once a year and will be invited to have an input in the strategic decisions of ExPO-r-Net. However, interactions with individual leukemia and tumour groups are planned throughout the year.
Another important committee to be addressed is the Parent/Patient Advocacy Committee (PPAC). The PPAC aims to i) identify the PP perspectives on cross-border health care, ii) advance prevention and cure of childhood cancer, iii) support improvement of diagnostics, treatment and follow-up care, iv) enhance communication and increase understanding among childhood cancer patients and their relatives and v) is a stakeholder voice at policy actions and events. Also the PPAC meets at least once a year and will interact with ExPO-r-Net, but will be available for necessary actions throughout the year.
Finally, the Ethical Advisory Committee (EAC) has to be embedded. It may address ethical issues raised by the ExeCom, family concerns and expectations related to cross border health care topics, act proactively

by identifying further relevant issues, addresses and study broader ethical and social issues relevant for ExPo-r-Net. Therefore, external experts from the EAC will provide advice to the project consortium.
The presentation was continued with a summary of the management activities, potential risks and their management were listed:

- Risk: Lack of resources to deliver full scope of project

Management: Seek synergies with associated & collaborative partners to integrate pre-existing knowledge and actions, benefit from major meetings as meeting platform with PO stakeholders to communicate, plan, optimize……

- Risk: Delayed Activities

Management: WP-leaders to identify reasons and to discuss with PC and PMT to identify solutions and/or alternate proposals for delayed activities, project management to provide planning and control tools, continuous monitoring of the project progress, consider eventually reallocation of resources
Internal risk management:
• Risk analysis by PMT (Month 3 to 6): i) what are the risks; ii) identify the risk level (high, medium, low); iii) what impact would it have on the project; iv) identify a contingency plan.
• Risk management by PMT: i) resolving conflicts; ii) identification and assessment of risks to the project and implement risk mitigation and contingency strategies; iii) identifying expenditure fluctuations against the planned spending profile and taking corrective action if necessary.

Finally, two slides summarizing the process indicators were shown:
Objective 1 process:
• Standardized questionnaires to define the needs with Paediatric Haemato-Oncology Leukemia and Tumour Clinical Trial Groups (PO ECTG, ECRC platform) based on their expertise for specific patients populations: particular medical conditions; lacking technologies; medical need for highly specialised services. **Outcome: summary report**.
Objective 2 process:
•Questionnaire to ECTG and named major PO sites in Europe checking on current standard of care profile and the availability of expert tumour boards and to identify specific cancer entity needs for crossborder healthcare. **Outcome: A PO-ERN Road-map guiding to sites to specific expertise. A proposal for a future benchmarking process**.
Objective 3 process:
•Identify pre-existing EU collaborative tumour boards. A questionnaire identifying further hospital sites ready to provide cross-border expertise. Identifying available IT tools based on E-Health concepts. **Outcome: Report on available TBs. Study report on available IT tools**.
Objective 4 process:
• Preparation of a self-assessment checklist, to identify a common process for certification of PO expert centres in Europe. Establishment of a PO assessment committee to monitor and to approve the centres fulfiling all criteria. **Outcome: A European PO ERN expert reference manual.**
Objective 5 process:
• Identify experts for late complications of treatment. Elaborate on the survivorship passport with PANCARESURFUP and ENCCA. **Outcome: Establish the virtual late effect centre for healthcare providers. Translate the survivorship passport into 15 EU languages and guidelines**.
Objective 6 process:
•Collaborative work between the European National Groups on very rare tumour and very rare STS resulting in guidelines on accurate diagnosis and evidence-based treatments. **Outcome: Standard of care guidelines for VRTs and STSs. Establishment of a VRT and STS reference website.**

See presentation 4_Ladenstein WP1.pdf

Discussion:

The discussion mainly focussed on the slide presenting the proposed management bodies. Suggestions were made to expand the number of networks and Ruth Ladenstein explained that it is intended to include all tumour groups but the full number could not be displayed on the slide. Another suggestion was to decrease the number meetings for ExeCom from 4 to 2.

Contractual rules, financial and administrative requirements
Jurgita Kaminskaite, Consumers, Health and Food Executive Agency (CHAFEA), Project Officer

Ms Kaminskaite first introduced the funding organisation CHAFEA. She summarized the work of the funding body and presented relevant facts and figures (No. of staff, projects, partners and amount of funding money). She explained the connection between CHAFEA and the commission (DG SANCO), who have distinct responsibilities but close collaboration. DG SANCO sets priorities in annual public health work plans and liaises with member states and CHAFEA launches calls, monitors projects and improves efficiency of management and dissemination. Furthermore, she mentioned the objectives of the health programme 2008-2013, which were addressed in several action programmes to improve citizens´ health security, promote health (including reduction of health inequalities) and generate and disseminate health information and knowledge. The instruments for these objectives are i) grants for projects, ii) operating grants, iii) grants for conferences, iv) joint actions, v) calls for tender and vi) calls for expressions of interest.
Afterwards, she presented the administrative requirements for the ExPO-r-Net project:

- Contractual relationship (coordinator, associates and EU commission) and non-contractual relationship (collaborators, subcontractors and financial donors)
- Communication between project partners and CHAFEA (DG SANCO)
- Expected results: build a paediatric oncology ERN-roadmap to identified and certified reference sites and tumor boards, set up late-effects advisory centers for specific needs of childhood cancer survivors
- Reporting and monitoring: Interim technical and financial reports (M12+2, M24+2), Final technical and financial report (balance, M36+2), evaluation report, monitoring, on site visits, audit

The reporting procedure was explained in detail in the following slides including explicit information on the financial reporting, the documents to be kept and the provision of time sheets.
Jurgita Kaminskaite also gave an overview of the prerequisites for financial managements and the financial requirements of the funding organisation. This included information on the payments by the EC, the eligibility of costs, the financial cycle within the project and the procedure for amendments. She continued her presentation with useful links to the CHAFEA-website and the organisation´s rules and guidelines. She then gave practical suggestions for the associated partners to keep a copy of the grant agreement, all documents, correspondence and invoices, to provide bank account details to the coordinator, to ask the project coordinator, if something is not clear, since all correspondence should go through the PC. For the way forward within the project she presented typical risks and corrective action and finally announced the 3rd EU Health programme (2014-2020) with the following community actions in the field of health: i) Promoting health, preventing diseases and healthy lifestyles, ii) protecting citizens from serious cross-border health threats, iii) contributing to innovative, efficient and sustainable health systems, iv) Better and safer health care, patient safety.

See presentation 5_Kaminskaite_WP1.pdf

Day-to-day management, specific requirements, interaction between coordinator and partners, other issues
Barbara Brunmair, CCRI, ExPO-r-Net Project Manager

Barbara Brunmair briefly summarized in her talk the ExPO-r-Net fundamentals like project partners and total budget, co-funding of 60% by CHAFEA, number of WPs, objectives, deliverables and milestones and the reporting obligations. She then reported the management activities from WP1 which were already or

will be executed:

- Implementation of consortium corporate identity (logo, templates)
- Generation of templates for reporting (incl. deliverables, milestones, finances) after the kick-off
- Building the network - Contact list for dissemination
- Networking activities and identification of synergistic collaborations (related projects like ENCCA, PanCareSurfUp, ECRC)

In the continuous management the project coordination is carried out by the CCRI with responsibility for continuous scientific, financial and administrative management. The WP leaders are responsible for management activities and initiatives in the WPs. Project monitoring will be ensured by periodical written reports, where the project & grant manager Barbara Brunmair will be the central communication access point and day-to-day contact for the consortium. She has to provide answers to queries such as cost eligibility, financial reporting, fund transfer etc..

She then presented the deliverables, which are the reports to CHAFEA and the milestones of WP1 (organisation of the kick-off meeting, quality assurance plan, organisation of biannual consortium meetings). The quality assurance plan will be used to follow-up the quality of the project through several key indicators and to define the internal management rules. It is complementary to the existing official documents of the project (Grant Agreement).

She introduced the project partners in a proposed meeting schedule to be followed by the different project bodies PMT, ExeCom and GA. Since the budget of ExPO-r-Net is tight and a very limited amount of money is foreseen to cover costs for room rentals and catering during meetings, she suggested holding the biannual meetings at the local institutions of ExPO-r –Net WP leaders (AOPD, HULAFE, MUL ULUND, UOB and CCRI). Except for the CCRI, these partner institutions are public official and may be able to organize a meeting venue (lecture hall) for free. The catering costs for one lunch will be covered by the project overhead. The final meeting will be held at the CCRI, which can provide its seminar room as a venue without costs. The detailed meeting schedule is displayed in the respective presentation.

Ms Brunmair then went into detail about the financials by mentioning that the grant for ExPO-r-Net is a co-funding instrument covering only 60% of the total eligible costs of € 2.498.906,00. 40% of the costs have to be provided by own contribution. She showed the cost model displaying the expenditures of the ExPO-r-Net partners. She then explained in 2 slides, how the associated partners have to deal with their travel costs and how the coordinator foresees to reimburse the travel costs of collaborating partners.

Discussion:

During the presentation of the financial details, a discussion came up about the 60:40 ratio of co-funding and own contribution and its difficulty to be executed for travel costs. In this context, the project officer Jurgita Kaminskaite and the CHAFEA financial officer who also participated in the meeting explained that **each project partner has the freedom to fund cost categories not strictly in a 60:40 ratio, but some cost categories may be funded less (down to 0%) and others more (up to 100%), as long as the total budget per partner indicates own contribution of 40% and as long as there is no change of the EC contribution per partner.**

Therefore and for reasons of simplicity and compliance, the CCRI considers funding 100% of travel costs of collaborating partners taking into account, that this means a considerable loss of funding in other cost categories of the coordinator´s budget.

See presentation 6_Brunmair_WP1.pdf

WP 2-Project Dissemination Samira Essiaf, European Society of Paediatric Oncology (SIOPE)	11:40-12:05
Deliverables: • Dissemination Plan for cross-communication, knowledge transfer and activity integration • Multi-stakeholder conference	• **Month 6** • **Month 33**

Milestones: • Project Communication Strategy • Integrate dissemination tools - online and print • Translation of European Standards of Care into at least 4 further European languages • Mapping and communication of European reference networks news	• **Month 6** • **Month 10** • **Month 36** • **Month 36**

After introducing the mission, scope and activities of SIOPE, WP2 Leader Samira Essiaf explained that **SIOPE is the 'natural WP leader for Dissemination'** as the only pan-EU multidisciplinary organisation of-its-kind, with strong expertise in public affairs and in the dissemination of several EU projects to all kind of stakeholders (scientific/academic community, EU advocates and projects, parent/patient advocates, policy-makers, regulatory agencies and industry). SIOPE will disseminate ExPO-r-Net via the following **tools**:

- An webpage integrated in the SIOPE website;
- ExPO-r-Net news integrated in existing E-newsletters, social media and videos;
- Publications/adverts in scientific and policy-related journals;
- Brochures/bookmarks and dissemination toolkits;
- Promotion at congresses as well as policy events and parents/patients meetings;
- The translation of the Standards of Care for Children with Cancer in 4 further languages;
- The setup and roll-out of a multi-stakeholder conference.

SIOPE will act as the **reference point for all partners' communications**, in order to avoid duplication of efforts. SIOPE will build a platform for combined dissemination by helping partners, linking healthcare providers and experts centers at the EU level (promotion of the criteria for a paediatric oncology ERN), as well as promoting the project to the outside community. The two project **milestones** for WP2 are: a communication strategy for the project; the complete integration of the dissemination tools; the translation of the Standards into 4 EU languages and the mapping and communication on the ERN. Finally, Ms Essiaf underlined the fact that ExPO-r-Net is a very complex project to communicate, and that this will be the main **challenge** for SIOPE, who will act as a platform of combined internal and external dissemination.

See presentation 7_Essiaf_WP2.pdf

WP 3-Project Evaluation Richard Sullivan (representing Pam Kearns), European Cancer Research Managers Foundation (ECRMF)	12:05-12:30
Deliverables: • External evaluation report of project	• **Month 33**
Milestones: • Internal evaluation plan • Commence internal evaluation • External evaluation plan	• Month 4 • Month 6 • Month 12

Richard Sullivan represented the WP3 leader Pam Kearns, who could not participate in the kick-off meeting. He first introduced the Univeristy of Birmingham and its leading center for clinical trials. The Cancer Research UK Clinical Trials Unit is the largest Cancer Trial Unit in the UK and responsible for the national portfolio of paediatric oncology trials. Its main involvement in ExPO-r-Net is the co-ordination and delivery of the Evaluation WP3.

He then introduced the Kings College London. Its main involevement in ExPO-r-Net will be analysis and public policy and it focusses on mixed methods for analysis of global cancer public policy (economic, ethnographic, systems and scientometric).

He summarized the background of the WP as follows:

- The evaluation work package is mandatory: i) verifies if the project is being implemented as planned and reaches the objectives, ii) process and outcome evaluation need to be performed
- Internal evaluation: i) appraisal of the quality of the project (are project outcomes useful and will it meet the user needs, will project achieve its objectives and impact on the target group)
- External evaluation (public policy): i) appraisal of whether the project is achieving its objectives (are project deliverables achieved to time and target, is there an impact on relevant stakeholders, is the impact likely to be sustainable)

Richard Sullivan then described the WP 3 Objectives and their implementation:

- Development of a project evaluation plan
- Undertake internal evaluation of the project management and internal processes
- Systematic appraisal of quality of the project
- Systematic appraisal of the effects of the project

An important WP3 dependency is the interrelation with tasks inside ExPO-r-Net and with the community outside. This Relates to all the project partners but with specific relationship with collaborative partners ICCCPO, European Cancer Patient Coalition, St Anna Kinderspital Vienna. The evaluation process will be a rolling programme with feedback and suggestions for corrective actions

The WP3 deliverable is an external evaluation report of the project in month 33 of ExPO-r-Net including i) public policy analysis of PO care across Europe, ii) ensuring that all WP deliverables are translated into public policy impact.

Finally, Richard Sullivan summarized the milestones of WP3 (internal evaluation plan, commence internal evaluation, external evaluation plan, external evaluation report of the project).

See presentation 8_Sullivan_Kearns_WP3.pdf

Discussion:

Gilles Vassal addressed the difficulty of the conduction of this WP within such a short time span and David Walker mentioned the example of brain tumours, where different registration standards exist in EU member states, as well as different dimensions, impact on population, disabilities. All agreed that the full implementation of the ExPO-r-Net goals may go beyond the scope of the project and that further funding sources are highly needed in the future.

Lunch break

After the lunch break, the group picture was taken in the meeting room.

Session 3 CORE WORK PACKAGES 4-8

13:30-16:00

Chair: Richard Sullivan (representing Pam Kearns)

WP 4-Addressing needs and challenges of cross-border healthcare co-operations and current expert fragmentation Ruth Ladenstein, CCRI	13:30-13:55
Deliverables: • Report on specific needs of particular paediatric oncology patients • Report on the established roadmap identifying reference ERN centres and tumor boards	• **Month 18** • **Month 36**
Milestones: • Biannual meeting of the ECRC to identify and to agree on potential cross border Identification of reference sites eligible and willing to be part of ExPO-r-Net • A questionnaire within the respective ECTG committees developed and	• Month 6 • Month 12

circulated • Identification of reference sites eligible and willing to be part of ExPO-r-Net • Benchmarking report on reference sites	• Month 24 • Month 30

Ruth Ladenstein introduced the core data of the CCRI with its 10 research groups, core facilities and main involvement on ExPO-r-Net, which is project coordination, capitalise on PO networking thus improving outcome of young people with cancer. She specifically pointed out the CCRI interface between research, diagnostics and therapy (the Unit of Studies and Statistics for Integrated Research and Projects (S2IRP), the working group Clinical Cell Biology and FACS Core Unit, activities as a tissue bank and GMP conform production of haematopoietic stem cells prepared for pts. and the production of cellular therapeutic agents). The CCRI interacts closely with the St. Anna Children's Hospital and other paediatric oncology clinics and research institutions in Austria, Europe and beyond.

The background for WP4 are previously coordinated projects like FP7 ENCCA, FP5 SIOPEN-R-NET, Longstanding experience in PO, past roles as SIOPEN and SIOPE president and Clinical Trial Chair of SIOPEN high risk neuroblastoma trials HRNBL1 (1.5)/SIOPEN. ExPO-r-Net will implement structures created within ENCCA like ECRC, PPAC, EAC and strong collaboration of IT partners. The quality of the partnership will be ensured by integrating SIOPE-stakeholders, ECRC platforms and parents and patients groups (ICCCPO, Panare). There is a share of common goals and objectives such as vision and mission of improving survival rates further as well as Quality of Life for children and young people with cancer and willingness to specify patients' needs for cross border health care with a focus on very rare cancer /tumour disease types and special needs based on distinct requirements during the patient's journey of cancer therapy. The project will create synergies between PO partners (pooling PO partner resources by identifying reference centres and tumour boards). Some communication tools will be i) SIOPEs WEB page with modern media (twitter, LinkedIn), ii) PO international and ECTG meetings iii) cost saving teleconferencing set ups. All partners are highly committed to the common goals based on enhanced networking that will lead into new structures (reference PO centres, tumour boards accessible for cross-border advice, VRT-network).

Ruth Ladenstein then summarized the objectives of WP 4 and outlined the expected result, i.e. a roadmap for public health care providers and patients. The WP has 2 deliverables: i) report on specific needs of particular paediatric oncology patients, ii) report on the established roadmap identifying reference ERN centres and tumor boards. These result in 4 milestones (biannual meeting of the ECRC, questionnaire within the respective ECTG committees, identification of reference sites, benchmarking report on reference sites).

The risks of WP4 are:

- Lack of awareness by administrative authorities managing the healthcare system and by institutions responsible for healthcare.

Risk mitigation: Implementation of the Dissemination Plan.

- Difficulties for a consensus on patients eligible for cross-border care.

Risk mitigation: Consensus conferences on guidelines and criteria rendering patients eligible for cross-border healthcare.

- Lack of resources to compensate tumour boards

Risk mitigation: Propose new compensation system for tumour board advise based on public health system

- Lack of national/supranational financial resources of referring member states.

Risk mitigation: Propose indemnification schemes if member states don't compensate costs generated through cross border health care collaborations.

- Language barriers across Europe (Lack of competence and willingness to perform necessary translations of vital documents.

Risk mitigation: Involvement stakeholders (doctors, parents, survivors)

- Lack of effective ICT data interoperability.

Risk mitigation: identify possible e-Health based solutions.

- Lack of adequate IT equipment to participate in tumour boards

Risk mitigation: emphasises on web-based IT solutions wherever possible. This means that a PC/laptop with Internet access and a web browser is all that is needed to participate in the ERN, i.e. to access information and services as provided within the ExPO-r-NeT. Even in a centers less developed the clinician may follow a tumour board in the country giving advice via laptop/PC. Allow also presentation to tumour board in more traditional ways, i.e. request via paper, CD, etc. remain an option.

See presentation 9_Ladenstein_WP4.pdf

Discussion:

MUL asks for an amendment to change public personnel to non-public personnel and the project officer confirmed that this is possible, as long as the net amount of the budget with 60% co-funding and 40% own contribution stays the same.

Kathy Prichard-Jones asks about electronic remote data systems for tumor boards and Ruth Ladenstein informs that so far there is no overall solution existing yet. Collaborating Partner (CP) Stephanie Klco-Brosius (University Clinic Münster, Germany) suggests the system which is used by her institution and which was established within ENCCA activities as a potential basis to be built on. She also explained the properties of the system. It was also suggested to include mobile devices, in particular for the use in small institutions with minor infrastructure.

Piotr Czauderna introduced the platform which he developed for pediatric liver cancer, which may also be utilized as a basis.

Ruth Ladenstein again emphasized the importance of a close interaction with pediatric tumor groups, e.g. by linking with them in their meetings. This was followed by identification of the respective tumor groups and how they could be addressed. She again informed that a full list of the relevant tumor groups will be presented to the ExPO-r-Net partners, was built within ENCCA and is hold up to date now by SIOPE.

WP 5-Paediatric Oncology tumour board ERN based on EHealth/ICT concepts for sharing and providing expert advice Adela Canyete & Günter Schreier, Fundacion Para La Investigacion del Hospital Universitario la Fe de la Communidad Valencia (HULAFE) & Austrian Institute of Technology GmBH (AIT)	13:55-14:20
Deliverables: • Report identifying European tumour boards of ECTGs providing ICT logistics	• **Month 24**
Milestones: • Evaluation of CURRENT EXISTING tumour boards THROUGH A QUESTIONNAIRE (SWOT analysis) • Definition of Standard Operating Procedures (SOPs) and road-maps on ExPO-r-NeT Tumour Boards • Development of ICT strategy and interoperability architecture for the ExPO-r-NeT	• Month 12 • Month 24 • Month 36

Adela Canyete presented HULAFE as one of the biggest and best equipped hospitals in Spain, offering highly specialized care and patient-oriented research. It was accredited as "Health Research Institute" (IIS) by Spanish Authorities in 2009, with 39 Groups, more than 10,000 m2 of laboratories to undertake research programmes in five priority areas, including cancer. HULAFE used standardized computerized systems to work in a-non-paper-environment connected with primary care and authorities, their Pediatric Tumor Board has functioned without interruptions since 1970. They lead as International sponsor LINES trial and WP 10 in ENCCA. In 2012, IIS La FE participated in 182 competitive projects (11 European) and had an income of 14.511.046 €. They bring as collaborating partners two institutions: 1/ Dirección General

de Salud Pública, whose NEOS portal is an Integrated and coordinated information system that allows a collaborative work in cancer care using XML technology and Codification CIE-9 SNOMED CIEO3. 2/ The Research Center On Software Production Methods (PROS) whose mission is to improve the tradicional software production methods, providing model-driven methods and techniques to develop quality software in a systematic and productive way.
The aim of HULAFE is to develop a strategy to build Expo-r-net Tumor Boards (TB) as tools for providing access to expert care to all European Children with cancer in a cross-border setting, working with common standards and using IT tools based on EHealth concepts for sharing and providing expertise and advise: TBs are the paradigm of multidisciplinary team work in Pediatric Oncological care and assemble experts that discuss clinical complex cases. Taking into account the burden of families seeking advice cross-border and the complexity of some cases, they will seek mechanism to facilitate movement of information and Expertise rather than people with an Information Communication Technology (ICT) strategy that warrants data interoperability, efficient data management and confidentiality, connecting the existing elements with an interoperability architecture within the framework given by Article 14 and eHealth Action Plan 2012-2020.
The expected outcome is that ExPO-R-NET will identify, connect and encourage to establish Tumour Boards as hubs of expertise embedded in the pre-existing expertise of CTG across Europe thus creating a virtual ExPO-R-NET TB platform. The vision is that the implementation of modern IT tools across borders will allow TB to share expert opinions for European children with cancer in need of special cross-border settings.
Methods: Adela Canyete pointed out that they will use validated, quantitative questionnaires for centres to identify the current functioning of their TB Using focus groups of health professionals, they will scope the requirements of centres submitting or receiving patient data for advice in diagnostics and therapeutic management. Definition of the core information is needed and will be generated by tumour boards. Those will be the basis of a Conceptual Model, for designing an advanced data repository. Development will be through well-integrated teams of clinicians (information providers) and IS experts (providing the know-how to generate data models and repositories) and a software platform using the most advanced data management facilities that the cloud metaphor makes feasible.
Deliverable: Report identifying European TB of ECTGs providing ICT logistics.
Milestones:
-Evaluation of current existing tumour boards through a questionnaire (SWOT analysis) (month 12)
-Definition of Standard Operating Procedures (SOPs) and road-maps on ExPO-r-NeT Tumour Boards (month 24)
-Development of ICT strategy and interoperability architecture for the ExPO-r-NeT (month 36).

Discussion:
Gianni Bisogno addressed the difficulty of acting on 2 levels, national and international and how to overcome the language barriers. David Walker mentions that he is not aware of national standards in the UK,however, there are national arrangements. Gilles Vassal thinks that the national level is not so important for ExPO-r-Net because it is going to present a cross-border directive.
Enrique Terol suggests that some of the ExPO-r-Net products could be open source products to be offered to the networks and integrated to possible IT-platform planned.
Günter Schreier pointed out that the resources for people who deal with the tools are maybe the more important problem. People also need to be trained.

Günter Schreier presented some AIT key figures and the existing AIT experience with ICT infrastructures for networks based on previous projects like SIOPEN-R-NET, ENCCA and RegIonCo. In these projects AIT developed the ideas for their standards and interoperability based approach to the design of the ICT strategy for the ExPO-r-NeT. A special emphasis was put on Integrating the Healthcare Enterprise (IHE) based interoperability which has already solutions to a number of use cases that are supposed to be

crucial here as well, for example "Cross-Enterprise Tumor Board Workflow Definition Profile". Thus, the ICT concept will be very much aligned to the European Interoperability Framework which was briefly explained by Günter. He expects the challenges in the project being associated to the different levels of interoperability that need to be achieved:

1. Technical Interoperability – we need trust from the source systems (IT Administrators)
2. Semantic Interoperability - we need a common language – dataset standardisation
3. Pragmatic Interoperability - we need shared processes (workflow support)
4. Juristic Interoperability – we need common rules (roles and rights)

Günter's conclusions were:

1. IT needs to follow organization - Initially, we need to structure the RN
2. IT has the experience that will allow them to come up with an interoperable structure
    a. An ICT strategy and
    b. An ICT solution Architecture that is in line with the ECs eHealth strategy
3. We need to talk to other groups that share our challenges
    a. Tumour boards
    b. Health Information Exchange

More resources will be needed to come up with an ICT system for practical purposes that works!

Discussion:

Günter Schreier points out that the national reference networks have to be identified first to build the ExPO-r-Network on them.

Kathy Prichard –Jones asks who is going to lead the building of national networks. Günter Schreier says that this is still completely open and the EU adopted Intelligent Application Gateway (IAG) as possible tool (association between users and vendors. Users come with their use cases, vendors work out solutions based on existing standards).

Gianni asks if the IT-work foreseen in ExPO-r-Net will be based on the existing experience from ENCCA or if a new platform will be established. Günter agreed that there are plans to use aspects of ENCCA for this project.

See presentation 10_Cañete_WP5.pdf
and presentation 11_Schreier_WP5.pdf

WP 6- Defining criteria for a common process for identification and certification of PO expert centres in Europe Jerzy R. Kowalczyk, Medical University of Lublin (MUL)	14:20-14:45
Deliverables: • Identification and certification process for healthcare centers to be recognised within the European Reference Network	• **Month 24**
Milestones: • Definition of terminology used for the accreditation process • Description of quality management system to ensure that procedures are being carried out in line with agreed standards • Preparation of a checklist enabling self-assessment by treatment centres of their compliance with the European Standards • Self-assessment by treatment centres of their compliance with the European Standards	• Month 9 • Month 16 • Month 24 • Month 36

Jerzy Kowalczyk introduced the ExPO-r-Net Partner Medical University in Lublin: it was founded in 1944, educates more than 7 000 students each year and it engages 1600 employees including 1200 researchers. MUL is divided into 4 faculties: two Medical Faculties with Dentistry Division and English Language Division (since 1995), Pharmaceutical Faculty with Medical Analytics Division and Nursing and Health Science Faculty. MUL is expected to coordinate the preparation of principles for a system of

identification/certification of paediatric oncology centres in Europe.
Background: In 2009 SIOPE initiated a project in order to improve the quality of care of children and adolescents with cancer which resulted in the document "European Standards of Care for Children with Cancer". The Standards apply to all aspects of care of children with cancer and were developed by consensus from the contributions of experts in the field and parents organisations. According to recent survey a total of 370 units can be identified as Pediatric Hemato-Oncology units in Europe. However, these centres with full diagnostic services, all necessary drugs and supportive care to optimise the survival and minimise toxicity were identified in only half of European countries. Facilitation of the standards implementation process in EU Members States would be a vital step to improve the quality of care in children with cancer, increase survival rates and enhance the quality of life for childhood cancer survivors across Europe.
Jerzy Kowalczyk told the audience that the primary aim of WP6 is to promote high quality patient care in paediatric oncology centres through the implementation of an internationally recognised system of certification helping thus to reduce inequalities in care between centres and countries. Certification will be a process by which competency, authority and credibility is presented and confirmed. To achieve these objectives the principles for a system of identification/certification of paediatric oncology centres in Europe have to be established.
Participating entities within the WP 6 include Associated Partners: CCRI (Vienna), SIOPE (Bruxelles), IGR (Villejuif), HULAFE (Valencia), UCL (London) as well as Collaborating Partners: Brno (Czech Rep.), Milano (Italy), Riga (Latvija), Vilnius (Lithuania), Ljubliana (Slovenia), Nottigham (UK).
Jerzy Kowalczyk mentioned that this project will fulfil the vision of a more supportive environment for children with cancer with special needs by integrating pre-existing networks and knowledge across borders. It will launch an identification and certification process for healthcare centres to be recognised within the PO ERN and gather the information in a manual defining terminology and definitions used for the certification process describing quality criteria. By this means a centre can demonstrate that it is performing to a required level of practice in accordance with agreed Standards and that it operates an effective quality management system. The project is initially targeted at paediatric oncology units already recognized as centres of expertise at a national level in EU Member States.
As an outcome of the WP6, Jerzy Kowaczyk expects a European PO ERN expert reference manual.

See presentation 12_Kowalczyk_WP6.pdf

Discussion:
Gilles Vassal mentioned that the time from recommendations to the delivery of standard care will be another story. Defining the criteria on which centers will be accredited (certified) is a real challenge.
Jerzy Kowaczyk answers that their survey will be helpful. With the results of this they can see which centers of which countries fulfill the criteria.
Kathy Prichard-Jones: Defining centers with high quality treatment for cancer is important. They have to be labeled as a children´s cancer centers. We need to pick out within each country those who are capable to do the complex stuff.
David Walker: Maybe we could establish criteria that a center is able to receive cross border funding. This will be a small number of centers.
Gilles Vassal: The capacity to deliver expert high level treatment is also a factor.
Dominique Valteau-Couanet: We have to define centers according to the kind of treatment offered at a high expertise level. Then we may agree on using criteria for the patient treatment.
Enrique Terol: We have already a formal framework of criteria for the centers created this year. However, we do not have criteria for highly specialized pediatric systems. We do not need a quality system for the hospital. Therefore the focus should be on what we do not have yet.
Jerzy Kowaczyk appreciated the remarks, which will help to create WP6 and establish regulations how to go, guidelines for stakeholders, patients, authorities. We are going to give a guideline, prepare a list of

reference centers, which fulfill requirements on basic levels for standards of care.
Enrique Terol warns to prepare a certification system on a too high level. Gilles Vassal comments that it is planned to identify capable centers without certification, however it is not likely that ExPO-r-Net may deliver a certification process. Enrique Terol insisted however, that finally a certain certification system has to be established. Maybe SIOPE can do that in the future.
Kathy Prichard Jones announces that for rare conditions one may have only very few centers.
David Walker suggests a self-accreditation for centers. They should declare that they are prepared to offer facilities for international treatment, including patient involvement etc. which is more than just technical oncology and nursing levels. ExPO-r-Net needs to develop standards first and then centers may apply.

WP 7-Cross-border dimension of long-term follow-up: survivorship passport with crucial treatment & follow-up data Lars Hjort, Lund University (ULUND)	14:45-15:10
Deliverables: • Set-up a virtual late-effects advisory centre for specific care needs of childhood cancer survivors	• **Month 36**
Milestones: • Translations of the Survivorship passport started • Identification of experts for the Virtual late effects centre • Translations of the Survivorship guidelines started	• Month 6 • Month 12 • Month 30

The presentation of WP7 was presented by Lars Hjort and Riccardo Haupt as follows:

Background and development:

Continuing work done and on-going in current FP7 projects ENCCA and PanCareSurFup as well as in the International Guidelines Harmonisation Group (IGHG). Riccardo Haupt is leading the work in WP13, Quality of survivorship, in ENCCA and Lars Hjorth is Coordinator for PanCareSurFup. Providing first-hand survivor and parent input in the work through ExPO-r-Net Partner #17 ÖKKH with Anita Kienesberger. Maintaining the on-going work with CINECA (ExPO-r-Net Partner #10) and utilising the PanCare Network and SIOP-Europe (ExPO-r-Net Partner #1) and their partnerships.

Objectives:

To build a virtual paediatric oncology expert reference network for guidance on late effects after treatment for cancer in childhood and adolescence. To translate the Survivorship passport and relevant Guidelines into multiple European languages.

Interrelation of tasks inside ExPO-r-Net and with the community outside:

The Survivorship passport template needs to be provided by ENCCA and the Guidelines need to be provided by PanCareSurFup and the IGHG

Deliverable:

#9 – Set-up a virtual late-effects advisory centre for specific care needs of childhood cancer survivors. Delivery date is Month 36. The dissemination level is within the Scientific Community only.

Milestones:

#1 – Translations of the Survivorship passport started; Month 6
#2 – Identification of experts for the virtual late effects centre; Month 12
#3 – Translations of the Survivorship Guidelines started; Month 30

Risks

Work in ENCCA, PanCareSurFup and the IGHG need to progress on-time. Problems with finding the right methodology for translation of medical and other terms in order to avoid differences in the meaning of the texts between countries.

Opportunity

Producing Recommendations in “Plain” Language Intended for parents and survivors; the PLAIN working group in PanCareSurFup.

See presentation 13_Hjorth_WP7.pdf

Discussion:
Riccardo Haupt reluctantly mentioned that it takes one year for guidelines for one cancer, which means a lot of work for ExPO-r-Net. But he also announces that each guideline will end up with publication in high level journal.
Anita Kienesberger says that it is not clear yet how many people are needed to read all guidelines for any language and suggests to tell, what exactly is needed to be addressed in future meetings with parents and patients. The others agreed that this is a good idea which will be addressed.

WP 8- Integrating children with very rare tumours in a European Reference Network Gianni Bisogno, Regione del Veneto, Azienda Ospedaliera di Padova (AOPD)	15:10-15:35
Deliverables: • Standard of care guidelines for VRT and very rare STS	• **Month 24**
Milestones: • Establishment of VRT Network tumor board and working group on rare STS in collaboration with EpSSG • Establishment of a website dedicated to inform families and the public. This website will be linked to the main ExPO-r-NeT webpage • European meeting to reach consensus on guidelines for VRTs and rare STS	• Month 8 • Month 12 • Month 24

Gianni Bisogno first introduced his institution, Azienda Ospedaliera – Università di Padova, Paediatric Hematology Oncology Division, Padova, Italy to the consortium, then continued with the background of WP8. He defined rare diseases and very rare pediatric tumors according to epidemiologic and strategic criteria. He illustrated the history of diagnostic-therapeutic guidelines with the help of a timeline and listed currently existing tumor cooperative groups.
The objectives of WP 8 are integrating very rare tumors and soft tissue sarcomas into an European reference network through the identification and connection of Pediatric Oncology Centres and Cooperative Groups with the necessary expertise with the aim to the provide accurate diagnosis and evidence-based treatment to children with VRT in Europe (and worldwide).
Gianni Bisogno expects as results from WP8:

- The creation of a European Cooperative Group dedicated to VRT able to establish standards for diagnosis and treatment, support clinical and biological research, provide scientific based advice to Clinicians, provide scientific based information to patients and families
- The creation of VRT national cooperative Groups in countries where they do not exist

The main collaborating partners in WP8 are Fondazione IRCCS Istituto Nazionale dei Tumori, Milan, Italy (Andrea Ferrari) and Klinik fur Kinder und Jugendmedizin, Dortmund, Germany (Dominik Schneider). The main associated partner in WP8 is Consorzio Interuniversitario (CINECA), Bologna, Italy (Marisa De Rosa).There are several interactions of WP8 with other WPs in ExPO-r-Net like:
- Translations and dissemination of treatment guidelines (WP2)
- Identification of national cooperative groups dedicated to VRT (questionnaire) (WP4)
- Definition of SOP for tumor boards (WP5)
- Assessment of treating centres (WP6)
- Inclusion of patients with VRT in the survivorship passport project (WP7)
- Identification of Centres of reference (WP4)

The interaction with the pediatric oncology community is identified as follows: i) European soft tissue sarcoma Group (very rare sarcomas), ii) ECRC, iii) SIOPE, iv) Pediatric Oncology Centres (creation of a consulting desk and a dedicated website)
Gianni Bisogno then went into detail about the WP8 deliverable to establish standard of care guidelines for VRT and very rare STS and the steps that need to be addressed. He pointed out the challenge of data

sharing among different groups, creating a common scientific background and how to get from the expert to larger European reference networks.
The milestones of WP8 are: i) establishment of VRT network tumor board and working group on rare STS in collaboration with EpSSG, ii) European meeting to reach consensus on guidelines for VRTs and rare STS, iii) establishment of a website dedicated to inform families and the public.
The presentation was completed with a list of risks for WP8, i.e. Rarity of VRT (of course), different definition of VRT in different European countries, different national groups and protocols for the same tumors in different countries, lack of Cooperative Groups dedicated to VRT (especially in Eastern Europeancountries), diagnostic expertise not available in every country, treatment expertise not available in every centre, absence of economic resources to support diagnostic review, national group activities.
These problems may be overcome by actions undertaken as follows:

- Previous experience, manifestation of interest from many countries
- Harmonization of definition
- Common analysis of the available data to create a common background
- Disseminate information and guidelines and stimulate the creation of National groups dedicated to VRT
- Identification of references pathologists and reference laboratories
- Identification of Centres that can provide expert treatment to whom send the patients (at least for part of the treatment)
- Local/national projects
- Expert centres with Tumor Board for VRT

See presentation 14_Bisogno_WP8.pdf

Discussion:
Bernadette Brennan: a lot of written guidelines are already available, we need to get the best guidelines. The patients of interest are not in a trial structure, there is often little scientific evidence and lack of publications. That would be useful to be obtained how evidence based the treatments are? The focus should be set on rare pediatrics tumors who perform really badly and no improve in outcome was seen in the last 20 years.
Gilles Vassal: Expertise on these rare tumors is a most urgent need, which is spread at the moment in different groups and nations. Is there a national tumor board working on these cases or a consensus proposal on what needs to be done? This could be one of the major goals of ExPO-r-Net.
Gianni Bisogno: The tumor boards are not formally organised, we want to change this in ExpO-r-Net. We need to keep track on every patient. On the national level, we have reference people to give advice, but some tumors are so rare that most people never met them before. With very rare tumors it is much more improtant to work internationally. For example, the hepatoblastoma story is a strong success story.
Gianni Bisogno further points out that he would be happy to work closely with IT-people, because simple tools to communicate easily and for face-to-face consultation are needed.
Oskar Pastor: Data sharing is key point which can be very complicated. The right concepts are crucial to have a common set of data.
Gianni Bisogno: compared with SIOPEL very rare tumors have 20-30 patients maximum. In this case it is not so useful to build a complicated structure for retrospective analysis, better use prospective ways.
Piotr Czauderna explains SIOPEL. They have paved the way and established a global dataset for hepatoblastoma patients with 1600 cases in a uniform database. All of SIOPEL know-how can be used and copied by other groups in other settings. A Memorandum on this was signed.
Günter Schreier: What is needed is a simple kind of registry , then with this list you can add pieces of information on top.
Bernadette Brennan: We do not have 1600 patient in a database. It is not an issue to collect data on patients and there are no reference centers for very rare tumors.The issue is about setting up a European

level tumor board. You get multiple different types of tumors. For those who do very well, not too much energy should be wasted. An agreement on standards of treatment is needed. But sometimes we do not know yet.
Gianni Bisogno: For very rare tumors we need a lot of different competencies (different descriptions, staging system….). These are a lot of challenges.
David Walker suggests establishing an open access database to see what other people enter, e.g. survey monkey. This needs no ethical approval, but you can track changes in practice etc. Institutions can register as centers and you can check which data can be used.
Kathy Prichard-Jones gives the example of children in the UK with very rare tumors. The parents went to the NIH, and managed to establish a team for the specific disease. That clinic (including adult tumors) rapidly accumulates patients/data.
Piotr Czauderna states that Neuroblastoma is a rare tumor. But if one includes whole of Europe, Japan, etc. one gets a lot of cases. In this way we will be able to identify lots of prognostic factors, which is very valuable.
Gianni Bisogno agrees but mentions that he has lots of different tumors and sometimes patients don´t need reference centers but just advice.
Gilles Vassal. That is what a tumor board is all about.

Future meetings & next steps ahead and conclusions Ruth Ladenstein, CCRI, ExPO-r-Net Coordinator	15:35-16:00

Here Ruth Ladenstein summarized the most important findings, decisions and challenges of the ExPO-r-Net meeting. She says that the ExPO-r-Net consortium has now established where they wish to go. A meeting schedule has been sketched and the next meeting will take place at HULAFE in Spain. She informs that a QAP will be written and things have to be put into practice. The QAP will also provide information on how ExPO-r-Net will interact with clinical trial groups including identification processes how to interact with Leukemia and Tumor Clinical Trial Groups TG. With final thanks to all participants Ruth Ladenstein closed the kick-off meeting.
We will be in contact, announce about activities and how to interact in detail. Follow our e-mails, please.

End of Meeting