Die Bedeutung der Informationstechnologien bei Krebserkrankungen von Kindern heute und in Zukunft !

The Current and Future Role of Information Technologies for Childhood Cancer

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CCRI-S²IRP (Studien & Statistik), Vienna, Austria

Projekt Koordinator der

ENCCA und ExPO-r-Net Konsortien

European Network for Cancer research in Children and Adolescents

Cancer in Children and Adolescents
A Rare Disease

- > 60 different diseases from newborns to teenagers (even more if biomarkers are considered!)
- 15 000 new cases each year in Europe!
- 3000 will die each year
- 1 out of 1000 adults aged 18 to 40 is a paediatric cancer survivor

… a significant Public Health Issue

SIOP Europe

European Network for Cancer Research in Children and Adolescents

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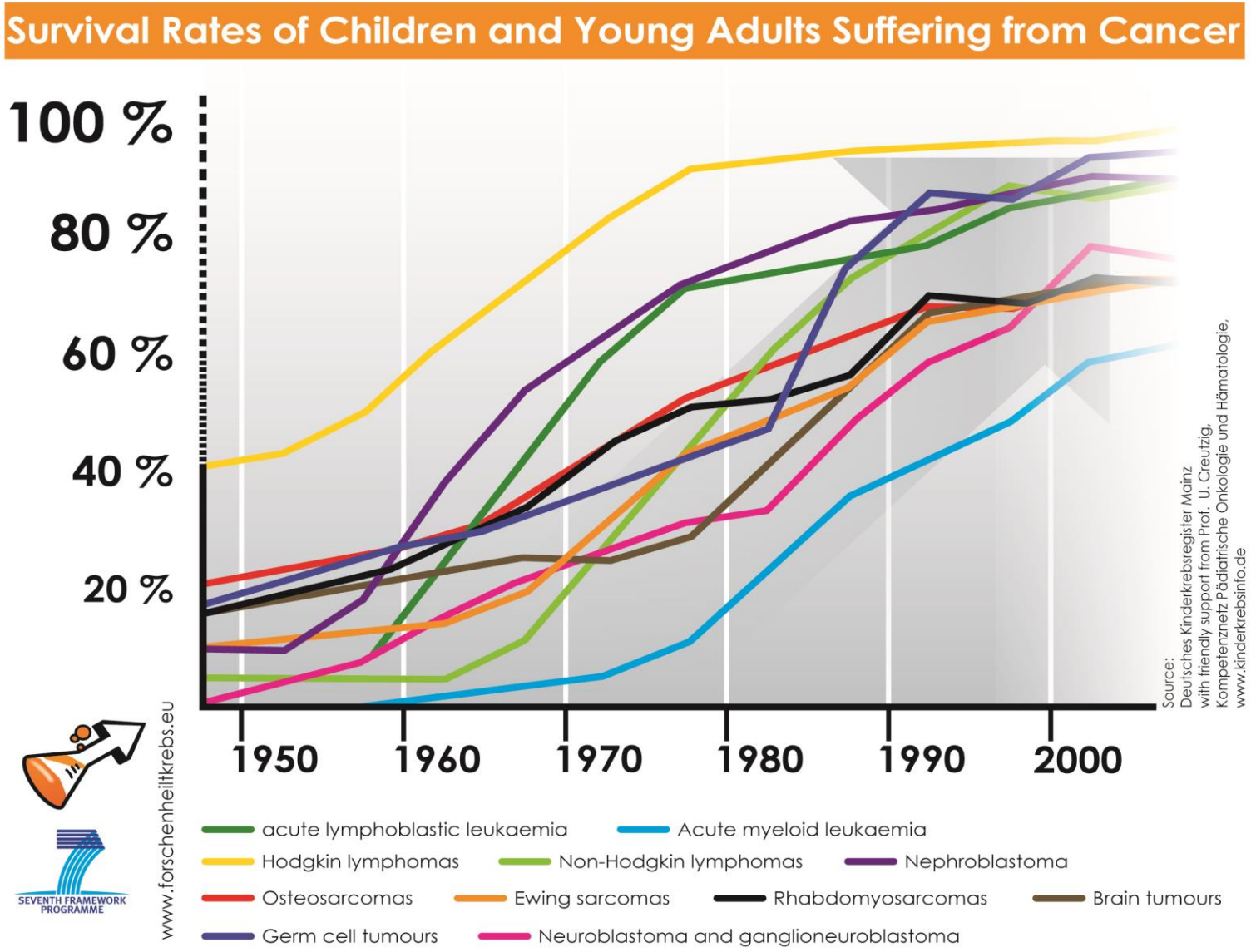
What is special about Paediatric Oncology in Europe ?

- EU public specialized centres
- Networking within clinical trial structures since late 60tes
  - **50% of patients treated within trials (phase I to III)**
  - **30% of patients treated according to standard within prospective studies**
  - **Less than 5% of pharma-sponsored trials**
- Many high-level research teams dedicated to paediatric tumour biology

A unique situation for an orphan disease !

A Major Academic Effort !



> 90% 2020

80% today

<10% < 1960

What have Academic Trials achieved Paediatric Oncology ?

➢ Contribution with Multi- Institutional /Multinational early trials: Phase I and Phase II settings

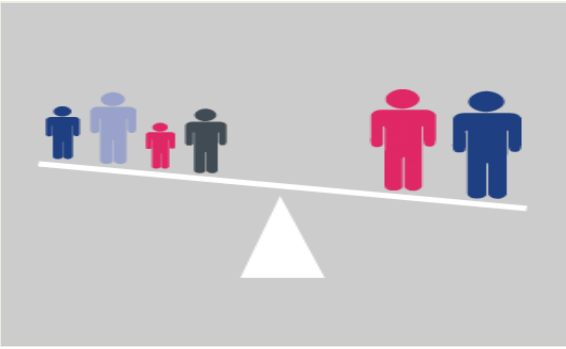
- An important step in drug development
- Dose finding and toxicity profile of new drugs
- Response rates to new drugs and drug combinations

➢ Multinational Clinical Phase III trials

- Vital for young person diagnosed with cancer
- Strategic and complex treatment plans
  (Multiple Chemotherapy Cycles - Surgery- Radiation- Immunotherapy **)**

A quality instrument to optimise treatment, care and outcome!

The New Clinical Trial Regulation & Data Protection
Huge Need for the right balance !

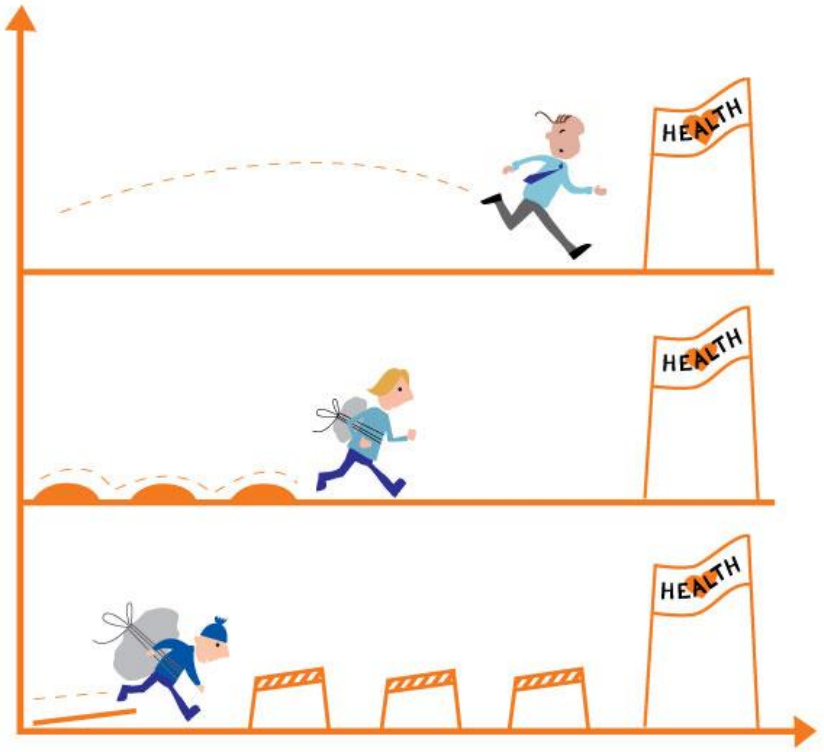


When patient protection may result in major health inequalities

Top 5 cancers

Personalised Medicine

Orphan diseases



large numbers
- licensed drugs
- economic interest

moderate numbers
- innovative drugs

small numbers
- no economic interest
- off lable drugs
- trials expensive
- burocratic burden

Clinical Trials

From Central Data Capture ⇨ Remote Data Entry Systems

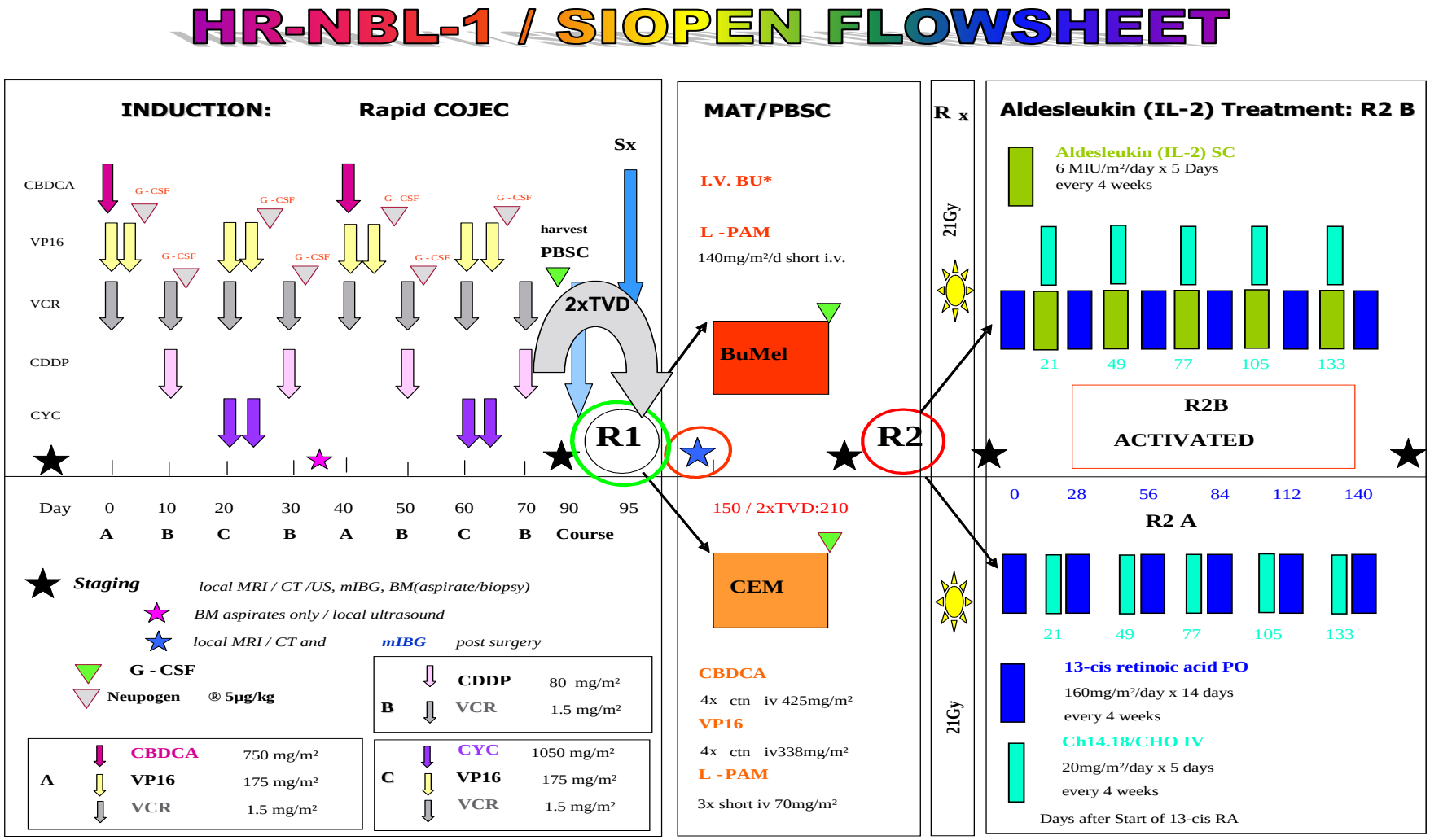
From Paper ⇨ electronic Case Report Forms

New Data Base Designs and Functionality

Risk based Monitoring and Surveillance

- Investigators brochure (+ updates) or SmPC
- Protocol and amendments (signed)
- Information sheet and consent form (+ updates)
- Financial aspects
- Insurance statements
- Signed agreements between parties
- EC opinion and composition
- MRHA authorisation
- Investigators CVs
- Medical and laboratory tests, including normal ranges
- Medicine labels
- Instructions for medicine use
- Shipping records
- Certificates of analysis
- Decoding procedures
- Master randomisation list
- Monitoring reports (pre-trial, initiation, close-out etc)
- List of persons responsibilities delegated to (+ updates)
- CRFs and corrections
- SAE notifications from investigators and to EC and MRHA
- EC/MRHA annual reports and final reports
- Subject screening log
- Subject identification code list
- Subject enrolment log
- IMP accountability at site
- Record of retained tissues
- Documentation of IMP destruction
- Completed subject identification code list
- Audit certificate
- Clinical study report

High Risk Neuroblastoma
Complex Treatments – Top of the Iceberg.....

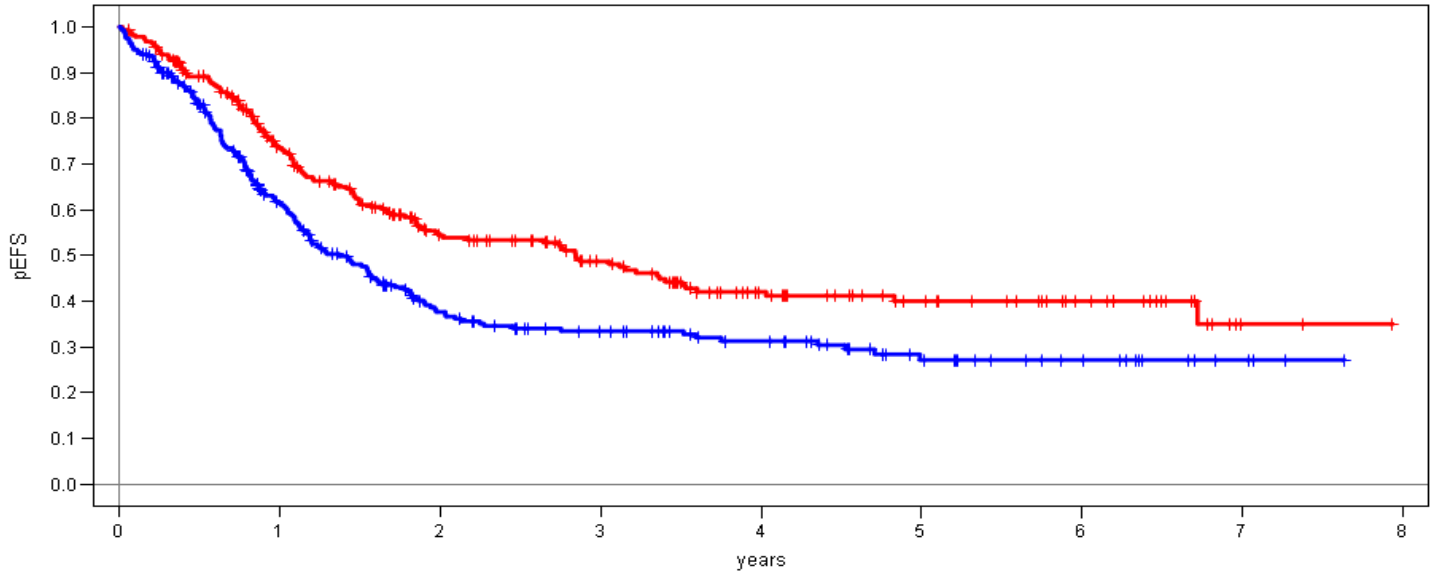


HR-NBL1 / SIOPEN

Comparing 2 International Treatment Standards in High Risk Neuroblastoma : **US** (CEM) **vs. Europe** (BUMEL)

Both previously published, peer reviewed and claimed superior to previous

➢ Which one is superior? [Plenary Session, ASCO Meeting 2011]

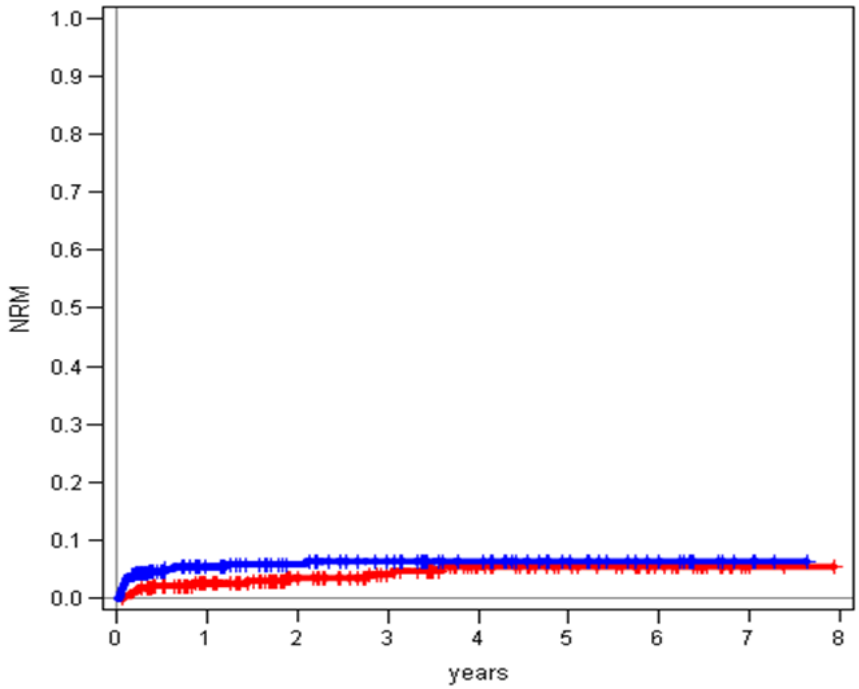


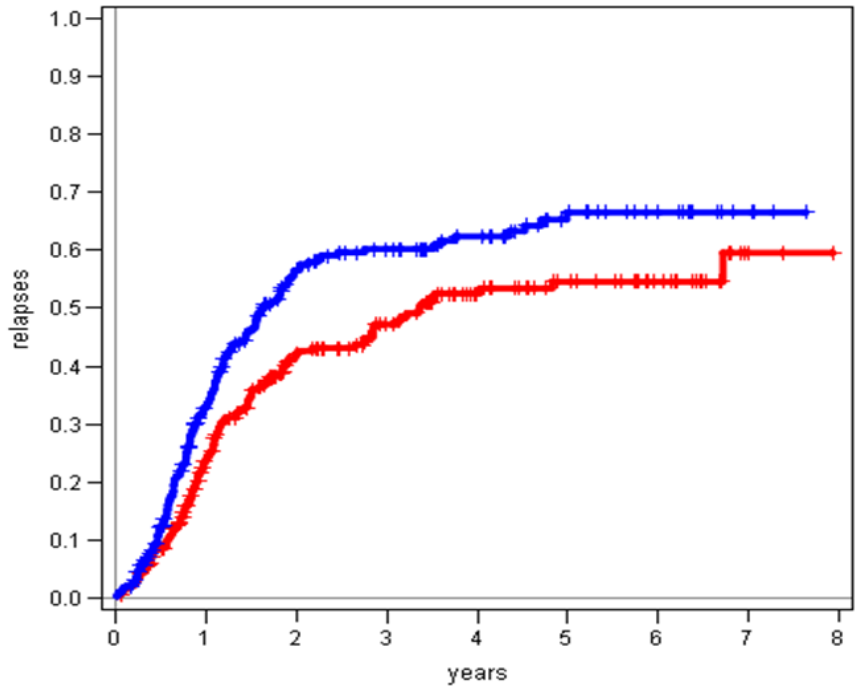
	Patients	Events	3-yrs. pEFS	p-value
BUMEL	281	136	0.49±0.03	<0.001
CEM	282	169	0.33±0.03	.

Toxicity vs. Relapse Rate

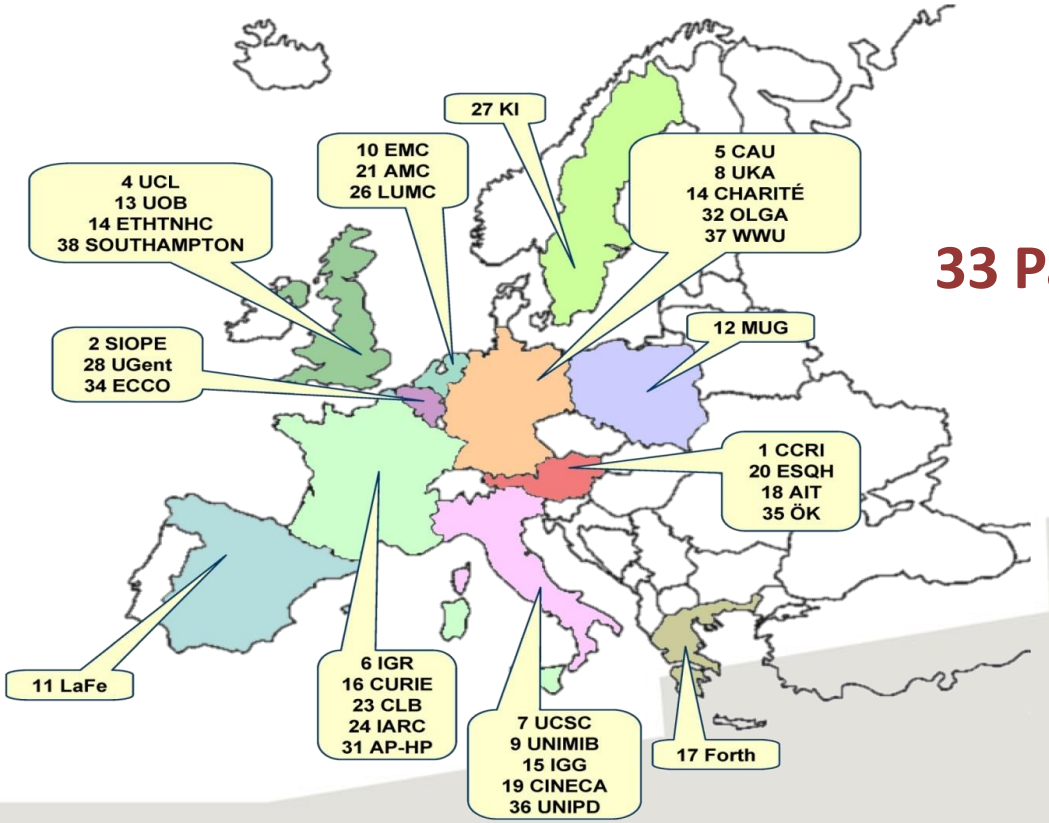
by Randomized Arm

BUMEL higher treatment efficacy !





	Patients		TRM		Relapses	EFS
BUMEL	281	12	0.04±0.01	124	0.47±0.03	0.49±0.03
CEM	282	17	0.06±0.01	152	0.60±0.03	0.33±0.03
log-rank		.	0.217	.	0.001	0.000
grey's test			0.325		0.004	



FP7 "Network of Excellence"

Kick Off January 2011

33 Partners / 11 European Countries

18 WP: 80 Milestones

82 Deliverables

St. Anna Kinderkrebs Forschung

SIOPE SIOP Europe

encca European Network for Cancer research in Children and Adolescents

European Network for Cancer Research in Children and Adolescents

European Network for Cancer Research in Children and Adolescents

Objectives

- Improve both cure and quality of cure of children and adolescents suffering of cancer
- Facilitate access to:
  - Innovative therapies and tailored medicines
  - Standard care across Europe
- Develop biology-guided therapies
- Propose a European Virtual European Institute for Cancer Research in Children and Adolescents

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ENCCA Virtual Institute

Towards the ENCCA Virtual Institute and fragmentation reduction in clinical and translational research in paediatric and adolescent oncology

- Harmonisation of care for children with cancer in EU
- Harmonised therapeutic strategies and access to drugs
- Referral schemes and easy access to care
- Better quality of life for children and teens
- High qualified and trained clinicians in Europe

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WEBSITE: www.encca.eu

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European Network for Cancer Research in Children and Adolescents

Home | Project | News & Events | Team | Community | Education | Dissemination and Deliverables | Intranet

ENCCA

Tweets Follow

SIOPE @SIOPEurope 1h

#multisciplinarity in Italy, le voci della ricerca a confronto @favo_it bit.ly/1brnplW

SIOPE @SIOPEurope 6 Dec

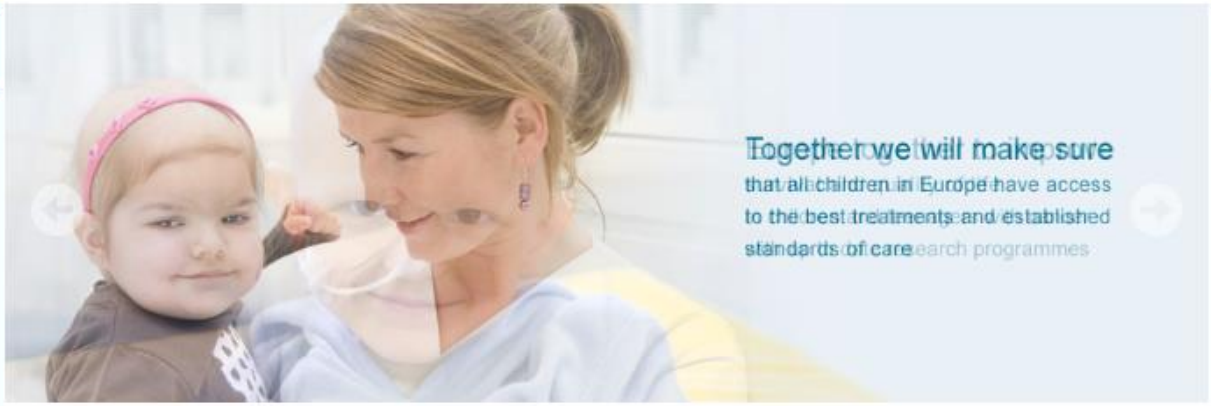
Lovely Vienna under the snow: #ENCCA & #ECRC meeting coming soon! siope.eu/?p=1176 bit.ly/IsHkF9

Tweet to @SIOPEurope

Upcoming Events

JANUARY 15

ENCCA General Assembly Meeting and ECRC meeting
Location: Vienna
Time: 12:00 AM



Latest News

The TRANSCAN Call has been published: 'Translational research on tertiary prevention in cancer patients'

TRANSCAN

The ERA-NET TRANSCAN Third Joint Transnational Call for Proposals (JTC 2013) has been officially launched on the topic "Translational research on tertiary prevention in cancer patients". ... (more)

Joint 25th Annual Meeting of the I-BFM SG & 9th Biennial Childhood Leukemia Symposium

Important Announcement!

ENCCA General Assembly Meeting and ECRC meeting on 15 - 17 January 2014 in Vienna.

REGISTER NOW

Search

European Clinical Research Council

Chairs of European Paediatric Oncology Research Groups

CWS (Cooperative Weichteilsarkom Studiengruppe or Cooperative Soft Tissue Sarcoma Study Group)

I-BFM (The International BFM Study Group)

SIOPEL (SIOPE-Epithelial Liver Tumour Study Group)

EHL (European Hodgkins Consortium)

SIOPEN (SIOP Europe Neuroblastoma Group)

EBMT (European Group for bone marrow and stem cell transplantation - Paediatric Working Party)

ITCC (Innovative Therapies for Children with Cancer)

EpSSG (European Paediatric Soft Tissue Sarcoma Study Group)

EWOG-MDS (myelodysplasia)

EICNHL (European Inter-group cooperation on childhood and adolescent Non Hodgkin Lymphoma)

EURAMOS (osteosarcoma)

EURO-E.W.I.N.G.

Germ Cell Tumours

SIOP-RTSG (SIOP Wilms Tumour)

UK Novel Agents Subgroup

Histiocyte Society

SIOP Brain tumour group

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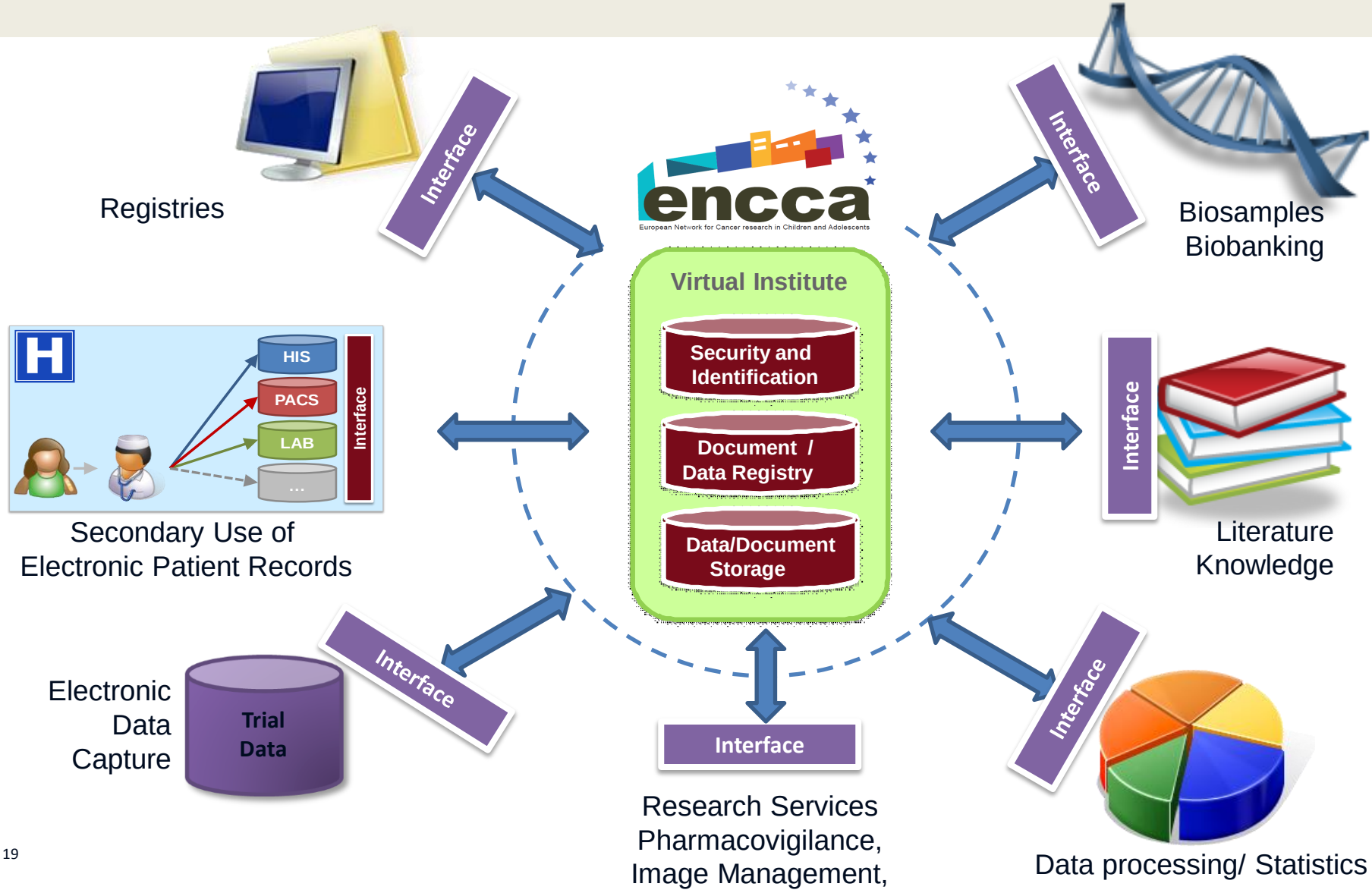
European Clinical Research Council
Chairs of the National Societies
of Paediatric Haemato-Oncology in Europe

- **Blue or pink**: European countries with NaPHOS (blue: in EU / pink: non-EU)
- **Dashed countries**: European countries without a NaPHOS

Elements of a Biomedical Research Infrastructure



What could be a solution for the encca requirements ?

This situation is similar to healthcare …

→ Adoption of a solution based on the

Integrating the **H**ealthcare **E**nterprise (**IHE**)

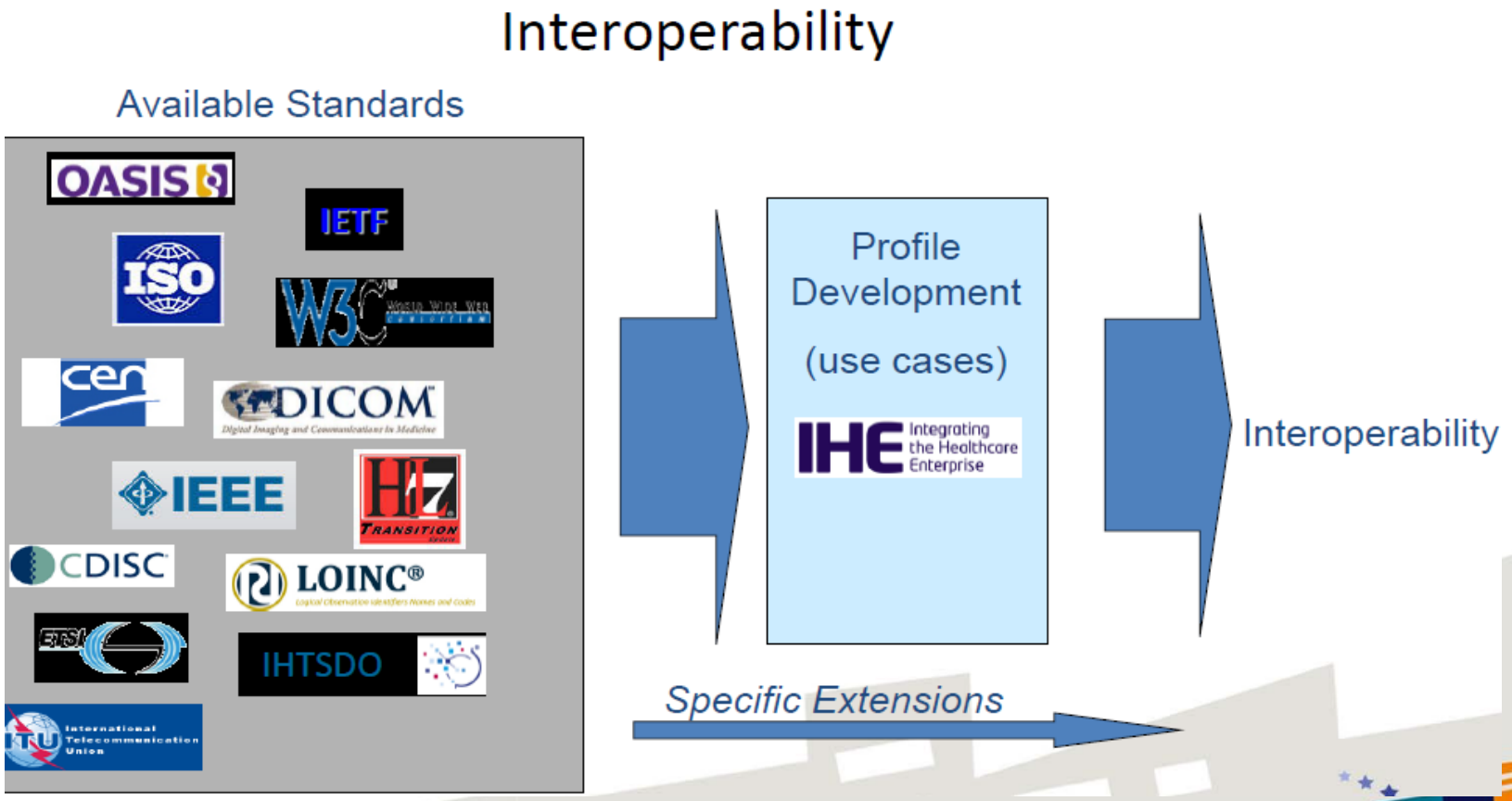
IHE Integrating the Healthcare Enterprise www.ihe.net

Integrating the Healthcare Enterprise

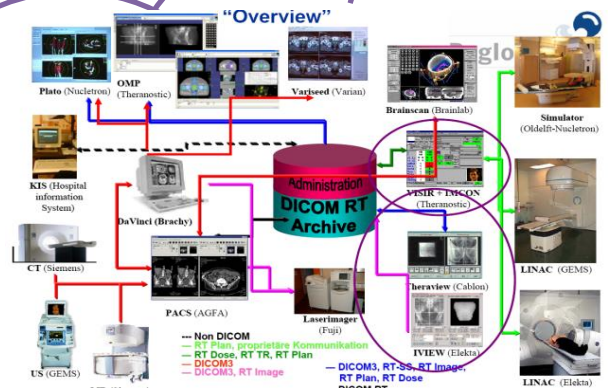
- IHE is designed for **interoperability**
- IHE is already **established and approved** in healthcare
- IHE is based on **standards commonly used** in healthcare and biomedical research
- IHE represents a **fully open approach**

- Integration of data
  - document based repository
  - no complete database model needed upfront
  - Takes care of the diversity of data, processes and research questions
  - Well poised for secondary use of data

To allow the exchange of information and the access to the various bio-banks and registries, ENCCA is planning to develop an interface allowing the exchange of information and access to different bio-banks and registries that is in compliance with respective EU data protection laws,



ICT Landscape



Institutional IT Systems

DICOM
Digital Imaging and Communications in Medicine

LOINC®

HL7

IHE Integrating the Healthcare Enterprise

Interoperability Initiatives

elga
Meine elektronische Gesundheitsakte

epsos
EUROPEAN PATIENTS SMART OPEN SERVICES

Health Information Exchange Systems

Directive 95/46/EC

ELGA-G

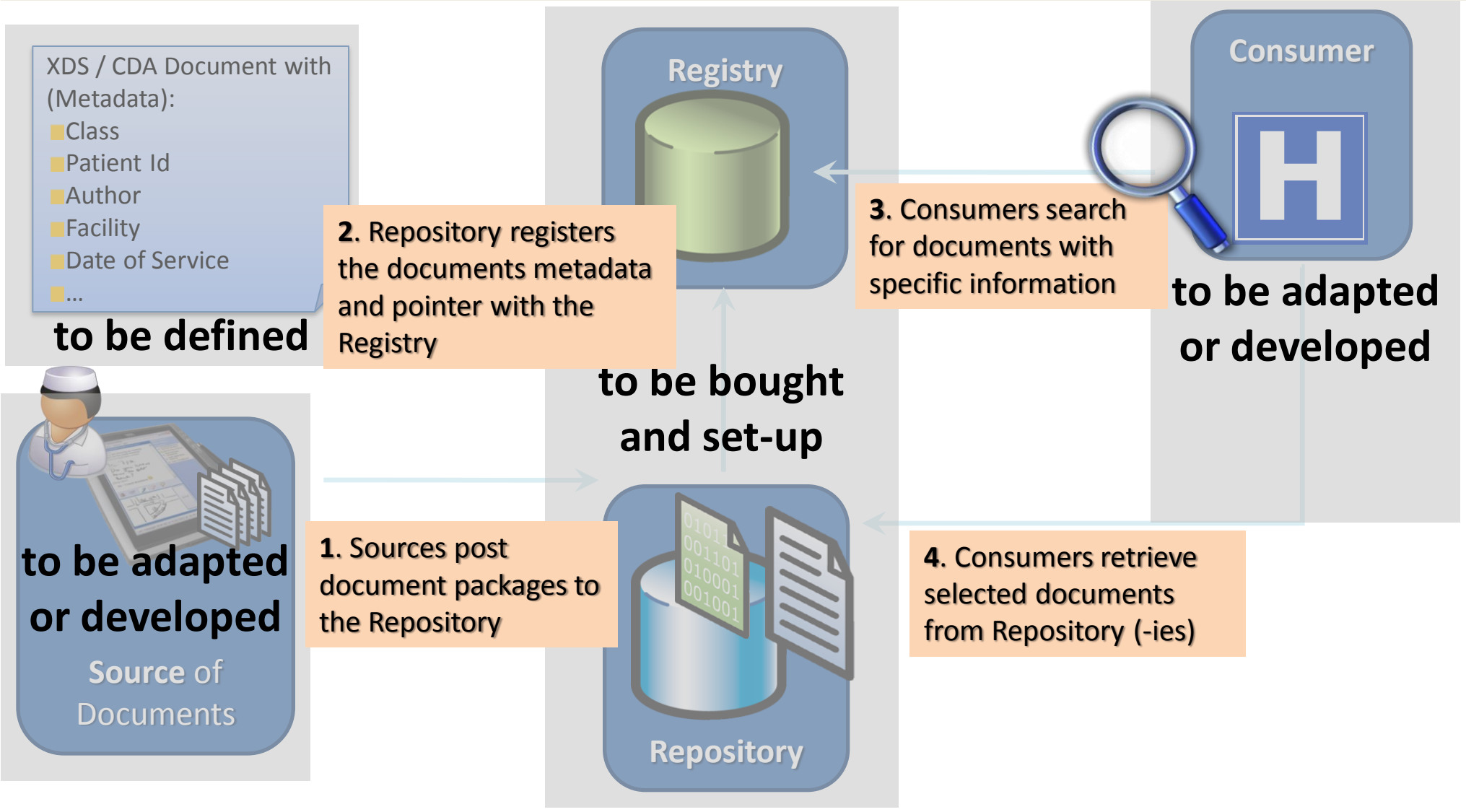
Directive 2011/24/EU

National and international Regulations

IHE Profiles

- Healthcare and research share similar needs, e.g.
  - Identity management
  - Security and Auditing
  - Image management
  - Consent management (Heinze O. et al BMC 2011)
  - Notification and update
  - Workflow support
  - …
- The IHE approach is designed for system-scale interoperability and
  - Sustainability (as standardised as possible)
- A core element is the Cross-Enterprise Document / Data Sharing (XDS) profile
  (one of many available IHE profiles)

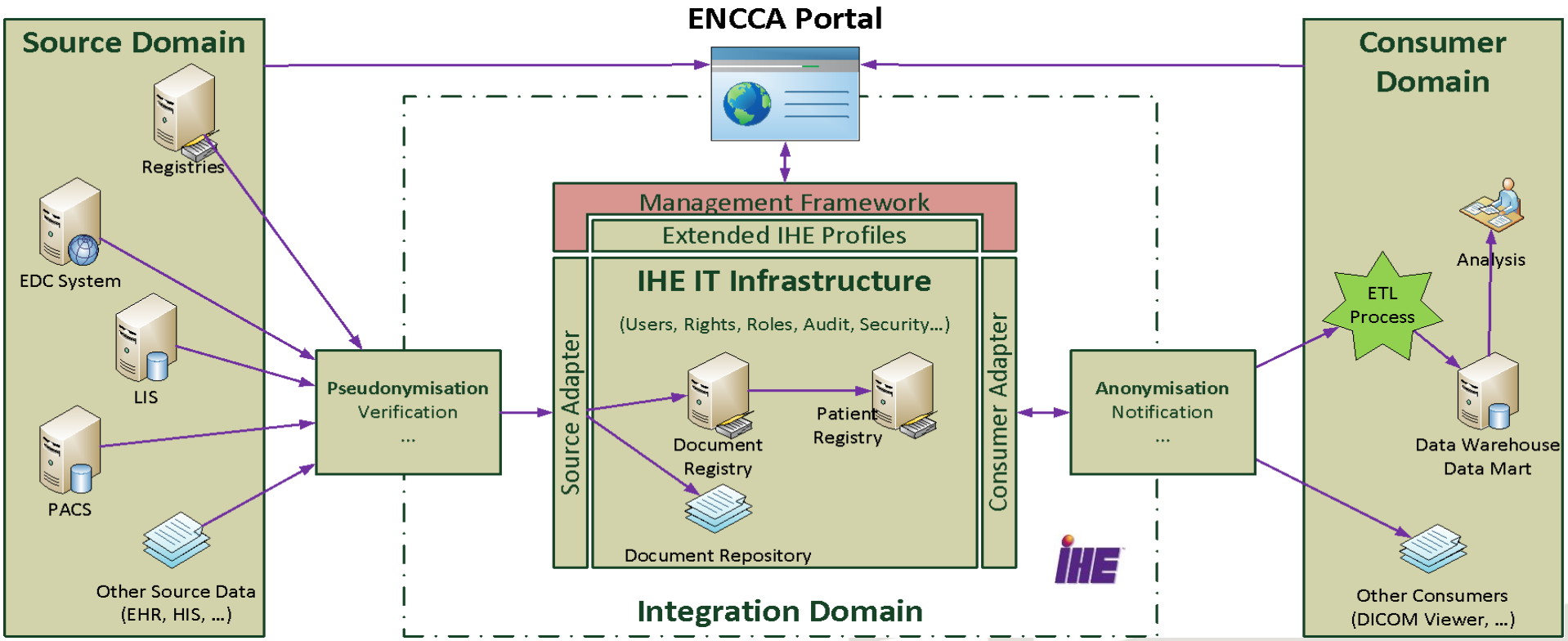
XDS Flow and Interactions



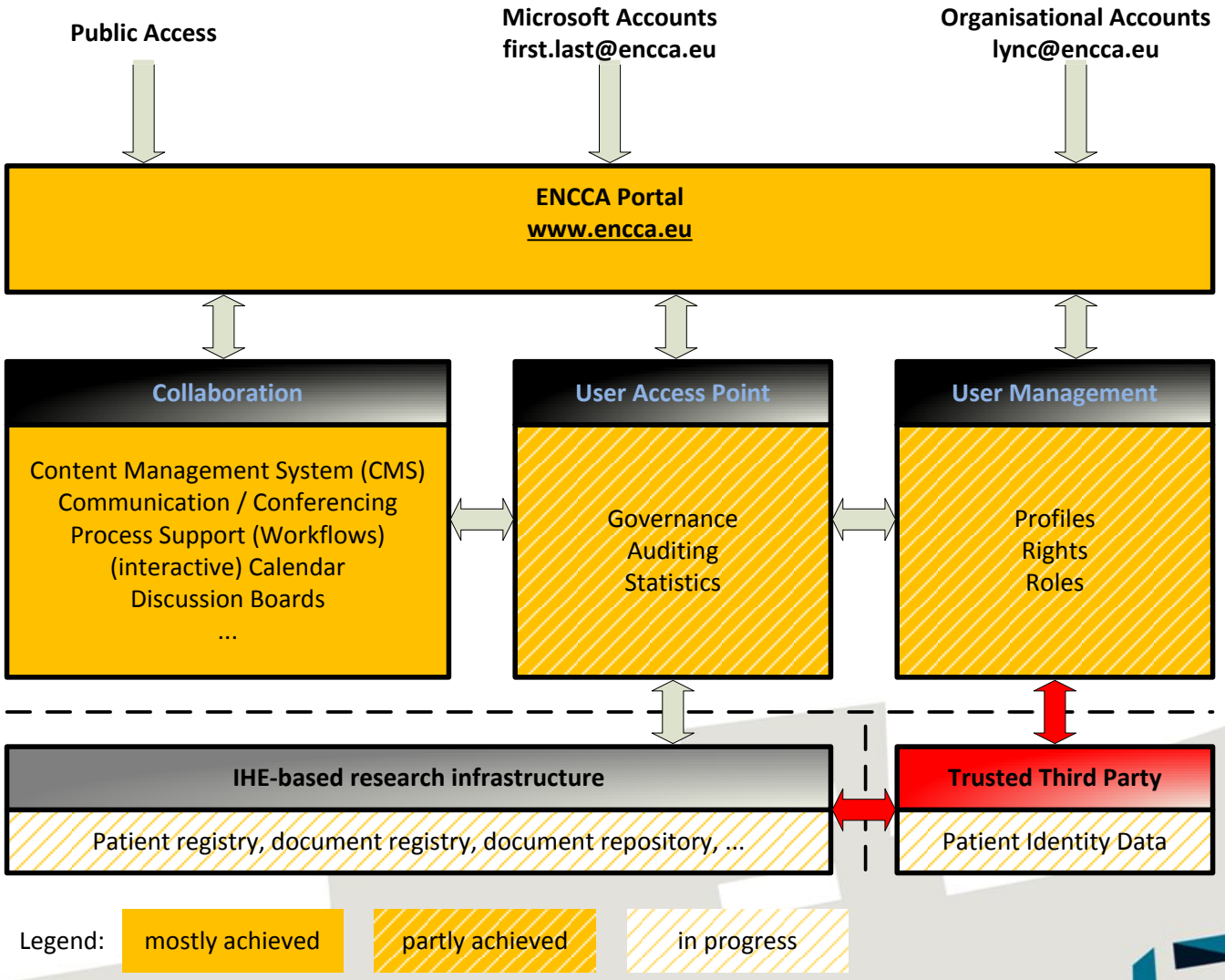
The encca virtual institute basic solution approach:

ABCD-4-E

Advanced **B**iomedical **C**ollaboration **D**omain **4** **E**NCCA



The ENCCA Virtual Institute Portal Approach



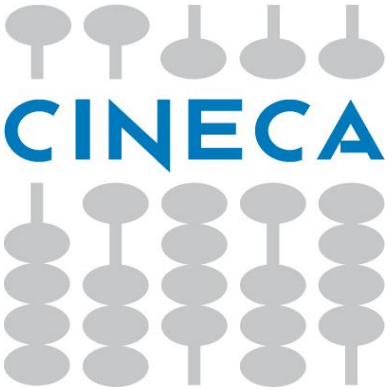
Bio-banks

- **ENCCA is developing a strategy to have a unique access point with standardised dataset to existing biobanks and databases, to facilitate data analysis and eventually new studies in paediatric oncology.**
- Federation of ENCCA biobanking resources is the **introduction of a unique patient identifier for every paediatric cancer** patient treated
- **Unified concept for patient consent forms** that is in accordance with national data protection laws in European countries.
- The consortium aims at interconnecting existing bio-banks **to arrive at a sustainable base for future joint data analysis and research.**

Next steps …

- Setup of a demo / prototype IHE infrastructure
- Implementing a typical use case:
  - short list:
    - Patient Registry
    - Image Management Service
    - Biomaterial Registry

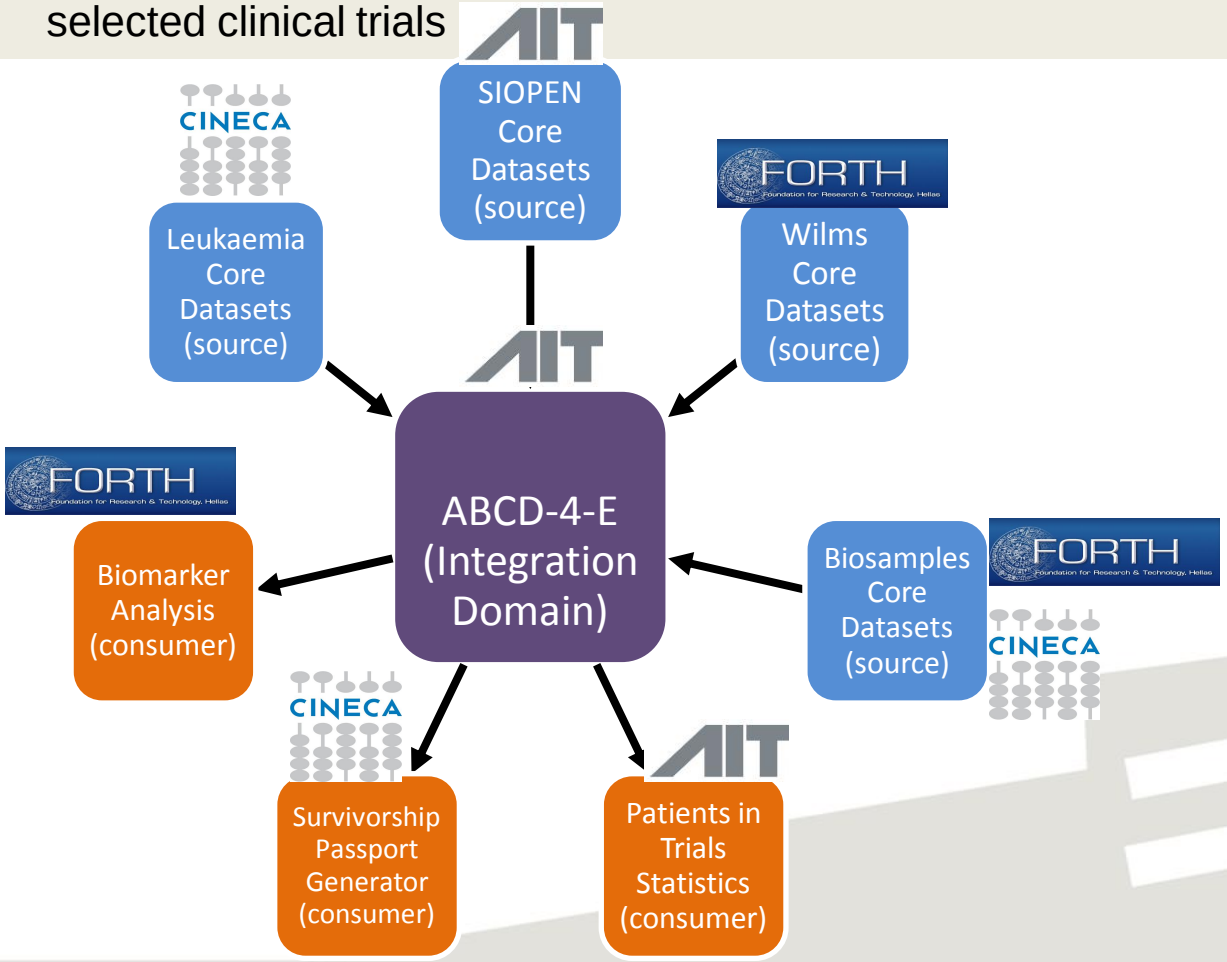
The 3 IT Partners



ABCD-4-E

Advanced Biomedical Collaboration Domain for ENCCA

- European Patients in clinical trials statistics (AIT)
- Survivorship Passport Generator (CINECA)
- Biomarker Analysis Suite (FORTH)
- Support the development and maintenance of standardised core datasets for selected biobanks and selected clinical trials



USECASE

PORTFOLIO

- 4 Source Systems
- 3 Consumer Systems
- 3 IT partners involved

The Survivorship Passport

PanCare
Pan-European Network for Care of Survivors after Childhood and Adolescent Cancer

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Pancare Childhood and Adolescent Cancer Survivor Care and Follow-up Studies
PanCareSurFup

- Riccardo Haupt
- Silvia Caruso
- Francesca Bagnasco

IGG

- Giulia Stabile
- Maurizio Ortali
- Davide Saraceno
- Roberta Amato

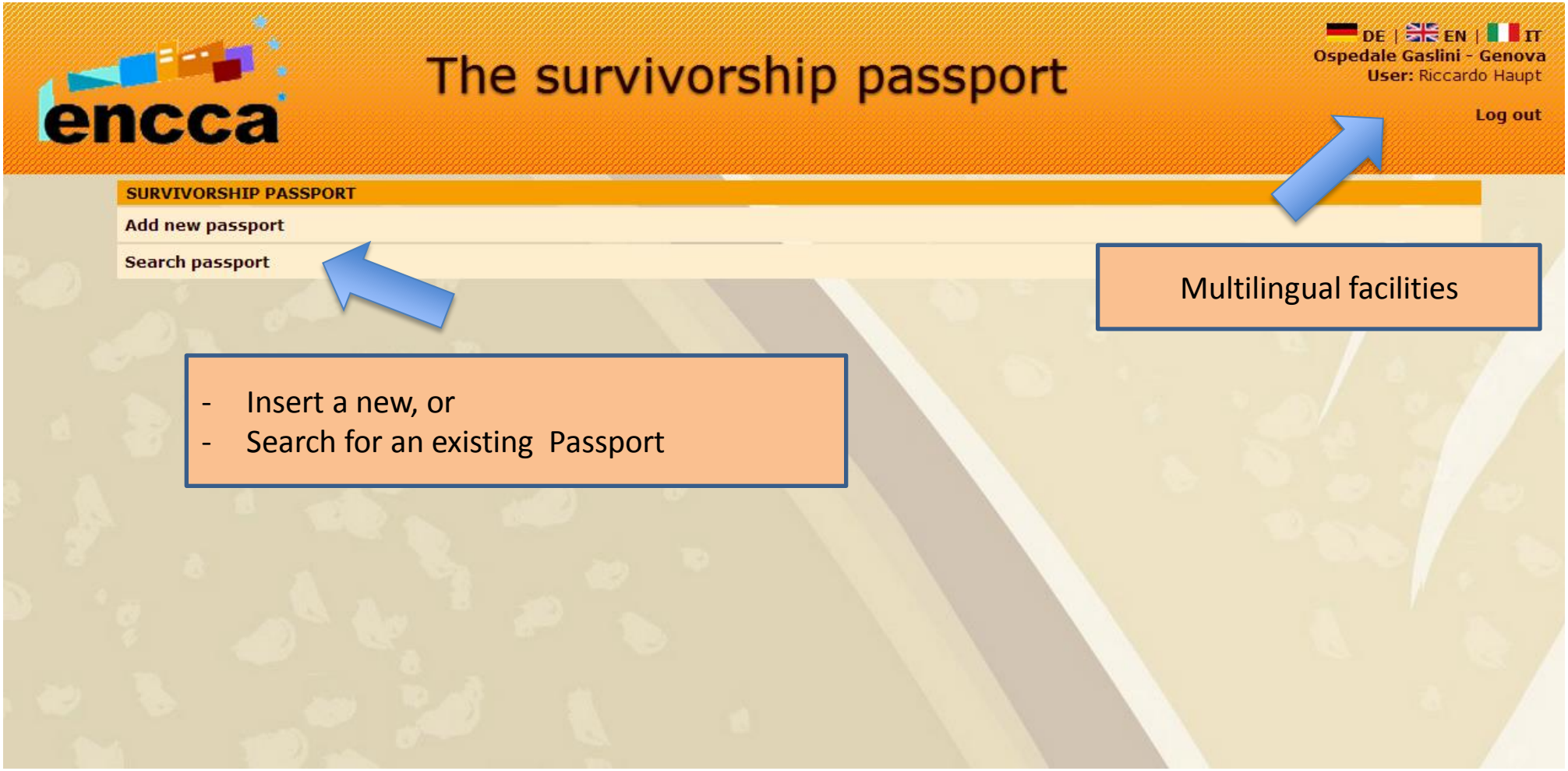
CINECA

- Sabine Karner
- Anita Kienesberger

ICCCPO

All partners of:
ENCCA: WP 13
PanCareSurFup: WP6

Home page


encca
The survivorship passport
DE | EN | IT
Ospedale Gaslini - Genova
User: Riccardo Haupt
Log out
SURVIVORSHIP PASSPORT
Add new passport
Search passport
Multilingual facilities
- Insert a new, or
- Search for an existing Passport

Diagnosis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The survivorship passport
DE | EN | IT
Ospedale Gaslini - Genova
User: Riccardo Haupt
Log out
Home >> Passports list >> Passport's View >> Diagnosis
N. passport
Initials
Date of Birth
Date of Registration
Diagnosis
IT001201304121011
DOE JHON
21/03/1999
12/04/2013
-
DIAGNOSIS FORM
Fields containing * are mandatory.
Date of diagnosis*
21
08
2007
dd/mm/yyyy
Primary treatment Center*
This Institution
DIAGNOSIS
Cancer category*
Ewing tumor and Askin tumor of bone
Diagnosis*
Diagnosis description
Askin tumor
Ewing sarcoma
Ewing tumor
SITE
Site description
Laterality
DETAILS
Cancer category according to ICCC-3 diagnostic group/division

Summary and Events after elective end of therapy

N. passport	Initials	Date of Birth	Date of Registration	Diagnosis
IT00120130227997	MARK SMITH	18/01/2009	27/02/2013	

Demographics

- [x] Demographic data

Diagnosis

- [x] Diagnosis

Clinical course

- [x] Front line treatment
- [x] Chemotherapy (from 05/02/2011 to 06/04/2012)
- [x] Stem Cell transplantation n.1 (03/09/2011)
- [ ] New: Stem Cell transplantation
- [x] Radiation Therapy
- [ ] New: Radiation Therapy
- [x] Surgery
- [ ] New: Surgery
- [x] Relapse/Progression n.1 (01/11/2011)
- [ ] New: Relapse/Progression
- [ ] New: Other relevant clinical events
- [ ] Medical suggestions

Relapse after first elective end of treatment

- [ ] Relapse/Progression

Second malignant tumor

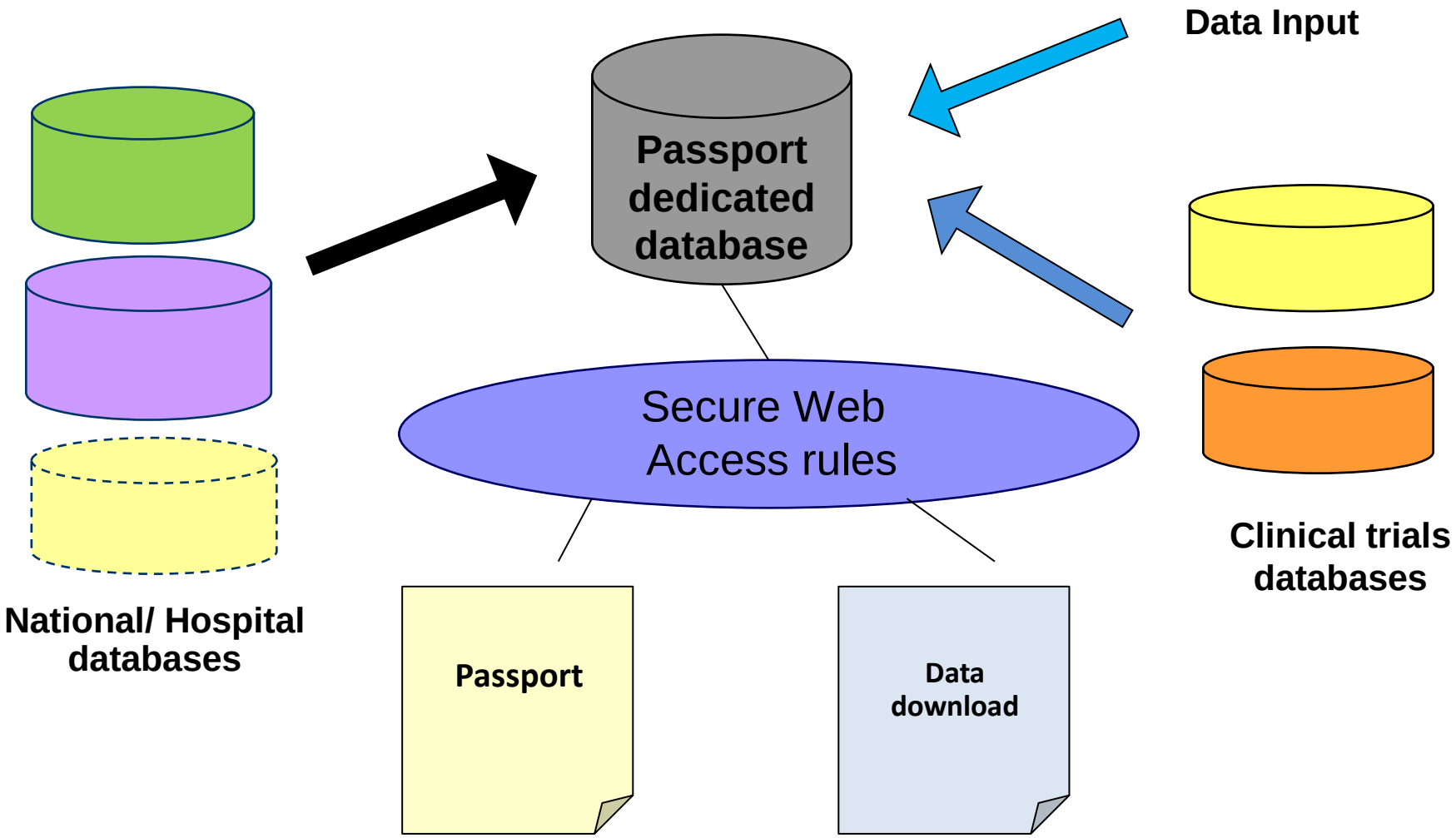
- [ ] Second malignant tumor

In case of relapse/progression after first elective end of treatment) a separate form is available

The survivorship passport
Data integration options

- Integration with existing data flows through **standard format files**
- Automatic or on-demand **data import** from local databases to Passport central database
- **Integration** with Clinical Trials databases
- **DB download** for hospitals according to data access rules
- Possibility to develop specific web services for seamless data integration

The survivorship passport data flow



The survivorship passport
Data integration

Data integration options are currently under testing to simplify the passport creation and let it be smoothly integrable among the interested parties

A first data mapping has been performed against:

- ✓ AIEOP ALL 2000 Protocol (Leukemia)
- ✓ AIEOP ALL 2009 Protocol (Leukemia)
- ✓ EPPSSG (Sarcoma)

Printable passport available

This Survivorship Passport is a short summary extracted from the information reported in the medical record. It describes the disease and its clinical course as well the treatments you received.
This document does not replace the medical record that is always available at our center.

JOHN KARTER

Passport number: IT001201304121012

Demographic data			
Date of birth	15/01/1988	Gender	M
Place of residence	BOLOGNA		
Contact belonging to	Survivor		
E-mail	d.saraceno@cineca.it		

Diagnosis			
Date of diagnosis	02/02/2012		
Institution	Ospedale Gaslini - Genova		
Cancer category/name	Hodgkin lymphomas		
High risk	No	Grade	2

Other diseases	
Predisposing genetics syndromes	No
Other medical conditions	No

Therapy			
Malignant tumor			
The treatment has been executed following	A trial		
Protocol	INTERL YM203	Arm/Randomization	II
Summary of major treatments	Chemotherapy Radiation therapy Major toxicity	Yes Yes No	

Chemotherapy		
Malignant tumor	Date	from 09/02/2012 to 12/06/2012
Drug	Total cumulative dose	
Doxorubicin	187 mg/m2	
Lucostin	8.5 gr/m2	
Nitrogen	5 UI/m2	

Radiation therapy	
n. 1	from 09/07/2012 to 13/07/2012
Site details	heart
Total dose	1890 cgy

Other relevant clinical events		
Malignant tumor	Fertility preservation	NK

Data are updated to the date of issue of the passport or the date of the last clinical examination certified by the physician.

Passport issued by Riccardo Haupt
Institution Ospedale Gaslini - Genova
Date 15/04/2013

Istituto Giannina Gaslini
UOC Ematologia e Oncologia
Responsabile Dott. G Dini
UOS Epidemiologia e Biostatistica
Responsabile Dott. R Haupt

The passport can be printed and signed by the clinician

Link to guidelines for follow-up

Clinical Recommendations

STRONG recommendation "*is recommended* "

MODERATE recommendation "*is reasonable* "

WEAK recommendation "*may be reasonable*"

NOT TO DO recommendation "*is not recommended*"

Definition of Risk Groups

- **Providers and women treated with chest radiation should be aware of breast cancer risk.**
- **Breast cancer surveillance *is recommended* for women treated with ≥ 20 Gy chest radiation.**

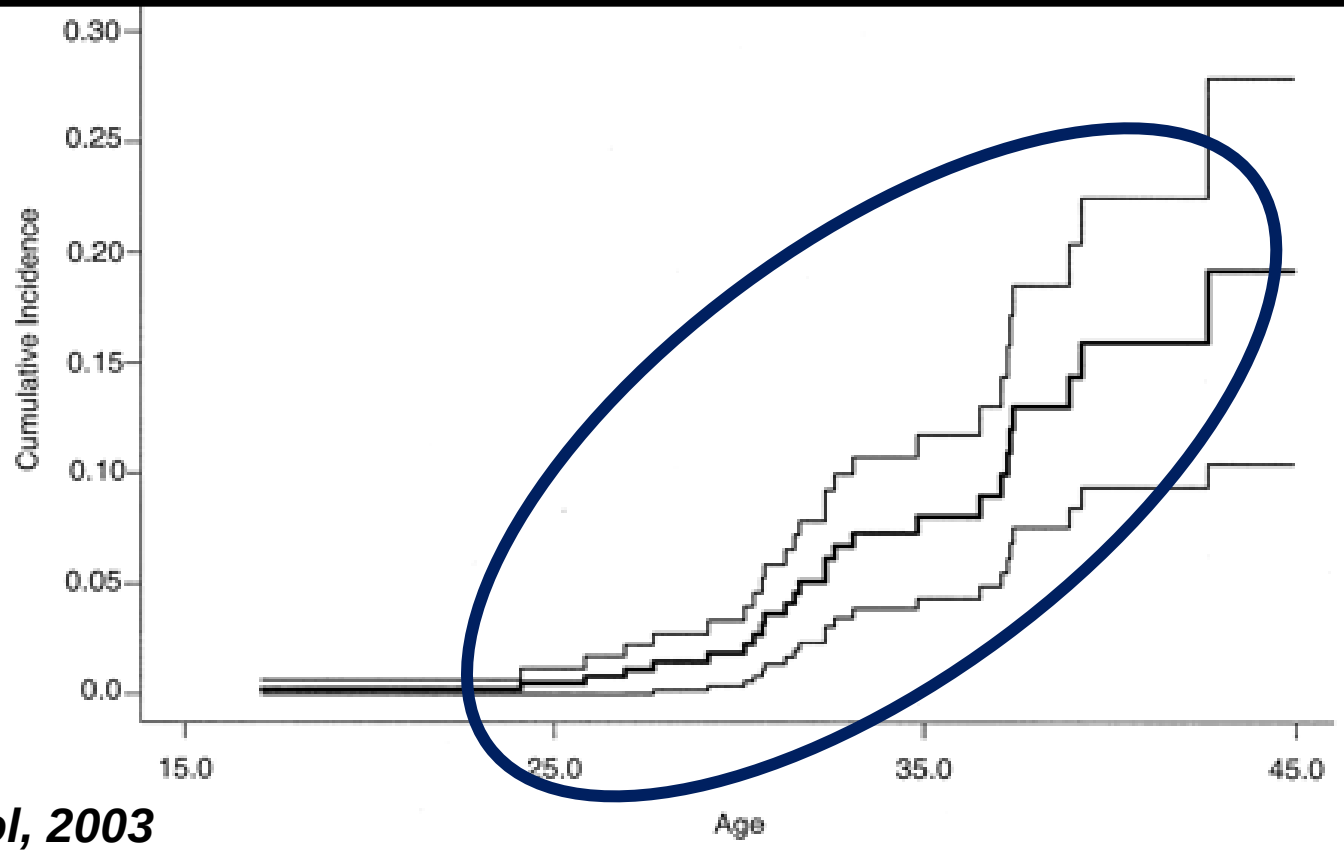
- **Breast cancer surveillance *is reasonable* for women treated with 10-19 Gy chest radiation based on clinical judgment and considering additional risk factors.**

- **Breast cancer surveillance may be reasonable for women treated with 1-9 Gy based on clinical judgment and considering additional risk factors.**

Age at Initiation of Surveillance

- **Initiation of breast cancer surveillance *is recommended* at age 25 years or ≥ 8 years from radiation (whichever comes last) for women treated with chest radiation.**

Median time to diagnosis of breast cancer from radiation exposure is 15 to 20 years, with cases being diagnosed as early as 8 years from exposure.



Bhatia et al. J Clin Oncol, 2003

Frequency of Surveillance

- **Annual breast cancer surveillance *is recommended* for women treated with chest radiation for at least up to 50 years of age**

- **Additional breast cancer surveillance (beyond that recommended by national health care systems) in women older than 50 years of age *is reasonable* based on clinical judgment and pending availability of further data.**

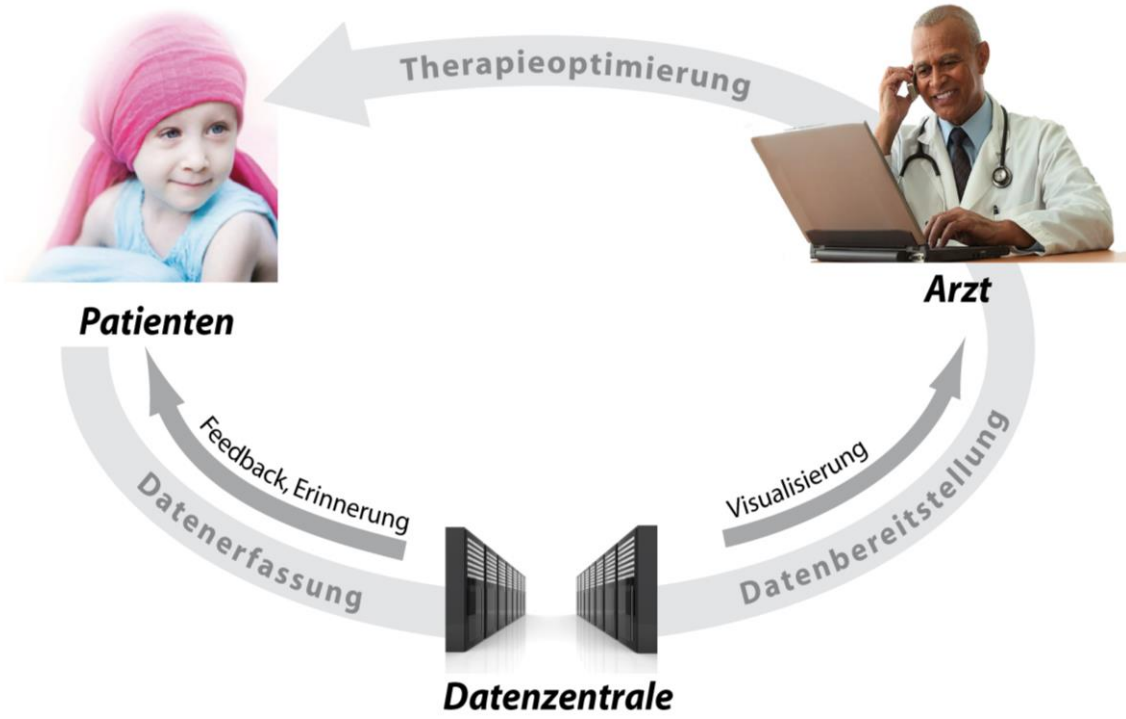
The Survivorship Passport
Present status and future vision?

- A template for the individual patient at the moment of the elective end of therapies containing standardized and condensed cancer history and relevant therapy information
- Paper and electronic based, potentially including images and other relevant medical source documents.
- To provide advice and guidance on patient-specific long-term follow-up of possible late effects
- **All languages of the EU ⇨ ExPO-r-Net**
- **Integration into future eHealth based platforms & tools for the survivor population allowing life long best possible care based on accurate information and paying tribute to Europe mobility**

Future expansion
Telehealth in Pediatric Heamato-Oncology

AUSTRIAN INSTITUTE OF TECHNOLOGY

- Interactive outpatient care
- Home surveillance of well being in modern treatment settings
- Prolonged ctn. low dose infusion of anti cancer drugs or immunotherapy (basic vital parameters, ..)
- Palliative Care Settings



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European Network for Cancer research in Children and Adolescents

A harmonised and integrated approach to the rationale introduction of molecularly targeted treatment in **clinical trials on leukaemia**

Task: Standardised comprehensive diagnostic approaches in leukaemias

Main achievements:

- After a **comprehensive survey among the partners** of the AIEOP-BFM ALL 2009 trial (AIEOP, BFM-A, BFM-CH, BFM-G, CPH, INS), on cytomorphology, immunophenotyping, cyto- and molecular genetics, MRD, TPMT genotyping and asparaginase monitoring plus several questions regarding infrastructure and biobanking, **diagnostic recommendations (guidelines) for ALL in clinical trials** have been generated and are published on the ENCCA website and on the website of the I-BFM study group (http://www.bfm-international.org).
- **Similar recommendations were finalized for AML.**

A harmonised and integrated approach to the rationale introduction of molecularly targeted treatment in **clinical trials on leukaemia**

Task: Establishment of a harmonized pipeline for molecular diagnostics in a European virtual laboratory setting using very high-risk ALL (VHRL) as a model system

- Main achievements:
  - **Scopeland software** has started to be used by German and Swiss AIEOP-BFM ALL study centers and the relapsed ALL trial at Charité.
  - **Agreement on a defined shared dataset on pediatric ALL.**
  - A meta database for interfacing Scopeland and other systems has been set up **(p-BIOSPRE),** is functional between Scopeland users and close to be functional for interconnecting additional partners.

  - **Successful TRANSCAN application (TRANSCALL) !**

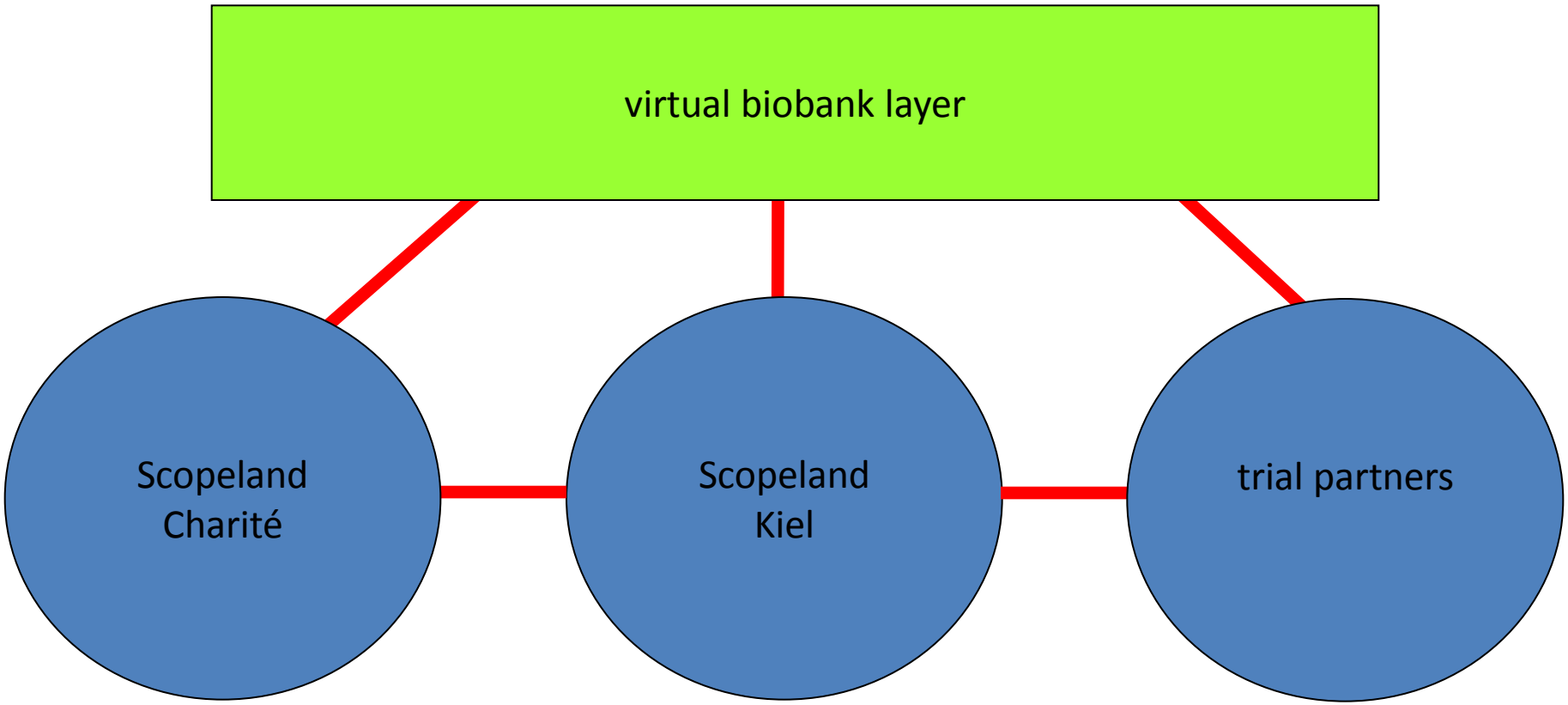
A harmonised and integrated approach
to the rationale introduction of molecularly targeted treatment in
clinical trials on leukaemia.

Scopeland

- laboratory infrastructure management system
- developed by Charité and Kiel
- web-based
- GCP-conformity assured
- four main modules:
  - cytomorphology
  - MRD
  - research
  - specimen bank
- generates reports and is fully flexibel

A harmonised and integrated approach
to the rationale introduction of molecularly targeted treatment in
clinical trials on leukaemia.

Scopeland database



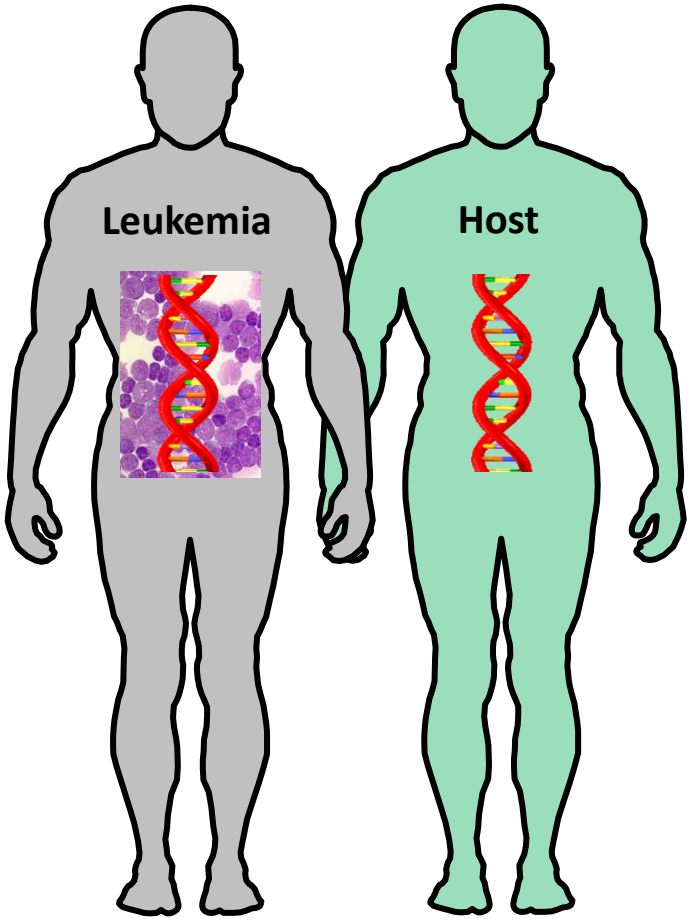
ALL: levels of genetic characterization

Initiation
- ETV6-RUNX1
-BCR-ABL1
- TCF3-PBX1
- Hyperdiploidy

Promotion / Progression
- PAX5, EBF1, IKZF1, BTG1
- CDKN2A/B, TP53, RB1
- CRLF2, JAK2/3, ABL1, PDGFRB, SH2B3, EPOR
- NRAS, KRAS, PTPN11, NF1, FLT3
- CREBBP
- NOTCH1, FBXW7, PTEN

Relapse
- NT5C2, HGPRT,
- CREBBP

- Cell cycle, self-renewal
- Lymphoid differentiation, hematopoiesis



- Tumor suppressors
- Cytokine receptors, kinases
- Ras signalling
- Epigenetic regulation

Hereditary genetic variants
- IKZF1, ARID5B, CEBPE, TP53, PTPRJ, PIP4K2A, GATA3

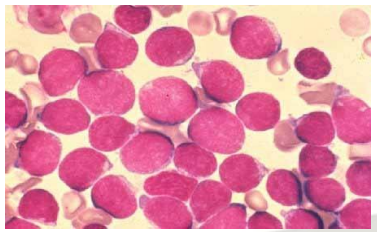
Predisposition syndroms
- Down syndrome,
- BLM, ATM, TP53, NBS1
- PAX5, IKZF1

Rational targeted treatment of ALL

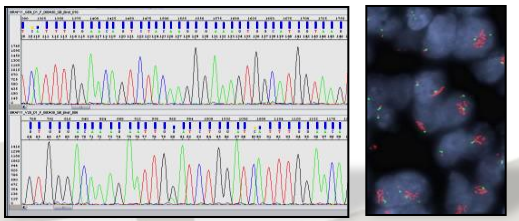
Leukemia patient

Clinical information

Bone marrow specimen



Routine diagnostics



Molecular diagnostics

Individualized treatment

Preclinical testing

A harmonised and integrated approach to the rationale introduction of molecularly targeted treatment in **clinical trials on leukaemia**

Task: Integration of a molecular diagnostic pipeline with preclinical model systems for molecularly targeted treatment and application of algorithms for identification and prioritisation of molecular targets

Main achievements:

- **Continuing joint assessment of molecularly defined entities by several groups** (e.g., IKZF1-deleted, CRLF2, ERG, TCF3/HLF) and data merging for joint analyses.
- Further extension of molecularly defined entities which have been amplified in mice (e.g., TCF3/HLF; TCF3/PBX1).

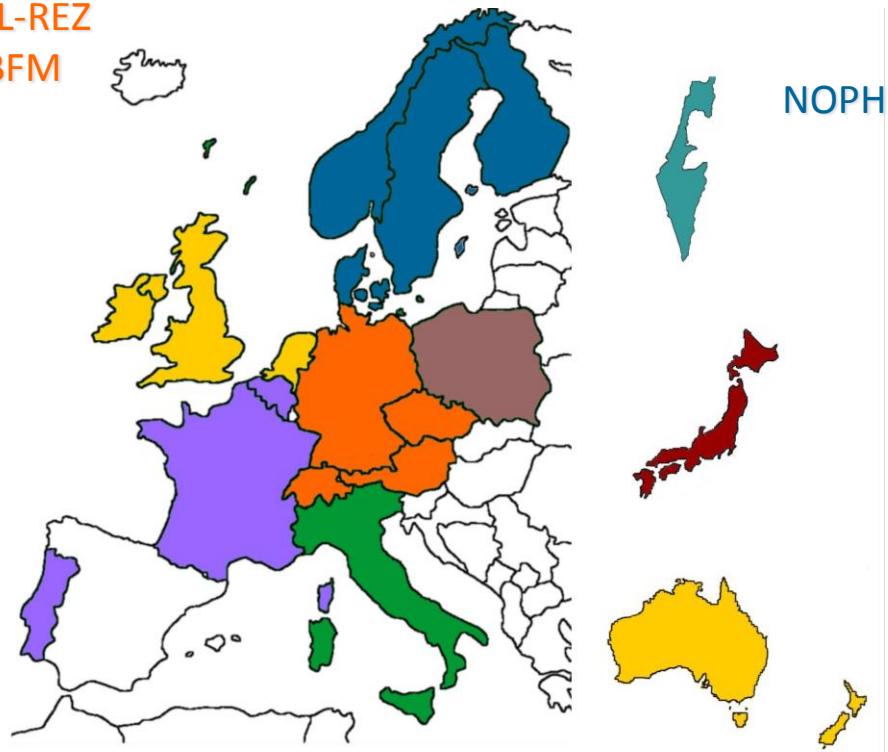
IntReALL 2010

International Study for Treatment of Childhood Relapsed ALL

Task: **Harmonization and integration of clinical platforms for the introduction of molecularly targeted treatment in leukaemias**

- Main achievements:
  - Further development of integrational acitivties regarding existing biobank data systems of different frontline and secondline clinical trial groups completed (p-BIOSPRE-based).
  - **IntReALL trial platform is functional.**

IntReALL



Austria: St. Anna

Czech Republic: MOTOL

Germany: Charité, MHH, XClin, TP21

Norway: OUH

Denmark: RH

Sweden: KI

Switzerland: UHZ

ALL-REZ BFM

NOPHO

USA: Immuno

Finland: TUH

UK: UMAN, UOXF, PGT

ALLR3

Poland: WMU

The Netherlands: UNMC, ICCPO

Israel: SCMC

Belgium: HURF

Japan: JPLSG

COPRALL

Portugal: IPOL

France: CHU

Italy: OPBG

Australia & New Zealand: ANZCOG

ENCCA network of collaboration: FP6 and 7 projects

name	Area of collaboration
PanCareSurfUp (FP7)	European sustainable strategy for clinical trial paediatric oncology. Clinical epidemiology and prospective registries for patients on standardised protocols Quality of survivorship (integration of late effect aspects into the survivorship passport creating personalised and risk based recommended health-checks)
CONTRACT (FP7)	Informed consent Legal and technical aspects and solution
EuroCanPlatform (FP7)	Bio-banking, e-mobility, training courses, regulatory issues concerning clinical trials, contact with industry. One of the member of the Steering Committee , Ulrik Ringborg, KI, is part of the SAB of ENCCA
IntReALL (FP7)	Improved therapeutic strategies using predictive biomarkers in leukaemias
P-MEDICINE (FP7)	Integrated clinical research infrastructure
EUROCOURSE (FP7)	Clinical epidemiology and prospective registries for patients on standardised protocols
ASSET (FP7)	Integrating clinical trials and tumor biology research in bone sarcoma
EuroBoNeT (FP6)	Integrating clinical trials and tumor biology research in bone sarcoma Development of a European Tumor Board for Centralised Local Therapy Planning

H. Kovar et al., "The First European Interdisciplinary Ewing Sarcoma Research Summit", Frontiers in Paediatric Oncology, 2012

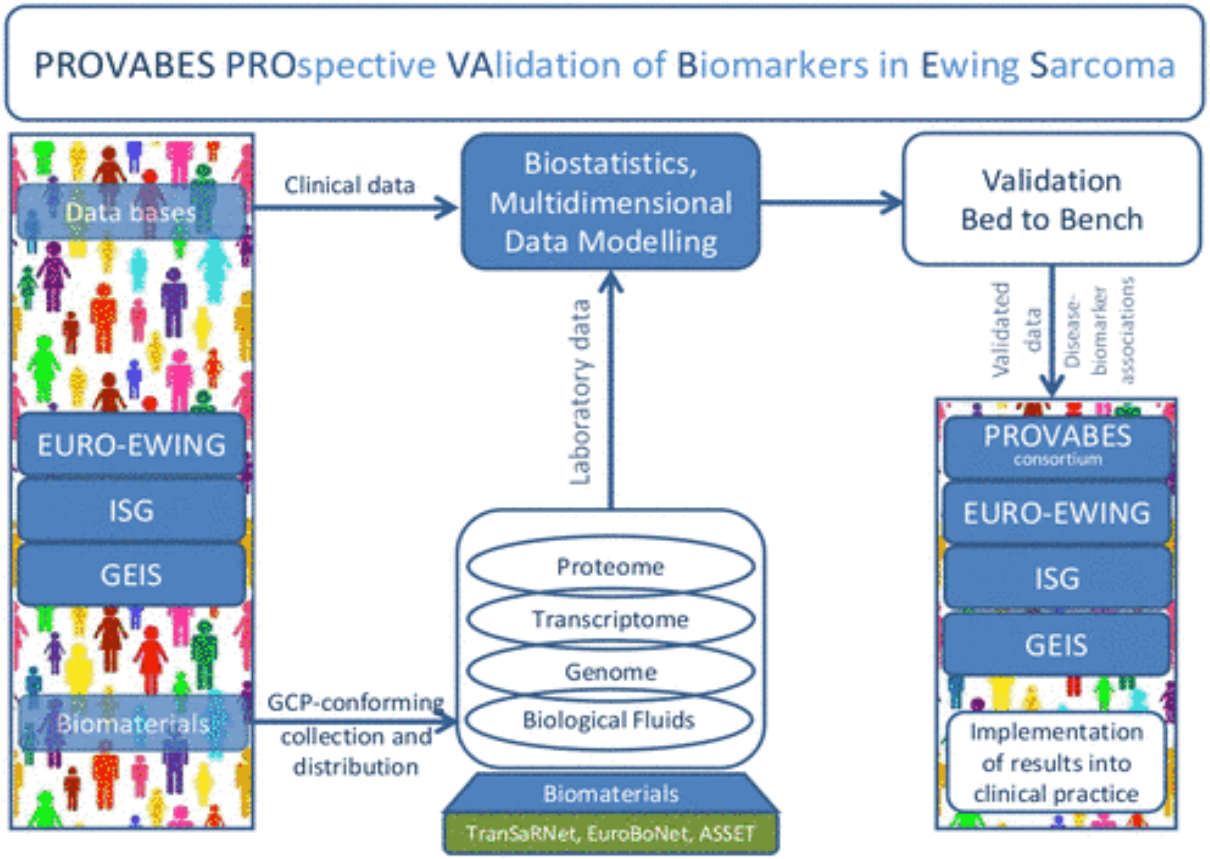
PROVABES

proving research

medizinische fakultät
Westfälische Wilhelms-Universität Münster

Concept

Overview on the PROVABES consortium and the respective objectives.



European Reference Networks

http://ec.europa.eu/health/cross_border_care/policy/index_en.htm

Directive 2011/24/EU on the application of patients' rights in cross-border healthcare

Enrique Terol MD; PhD, Seconded National Expert. Policy officer
European Commission, DG SANCO

Health and Consumers

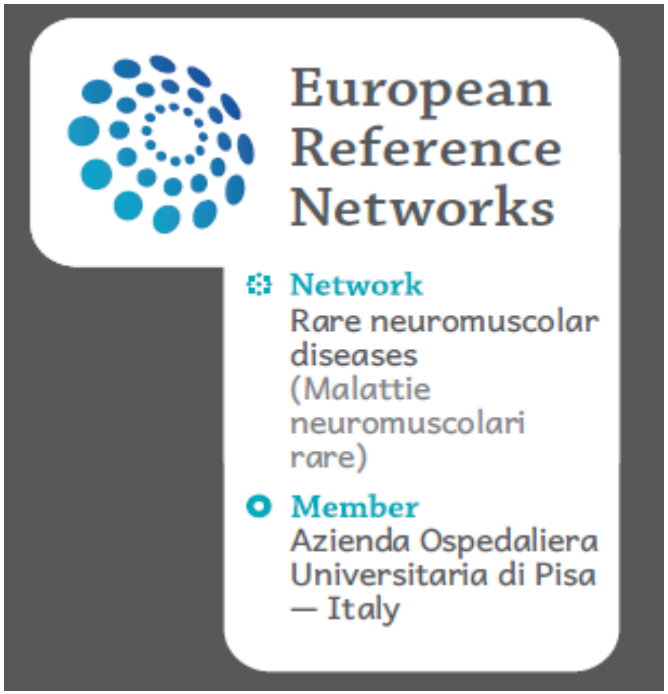
European Reference Networks (ERN): aim of Article 12:

(Directive Patient's Rights to Cross border Healthcare)

- **Support the development of European Reference Networks**
- Improving **access to highly specialised healthcare for patients suffering of** diseases and conditions**:**
  - **low prevalence/rare**
  - **complex and cost-intensive**
  - **requiring a particular concentration of expertise**

European Commission

European Reference Networks



Criteria and conditions for Networks

- ✓ *1. A.1.- have **knowledge and expertise to diagnose, follow-up and manage patients** with evidence of good outcomes*
- ✓ *1.A.2.- Follow a **multi-disciplinary approach***
- ✓ *1.A.3.- Offer a high level of expertise and have the capacity to **produce good practice guidelines** and to **implement outcome measures and quality control***
- ✓ *1.A.4.- Make a contribution to **research***
- ✓ *1.A.5.- Organise teaching and **training** activities*
- ✓ *1.A.6.- **Collaborate** closely with other centres of expertise and networks at national and international level*

Facilitate: **cost-effective use** of resources

Focusing on: **highly specialised healthcare / treatment recognised by international medical science**
(safety, value and positive clinical outcomes)

Criteria
Healthcare Providers

European Commission

General criteria for all Members in an ERN *(several sub-criteria for each criteria)*

(a) patients empowerment and centred care

(b) organisational, management and business continuity of the healthcare provider

(c) research and training capacity

(d) ***exchange of expertise, information systems and e-health tools***

(e) expertise, good practice, quality, patients safety and evaluation

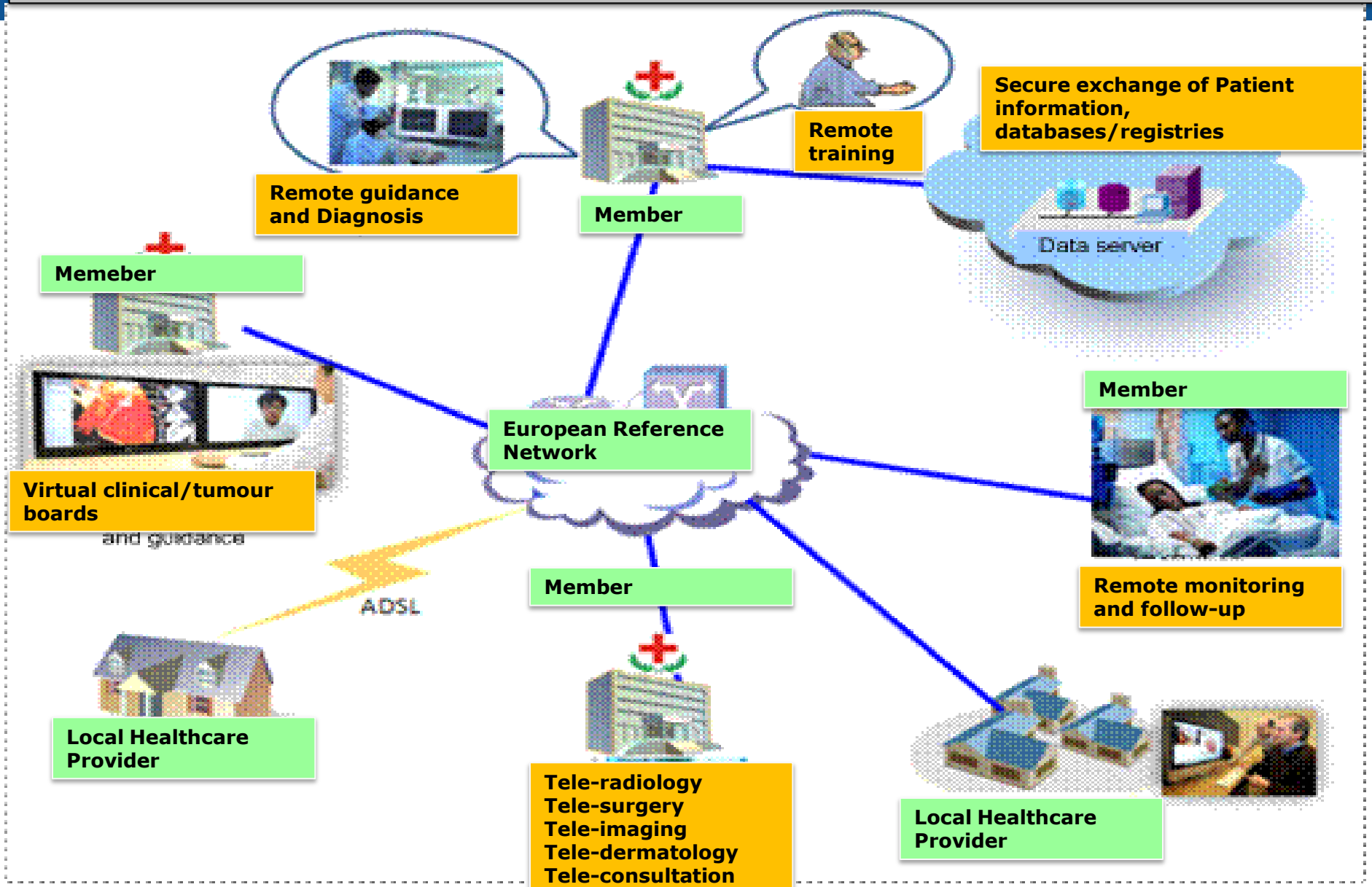
Specific Criteria for the Members adapted to the scope of the Network *(area of expertise, disease or condition)*

(a) competence, experience and outcomes of care

(b) specific human structural and equipment resources and organisation

Based on the evidence and consensus of the scientific, technical and professional community

Telemedicine and other IT solutions and tools are the basis for this project



Aim of the exploratory work on the networking dimensions of the Networks

- ✓ *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 **implement and analyze the feasibility** of the use at EU level of networking tools and IT solutions (virtual boards, transfer of images, e-learning etc..)*

Co-funded by
the European Union

Consumers, Health and Food
Executive Agency

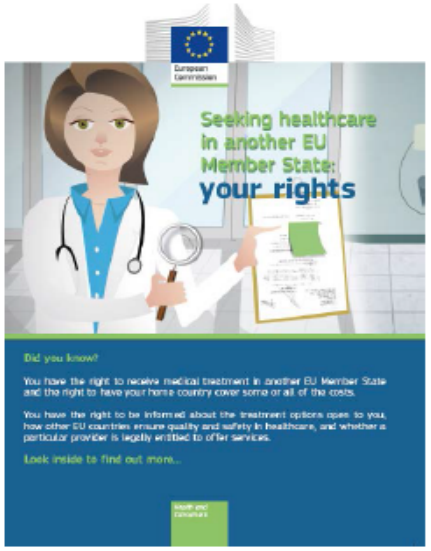
European Expert Paediatric Oncology Reference Network for Diagnostics and Treatment (ExPo-re-Net)

2013 12 07 ExPO-r-Net
Call: 4.2.2.7. Pilot networks of cooperation under Directive 2011/24/EU

European Commission

Key issues addressed by the Directive

Directive 2011/24/EU of patients' rights in cross-border healthcare



focussing on patients' rights & healthcare across the Union:

- Right to **choose and be reimbursed**, under certain circumstances for, **healthcare provided** by public or private providers located in the EU.
- More **transparency about their rights**, treatment options or , the quality and safety levels of healthcare providers
- Strong focus on **cooperation among Member States**:

Entry into force at National level 25 October 2013

Health and Consumers

EUROPEAN REFERENCE NETWORKS

Kick- Off, Luxemburg March 21st, 2014

2013 12 07 ExPO-r-Net

18 associated partners and 42 collaborating ones.

18 Associated Partners	Name	Country
CCRI (*Coordinator*)	St. Anna Kinderkrebsforschung e.V.	Austria
SIOPE	European Society of Paediatric Oncology	Belgium
IGR	Institut Gustave-Roussy	France
MUL	Medical University of Lublin	Poland
HULAFE	Fundación para la Investigación Hospital Universitario La Fe	Spain
ULUND	Lund University	Sweden
AOPD	Azienda Ospedaliera di Padova	Italy
IGG	Istituto Giannina Gaslini	Italy
CAU	Christian-Albrechts-Universitaet zu Kiel	Germany
AIT	Austrian Institute of Technology	Austria
CINECA	Consorzio Interuniversitario	Italy
INT	Istituto Nazionale dei Tumori	Italy
KlinikumDo	Klinikum Dortmund GmbH	Germany
UCL	University College London	United Kingdom
UOB	Lund University	United Kingdom
ECRMF	European Cancer Research Managers Foundation	United Kingdom
Charité	Universitätsmedizin Berlin: Charité	Germany
ÖKKH	Österreichische Kinder-Krebs-Hilfe	Austria

OVERALL AIM:

To reduce the current inequalities in survival by improving the quality of the current healthcare provided accross Europe , in particular European countries with lower healthcare.

Link pre-existing reference centres of excellence, seeking mechanism to facilitate movement of information and knowledge rather than patients (ICT tools, e-Health).

SPECIFIC OBJECTIVES:

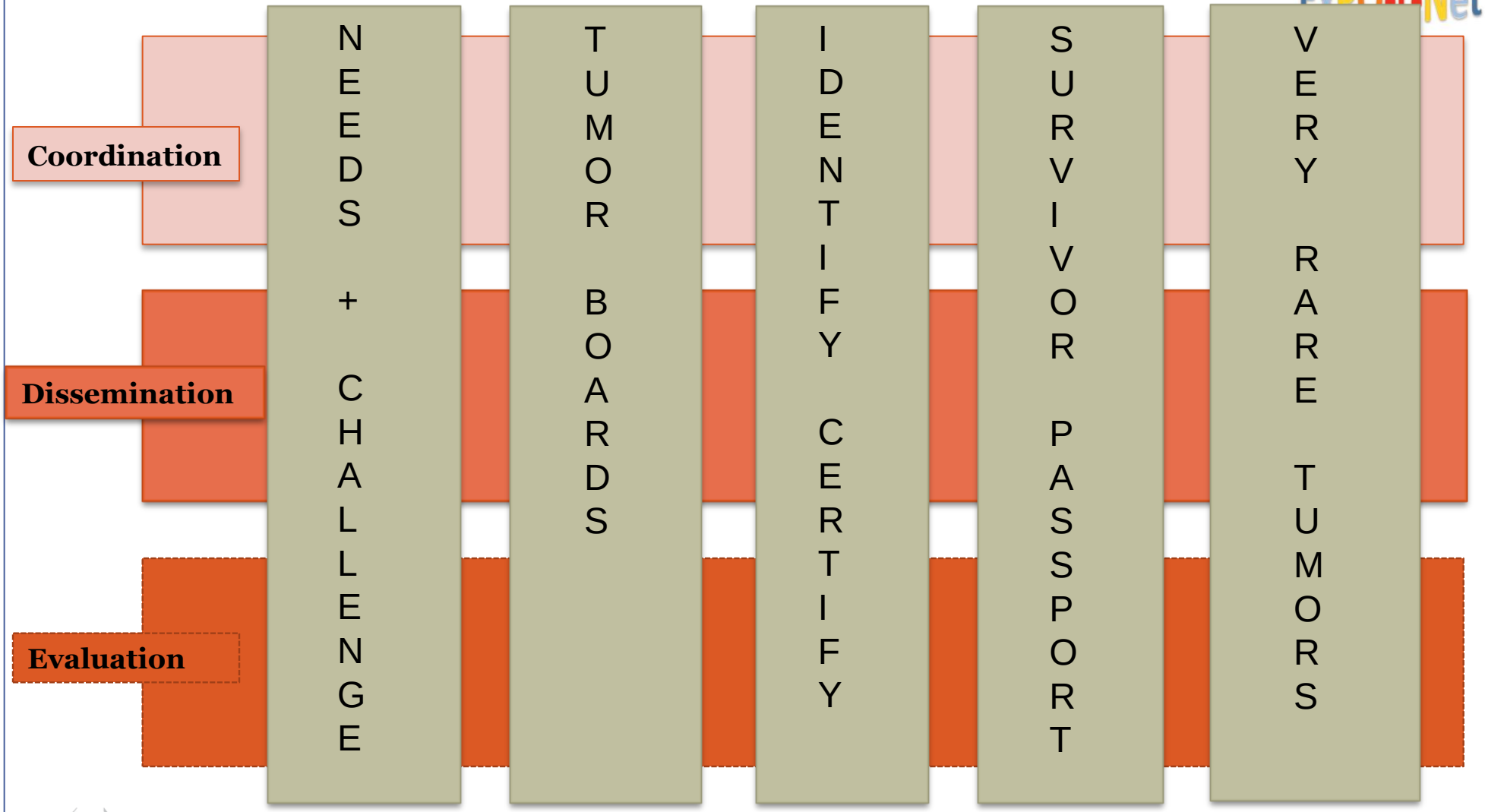
- Identifying needs of rare childhood and young people cancer types with experts (ECRC).
- Building a Paediatric Oncology ERN–roadmap to identified and certified reference sites and tumour boards.
- Establishment of a Paediatric Oncology tumour board ERN (IT tools –Ehealth)
- Defining the criteria for a common process for identification and certification of paediatric oncolog expert centres in Europe.

- The cross-border dimension of long-term follow-up of childhood cancer survivor in Europe: the survivorship passport.

- Integrating very rare tumors and sof tissue sarcomas into an European reference network.

THEMES

Project Coordinator Ruth Ladenstein



Structure

3 Horizontal Work Packages		Leader
1	**Coordination** of the project	CCRI
2	**Dissemination** of the project	SIOPE
3	**Evaluation** of the project	UOB
5 Core Work Packages		**Leader**
4	Addressing needs and challenges of cross-border healthcare co-operations and current expert fragmentation.	CCRI
5	Paediatric Oncology tumour board ERN based on E -Health and ICT concepts for sharing and providing expert advice.	HULAFE
6	Defining criteria for a common process for identification and certification of PO expert centres in Europe.	MUL
7	Cross-border dimension of long-term follow-up: survivorship passport with crucial treatment & followup data.	ULUND
8	Integrating children with very rare tumours in a European Reference Network.	AOPD

WP 4: CCRI

ExPO-r-Net

Addressing needs and challenges of cross-border healthcare co-operations and current expert fragmentation.

✓Identifying special therapeutic needs of young people with cancer with experts of the ECTG (ECRC) requiring high expertise interventions (i.e. special surgery, radiotherapy (proton therapy), stem cell transplants).

✓Addressing also the challenges (costs, resources, psychological burden and ethical aspects).

✓Identify European institution ready to engage as reference centers by establishing a/o rolling out tumor boards .

✓Identify European Institutions /hospitals offering top level expertise for special therapeutic interventions

Roadmap for public health care providers and patients

European Commission

WP 5: La Fe

Paediatric Oncology tumour board ERN based on EHealth/ICT concepts for sharing and providing expert advice.

- ✓ To develop a strategy to build Expo-r-net TB as tools for providing access to expert care to all European children with cancer in a cross-border setting.
- ✓ Implementation of modern IT tool across borders will allow TB to share expert opinions for European children with cancer in need ofspecial cross-border settings..

Expo-r-net Tumor Boards= Hubs of expertise

WP 6: Lublin

To promote high quality patient care in paediatric oncology centres through an internationally recognised system of certification and to reduce inequalities in care among centres and countries

- ✓ Build a Ped O ERN-roadmap to identify and certify reference centers and tumor boards.
- ✓ Define the criteria for a common process to achieve those.

Outcome: A European PO ERN expert reference manual.

WP 7: ULund

Cross-border dimension of long-term follow-up: survivorship passport with crucial treatment & follow-up data.

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

WP 8: Padova

Integrating children with very rare tumours in a 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)

Creation of a European Cooperative Group devoted to VRT

VISION:
OVERCOME INEQUALITIES IN EUROPE

A huge task and role

for Information Technologies

to treat Childhood Cancer and to improve outcomes!

Special thanks to IT partner
in Clinical Trial Management and
European Framework Projects
for more than a decade

AUSTRIAN INSTITUTE OF TECHNOLOGY

Objectives

Nb	Title
1	**Identifying the needs** of rare childhood and young people cancer types and entity subgroups with experts of the ECTG (ECRC) by addressing also the challenges (costs, resources, psychological burden and ethical aspects.
2	Build a **Paediatric Oncology ERN–roadmap** to identified and certified reference sites and tumour boards.
3	Establishment of a **Paediatric Oncology tumour board ERN** working to common standards and **using IT tools based on E-Hhealth** concepts for sharing and providing expertise and advise.
4	Defining the **criteria for a common process for identification and certification** of paediatric oncology **expert centres in Europe.**
5	The **cross-border dimension of long-term follow-up** of childhood cancer survivors in Europe: the survivorship passport as an instrument for crucial treatment and follow-up data.
6	Integrating **very rare tumors and soft tissue sarcomas** into an European reference network.