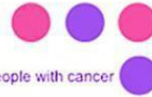




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Towards more and better cure - the critical role of collaborative clinical trial platforms

Professor Pamela Kearns

Chair of Clinical Paediatric Oncology, University of Birmingham

SIOPE President Elect

Overview

- How do clinical trials contribute towards **more and better cure**?
- What are **collaborative clinical trial platforms**?
- What are the **challenges now and in the future** ?



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How do clinical trials contribute towards more and better cure

How do doctors decide on the best treatment?



Training



Experience



Evidence
from
research
**Evidence
from clinical
trials**



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Building Evidence from Clinical Trials

- Clinical Trials provide the **scientific evidence** doctors need to make decisions on the best treatment for a individual patient
- **Clinical Trials test if a new treatment**
 - is safe
 - is effective
 - is better than current best clinical practice



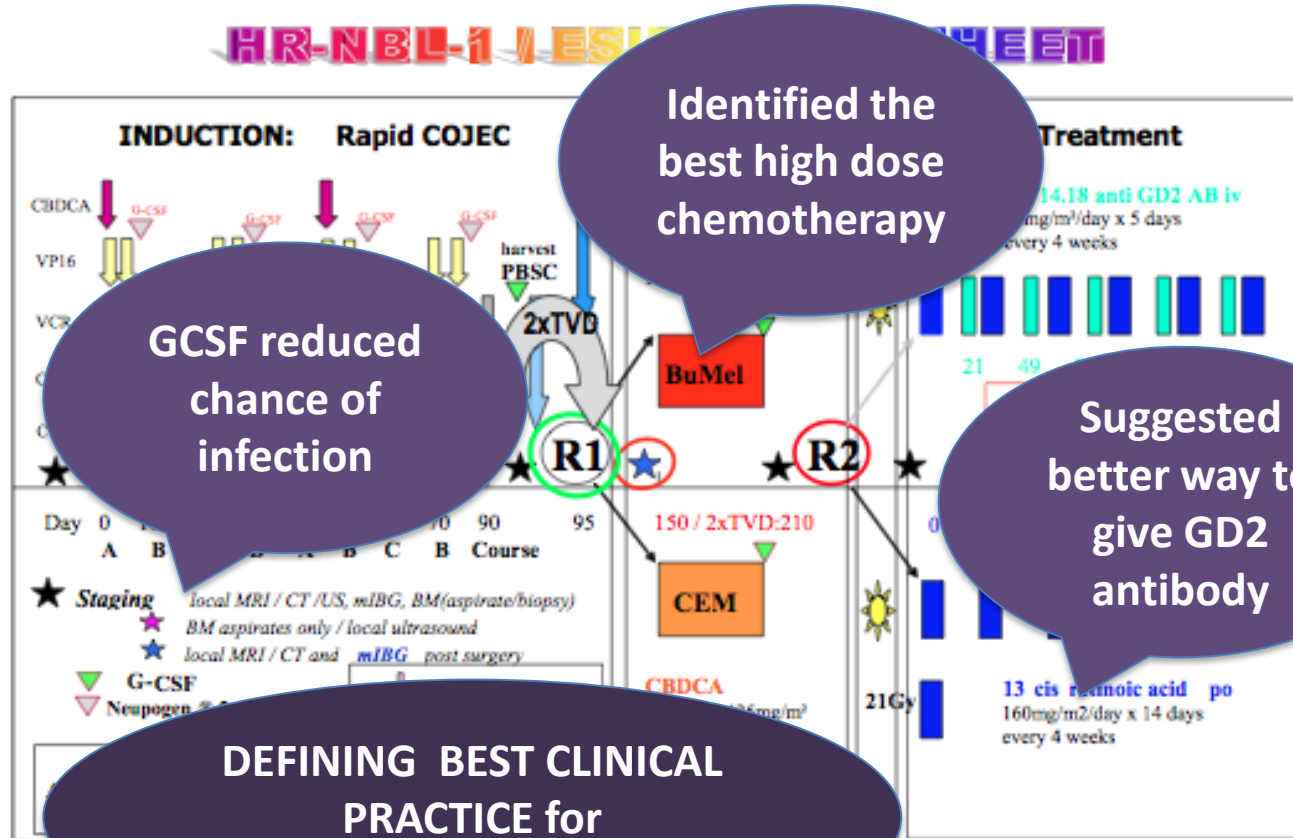
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Clinical trials change clinical practice

9



DEFINING BEST CLINICAL PRACTICE for NEUROBLASTOMA



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Delivering Clinical Trials for Childhood Cancer

- **Challenged by:**
 - Small patient groups
 - Balance between improved survival and less side effects
- **Need for:**
 - International collaboration
 - innovation in trial designs
 - Maximising what we learn from every patient on trials



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Collaborative Clinical Trial Platforms

SIOP-RTSG
(SIOP Wilms Tumour)

Renal Tumours

Soft Tissue Sarcomas

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

EpSSG
(European Paediatric Soft Tissue Sarcoma Study Group)

Soft Tissue Sarcomas

Stem Cell Transplantation

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

PanCare

Survivorship and Late Effects

Very Rare Paediatric Tumours

EXPeRT
(European Cooperative Study Group on Paediatric Rare Tumours)

EURBG
(European Retinoblastoma Group)

Retinoblastoma



European Clinical Trial Groups



SIOPEL
(SIOPE-Epithelial Liver Tumour Study Group)

Liver Tumours

Myelodysplasia

EWOG-MDS

SIOPEL
(SIOPE Europe Neuroblastoma Group)

Neuroblastoma

New Anticancer Agents

ITCC
(Innovative Therapies for Children with Cancer)

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

Non-Hodgkin Lymphoma

Osteosarcoma

EURAMOS

SIOPE
(Brain tumour group)

Brain Tumour

Ewing's Tumour

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

Germ Cell Tumours

Germ Cell Tumours

Hodgkin's Lymphoma

EHL
(European Hodgkins Consortium, EuroNet-PHL)

Histiocyte Society

Langerhans Cell Histiocytosis

Leukemias and Lymphomas

I-BFM
(The International BFM Study Group)

NAVIGATING THE REGULATORY FRAMEWORK

Clinical Trials Regulation

Human Tissue Act

2018

EU Clinical Trials Directives

Advanced Therapies

Research Ethics Frameworks

Data Protection

ICH Good Clinical Practice

Medicines Acts

Declaration of Helsinki

Nuremburg Code

ESSENTIAL BUT COMPLEX
& COSTLY REQUIREMENTS

1940s



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Collaborative Clinical Trial Platforms



European
Clinical Trial
Groups

In 2018: 54 INSTITUTIONS IN 14 COUNTRIES



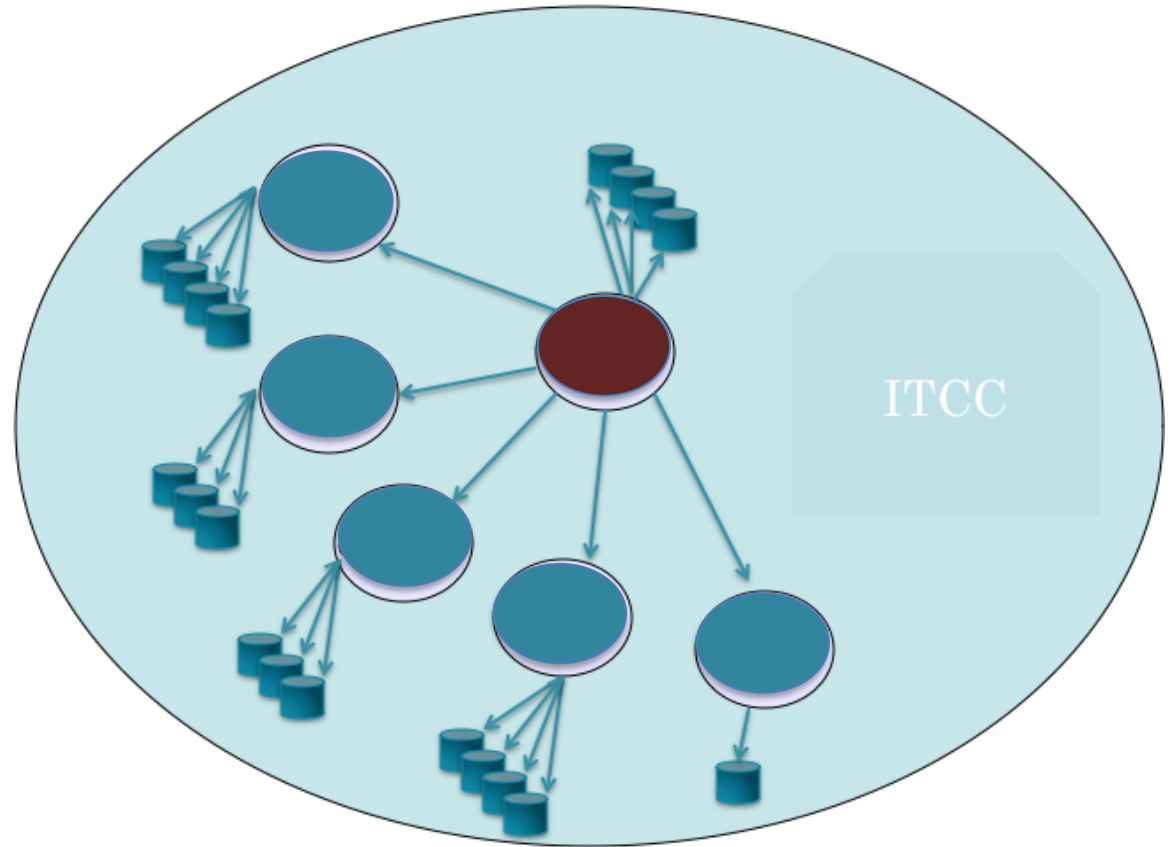
- ⚙️ **4 500 children / year** diagnosed with cancer in ITCC centers
- ⚙️ **20% relapse** and are offered to participate in ITCC trials
- ⚙️ **ITCC offers a comprehensive programme of early clinical evaluation of anticancer drugs for children and adolescents**

COLLABORATIVE PLATFORMS FOR TRIAL DELIVERY

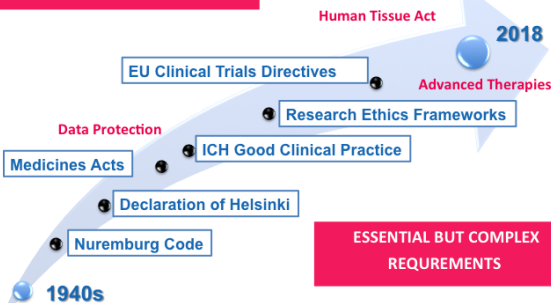
 **International Sponsoring Centre**

 **National Co-ordinating Centres**

 **Trial hospitals**

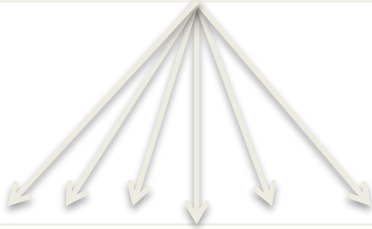


NAVIGATING THE REGULATORY FRAMEWORK

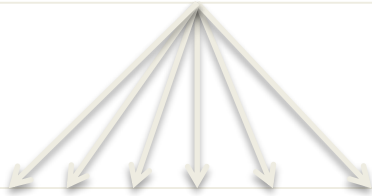


BEACON- Neuroblastoma

International Sponsor
University of Birmingham CRCTU
CI Lucas Moreno

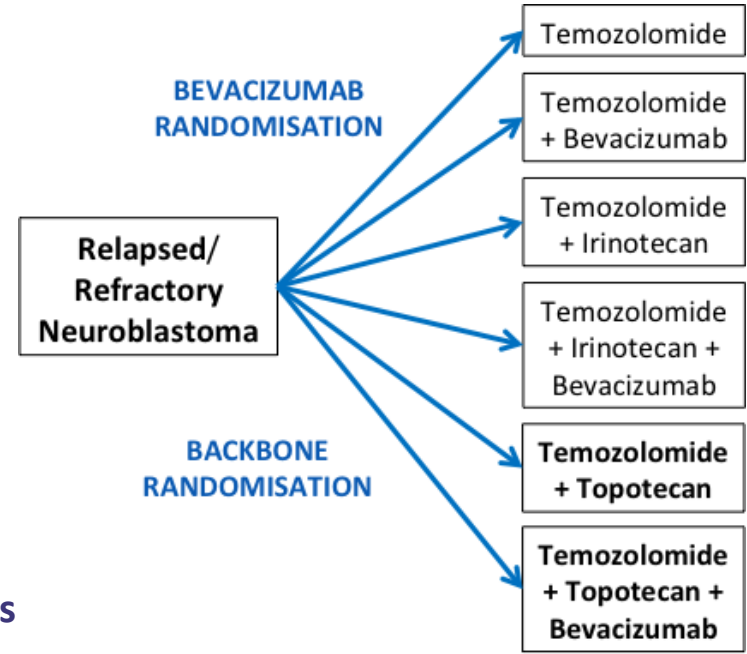


7 National Coordinating Centres
National coordinating investigator
identified in each country



20-26 Sites
Principal investigator in each site

- Regulatory submissions
- Initiation of sites
- Monitoring
- **Funding**



What are the **challenges now and in the future** ?

- **Sustainability of collaborative clinical trial networks**
- **Funding**
 - **Dissociated funding in different countries**



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Working to address the Challenges:

- Working together in collaborative research networks
 - Building on EU funding



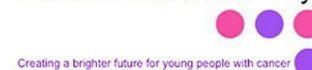
- SIOPE Clinical Trials Facilitation Platform
 - Clinical contract template
 - International Protocol template
 - Harmonising academic trial Sponsor activity



- Implementation of the EU Clinical Trial Regulation



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What are the challenges now and in the future ?

- **Sustainability of collaborative clinical trial networks**
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 - **Dissociated funding in different countries**



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Unified and accelerated by EU funding



ChiLTERN

Children's Liver Tumour

European Research Network

**1% of all childhood cancer
annual incidence of 0.8 per million
children**

*aim to **cure more children** with liver cancer, expose **fewer children to toxic chemotherapy** and ensure their surgery is both effective and safe*



PHITT

Paediatric Hepatic International Tumour Trial

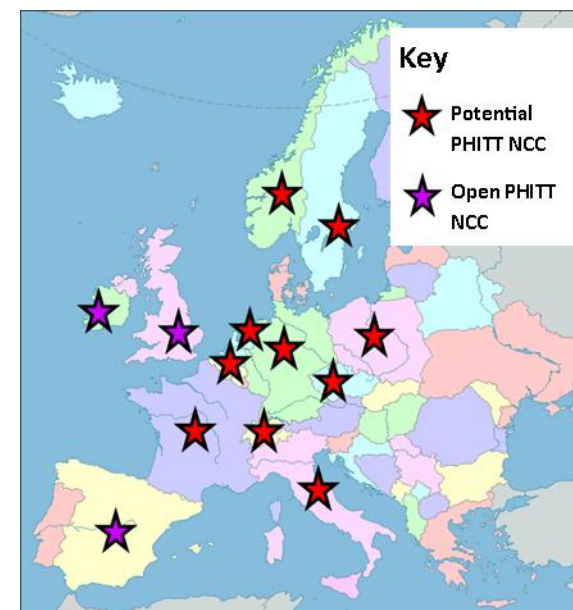
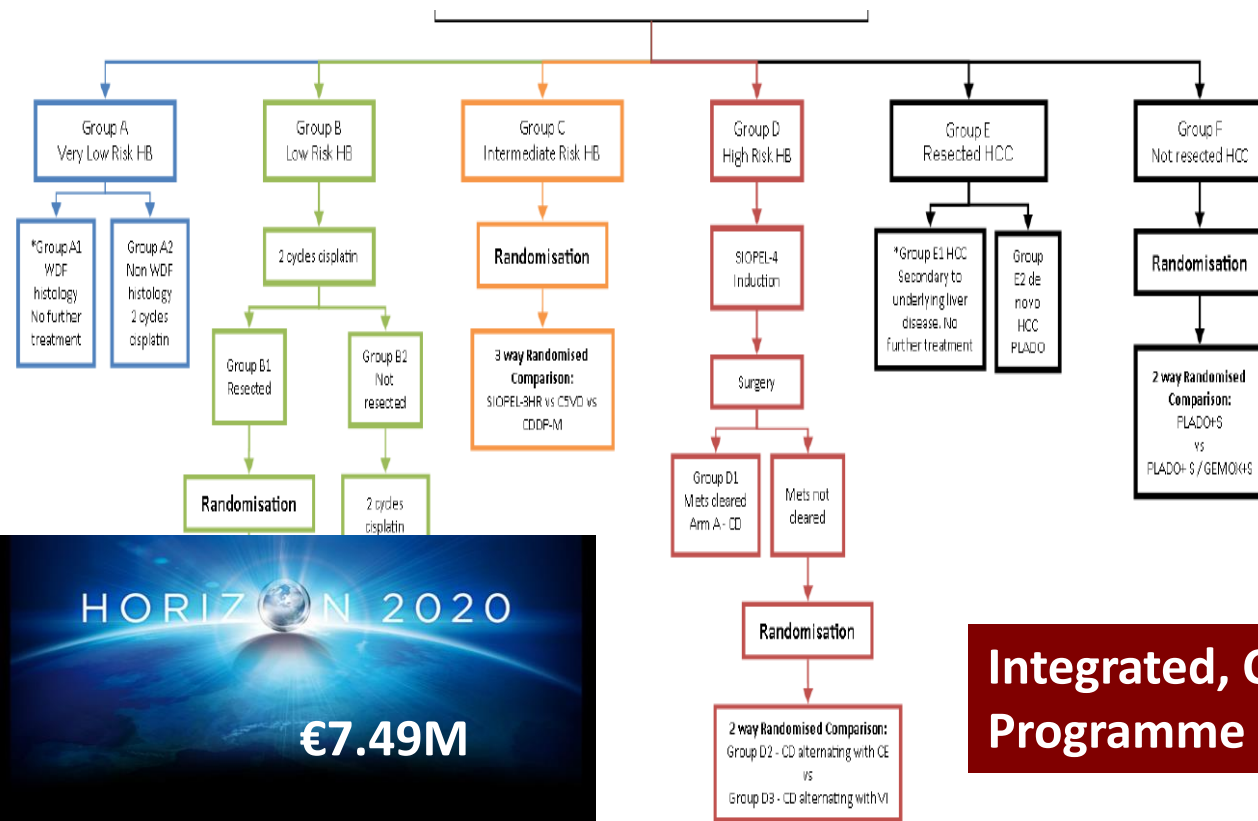


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One trial Multiple research questions Multiple collaborators



Integrated, Comprehensive Programme of Biological Research

1% of all childhood cancer annual incidence of 0.8 per million children



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Collaborative Clinical Trial Platforms

- **Essential** to deliver international trials for childhood cancers
- **Stable and sustainable** platforms support high quality and efficient research
- **Lack of coordinated funding is the single greatest challenge**



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A vision for FP9?

- FP9 Programmes that will:
 - Build **sustainable** clinical trial platforms
 - Support **international collaborations**
 - Fund collaborative clinical trial platforms towards **more and better cure** for children with cancer
- » **FUND RESEARCH THAT WILL ENABLE A VISIONARY CHANGE IN WHAT CAN BE ACHIEVED FOR CHILDREN WITH CANCER**



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Thank you for listening



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