

# UK CLL Trials Biobank

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# Introduction

- The whole point of biobanking is to provide material for research
- Different types of research have different biobanking requirements
- Local biobanks have evolved to suit the requirements of local researchers
- Harmonisation of existing local biobanking activity will increase research capacity
- Entirely new biobanking arrangements are required for clinical trials

# Biobanking requirements of different types of research

Type of research	Samples required	Cells required	Biological annotation	Clinical annotation	Type of biobank
Cell biology & drug action	Few	Lots	Yes	Not essential	Local
Biomarker discovery	Lots	Few	Yes	Yes	Local
Biomarker validation	Lots	Few	Yes	Yes	Local Trial
Therapeutic response prediction	Lots	Few	Yes	Yes	Trial

# Why do we need a new biobank for CLL trials?

- The MHRA now takes an interest in all aspects of clinical trials including biobanking
- Emphasis on quality assurance and sample tracking
- Old system does not meet required standards
- Failure to establish new biobanking arrangements will compromise translational research as part of future CLL trials

# Good Clinical Laboratory Practice

- Legal requirements for trial samples to be processed to a standard adopted by the pharmaceutical industry (GCLP) that is inspected by MHRA
- Defines the standards expected in the analysis of samples generated from a clinical trial
- The principles of GCLP ensure the reliability, quality and integrity of the results
- GCLP covers the facilities, systems and procedures by which samples from clinical trials are processed and analysed, the results generated and how they are reported.

# The plan

- UK CLL Trials Biobank - a national resource for translational research relating to clinical trials
- Will be run to GCLP standards and located in University of Liverpool GCLP Facility
- Two posts (manager and technician) to provide the necessary continuity and QC
- Fair and transparent sample access arrangements

# Progress hitherto

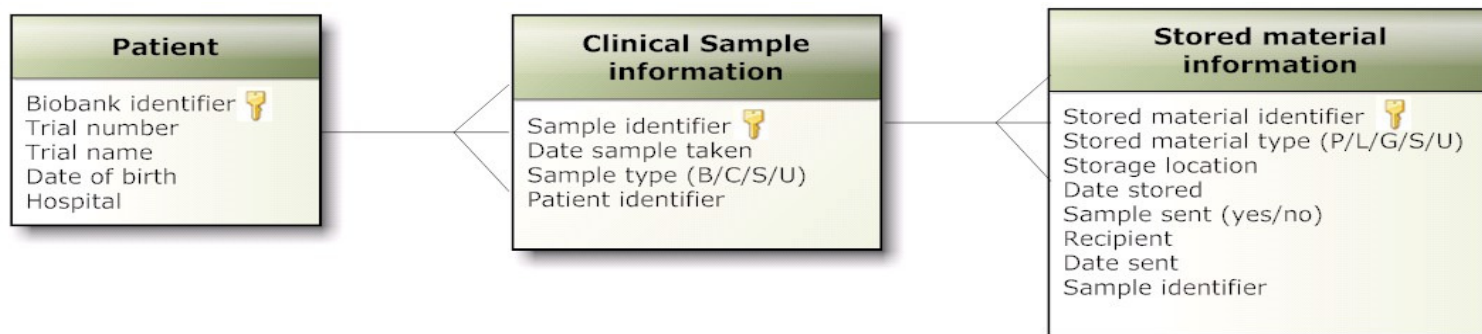
- Agreement from the LRF and CRUK to consider the proposal as a joint 4-year funding initiative linked to CLL6
- Initially turned down by LRF owing to concerns about
  - Data management
  - Sample access
  - Governance
  - Involvement of wider CLL community
- Concerns addressed
  - Attended CCLB steering committee in October 2007
  - Biobank workshop held in December 2007
  - Involvement of the Liverpool Cancer Trials Unit
- LRF (CTAP) approved their part of the project in February
- CRUK (TRICC) will look at the proposal in June
- Freezers provided by Roche (no strings attached)

# Governance committee

- Russell Patmore (independent chairman and NCRI rep)
- Andrew Pettitt (biobank director)
- Melanie Oates (biobank manager)
- Laura Marsh (IT expert from the LCTU)
- Susanna Dodd (statistician from the LCTU)
- Garry Bisshopp (patient rep)
- Stephen Devereux (UK CLL Forum)
- David Grant (LRF)
- Louise Jones (CR-UK)
- Representation from Cancer Research Technology (CRT)

# Data management

- All clinical and laboratory data will be stored centrally at the CTU running the trial (e.g. Leeds, Oxford)
- The biobank will keep an inventory of stored samples

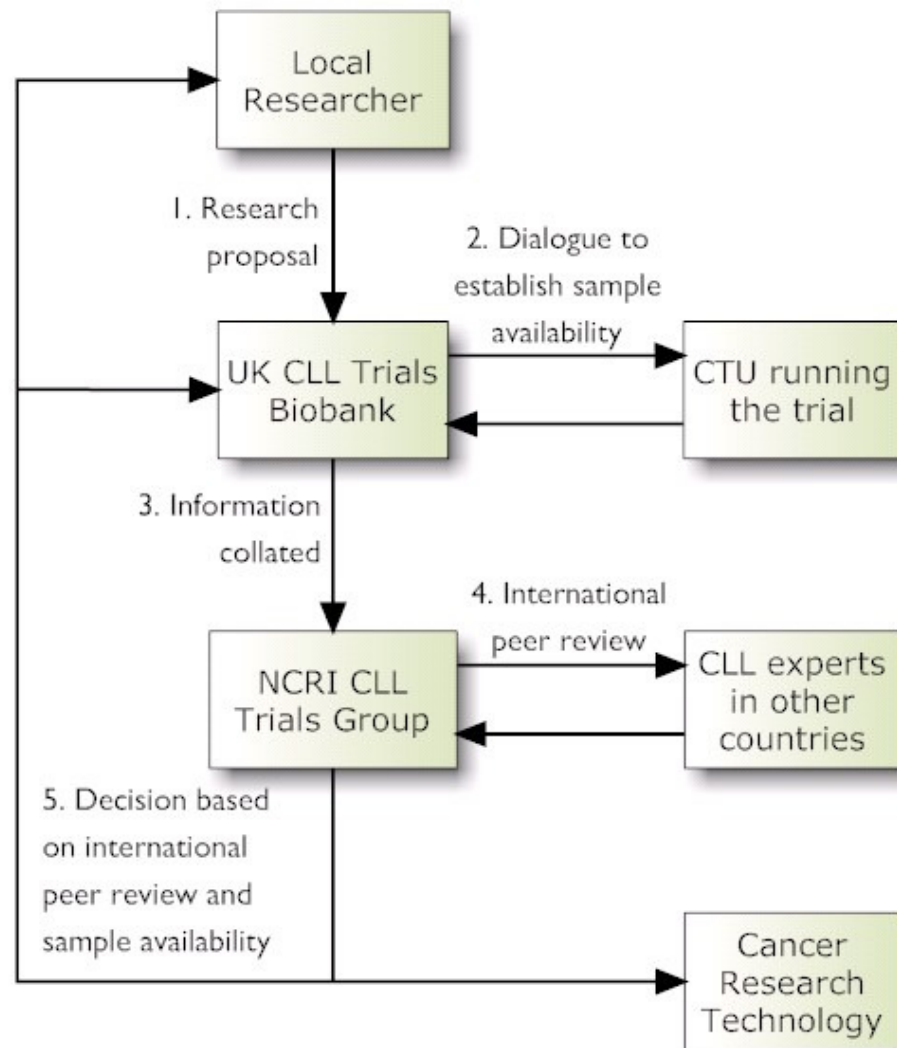


"Crows feet" on connecting lines indicate multiple clinical sample records per patient and multiple stored material records per clinical sample

Key icon indicates unique identifier for each record

B - Blood  
S - Serum  
C - Buccal Swab  
U - Urine  
P - Plasma  
L - Cells  
G - Germline DNA

# Sample access arrangements



# What next?

- All of the pieces are now in place apart from CRUK funding
- Planned start date October 2008
- Will hopefully coincide with launch of CLL6 trial
- Other trials will also need biobanking support