



# NCRI INFORMATICS INITIATIVE

**Data Sharing in Clinical Trials Workshop**  
**Royal Society of Medicine, London**  
**23<sup>rd</sup> - 24<sup>th</sup> January 2006**



Clinical trials yield high volumes of diverse data which are relevant to the problem of cancer. The diversity and complexity encompassed within this data is great and can only be fully exploited by acquiring high quality data in standard formats, storing the data in appropriate repositories and enabling appropriate mining of that data to generate new knowledge. Furthermore, the issue of how to appropriately share data about, and the results from, clinical trials needs to be addressed due to changes in regulatory requirements. The NCRI Informatics Initiative hosted a 2-day workshop to discuss data sharing in clinical trials.

## **Summary of Presentations**

Richard Begent introduced the aims of the workshop noting that data standards are needed for valid data sharing and integration of different data types e.g. clinical and molecular data. He introduced the NCRI Informatics Planning Matrix as a tool for researchers and posed some questions for the workshop participants: 'what are the issues for implementation of data sharing, and how do you as leaders of the research community want to proceed?'

Some of the funding organisations that constitute the NCRI have, in their own ways, been grappling with how data sharing should move forward. However, as a single body they have adopted an NCRI Data Sharing policy. Fiona Reddington outlined the progress that had been made on implementing this policy with a number of the organisations undertaking pilot studies and also how some of the NCRI Informatics demonstrator projects are showing how data sharing can be beneficial to the research community. Delving into more detail John Toy explained how Cancer Research UK had undertaken an 'information gathering' pilot study that would inform the development of an appropriate implementation strategy for the NCRI Data Sharing Policy. The pilot study involved a number of funding committees and asked grant applicants to submit a data sharing strategy as part of their application. Cancer Research UK have been encouraged by the positive response to the initiative by the research community and are examining various ideas for implementation of the policy.

The pharmaceutical industry has different pressures and incentives from academia in furthering research but there is recognition from industry of the advantages of standardisation of data collection, storage and preservation. Pablo Fernandez (of the Association of British Pharmaceutical Industries) described how pharma was engaged with the Clinical Data Interchange Standards Consortium (CDISC) initiative for describing clinical trial data and were also beginning to register clinical trials in various trials registries. Legislative pressure and that from journals is helping to drive this forward. Ideally registration of the trial would be followed by addition of the results of the trial once it is complete.

Unlike the sharing of genomics data, for example, which tends to be a global effort, handling and sharing of clinical trial data can be quite different across the world. Christo Adonyadis and Monica



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Jones gave a US and UK perspective on data sharing in clinical trials respectively. Christo introduced the cancer Biomedical Informatics Grid (caBIG) programme which is creating a virtual network connecting individuals and organizations to enable the sharing of data and tools, creating a World Wide Web of cancer research. The NCI has established a Clinical Trials Working Group and one of their recommendations is that the caBIG standard infrastructure should be developed to support clinical trials and interface caBIG with other databases utilizing standard elements. The NCI is also engaged with the Nationwide Health Information Network (NHIN) in the US.

Similarly, in the UK, the United Kingdom Clinical Research Network (UKCRN) is developing clinical trials infrastructure which will link with the developing National Programme for IT in the NHS. The electronic Remote Data Capture project is just into the second phase where it will demonstrate scalability across 30 different sites, 6 trials units involving 8 clinical trials. Trials data will be captured and shared in line with the NCRI Informatics Initiative.



Issues of ethics and consent in the secondary use of data were addressed by Peter Singleton. The legal framework around clinical data is complicated and researchers have to balance making data as available as possible with the issues of security, confidentiality and privacy. Peter described various approaches to gaining consent from patients, provided some interesting cost-benefit analysis of the various approaches and stressed the need for a pragmatic approach with each study, balancing the risks and benefits of different methods of consent.

Guidelines for reporting of clinical trials data already exist and Doug Altman explained the CONSORT guideline (<http://www.cancerinformatics.org.uk/CONSORT.htm>) which specifies a minimum set of items which should be reported with a trial. He also demonstrated the importance of good reporting of clinical trials, provided evidence of bad reporting and showed how bad reporting can lead to publication (dissemination) bias.

The CancerGrid project plans to build open and re-usable software and models for cancer clinical trials as part of a standard infrastructure which can support multiple trials. James Brenton described how the project will develop around a breast cancer pharmacogenetics trial (NeoTango) and has already forged strong collaborations with the NCI caBIG programme. The project demonstrates the open collaborative environment advocated by the NCRI Informatics Initiative through the development of common models and vocabularies and incorporates existing standards such as CONSORT.

One of the key components of the clinical trials workspace within the caBIG programme is the BRIDG model: a shared domain analysis model of regulated clinical research. Doug Fridsma described how BRIDG was an open community of stakeholders interested in developing standards for exchanging information about clinical trials and how it would 'bridge' not only between clinical trial domain experts and technical experts but also different models of clinical trials information. One key development will be the merging of CDISC and HL7 models with caBIG and work is already underway with this.



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## Breakout Sessions

Breakout groups were convened so that each group had a diverse mix of expertise (clinical, scientific, technical, etc). Three groups were chaired by workshop attendees and facilitated by members of the NCRI Informatics Initiative Coordination Unit. The groups were each asked to identify what they felt

the “burning issues” in data sharing related to clinical trials were, and to discuss amongst their group. The outcomes of each discussion were then reported back to the workshop by the chair of each group. The main topics identified were:



## Consent

- Transparency regarding data usage
- How to obtain consent for future/secondary research usage – need to explain to patients that accumulation of data is powerful
- Development of a standard statement used to take consent may be useful

## Anonymisation

- Need to address the issues of re-identification of patient data and possible disclosure of data
- Need to balance risk of participation with potential benefit

## Data

- Technical needs regarding data sharing
- It can be expensive to use/develop standards
- Journals need to mandate use of data standards/ensure appropriate recognition of shared data in publications
- How to find out what data is available and how to access it
- Need quality assurance surrounding the data itself and how it will be used
- Need to monitor re-use of data
- Need to address what we can do now and move forward in a step-wise fashion

## Funding

- How will data sharing be funded?
- Funding organisations should fund practical data sharing demonstration projects
- Data sharing needs to be mandated by the funders (e.g. make it easier to comply than not)
- Those who actually undertake the work (data collection and entry, enabling data sharing) need appropriate funding and recognition
- Should Connecting for Health provide funding to the research community for data sharing that will enable healthcare research?

In summary, the workshop provided a unique multi-disciplinary forum at which the current issues surrounding data sharing in clinical trials could be addressed. It is clear that there is overall support



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from the community that data sharing is a positive step but that there are issues regarding how to ensure sufficient infrastructure, support and monitoring mechanisms are put in place to enable the community to pragmatically and responsibly share data. The funders, journals, trials units, clinicians

and researchers will need to communicate clearly and frequently with one another during the introduction of the NCRI Data Sharing Policy to ensure a successful and useful roll-out of the policy.

The NCRI Informatics Coordination Unit will be key to facilitating this dialogue.





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## Workshop Participants

<b>Name</b>	<b>Organisation</b>
Roger A'Hern	Institute of Cancer Research – Clinical Trials Unit
Sarah Bathers	Birmingham Clinical Trials Unit
James Batchelor	University of Southampton
James Brenton	University of Cambridge
Francesca Buffa	Oxford University
Helen Campbell	Department of Health
Steve Canham	Institute of Cancer Research – Clinical Trials Unit
Charlotte Capener	Biotechnology and Biological Sciences Research Council
Iain Chalmers	James Lind Library
Jim Charvill	UK Clinical Research Network
Brian Clark	OnCore UK
Stephen Cook	Association of British Healthcare Industries
Will Crocombe	Clinical Trials Unit, University of Leeds
Jim Davies	University of Oxford
Alan Doyle	The Wellcome Trust
Dean Fennell	Queen's University Belfast
Liz Foster	Cancer Clinical Unit Scotland
Richard Frederick	Wales Cancer Trials Network
Tim French	AstraZeneca
Hani Gabra	Imperial College
Lone Gothard	Royal Marsden Hospital
Gareth Griffiths	Wales Clinical Trials Unit
Steve Harris	University of Oxford
Alexander Henzing	Edinburgh NTRAC Centre, University of Edinburgh
Julie Howard	NCRI Secretariat
Daljit Kaur	Cancer Research UK
Peter Kerr	NCRI Informatics Initiative
Danny Kirby	United Kingdom Children's Cancer Study group
Maria Lioumi	Cancer Research UK
Peter Maccallum	University of Cambridge
James MacKay	Institute of Human Genetics and Health, UCL
Paul Mason	Birmingham Clinical Trials Unit
Geraldine McBride	Clinical Trials Unit Beaston Oncology Centre
Alan Montgomery	Bristol Randomised Trials Collaboration (BRTC)
Anthony Moorman	University of Southampton
Mahendra Navarange	OnCore UK
Peter Parker	Cancer Research UK
Jim Paul	Clinical Trials Unit, Beaston Oncology Centre
John Parkinson	Medicines and Healthcare products Regulatory Agency
Philip Quirke	University of Leeds
Robin Rice	University of Edinburgh
Sue Richards	CTSU, Oxford
Carmen Ruiz de Elvira	European Group for Blood and Marrow Transplantation, London
Jo Shaw	NCRI Informatics Initiative
Justine Smith	Oncology Clinical Trials Office, University of Oxford
Allan Sudlow	Medical Research Council
Richard Sullivan	Cancer Research UK
Ric Swindell	Christie Hospital NHS Trust
Angela Poland	Medical Research Council Clinical Trials Unit
Kiki Tahtis	Breakthrough Breast Cancer
Marian Taylor	Oxford, Cancer Research UK
Hazel Thornton	Independent Advocate
Lawrence Truman	UK Clinical Research Network
Aidan Walsh	Cancer Research UK
Keith Wheatley	Birmingham Clinical Trials Unit

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Max Wilkinson

NCRI Informatics Initiative

## Speakers

Douglas Altman  
Christo Andonyadis  
Richard Begent  
Doug Fridsma  
Monica Jones  
Alfred Oliver  
Max Parmar  
Fiona Reddington  
Peter Singleton  
Richard Smith  
John Toy

University of Oxford  
National Cancer Institute Center for Bioinformatics  
NCRI Informatics Initiative  
University of Pittsburgh  
UKCRN  
NCRI Consumer Liaison Board (governance)  
Medical Research Council Clinical Trials Unit  
NCRI Informatics Initiative  
Cambridge Health Informatics  
UnitedHealth Europe  
Cancer Research UK

