Agenda

• Introduction to Cancer Research UK

• CRUK Stratified Medicine Programme

• Key Challenges and Lessons Learned
A BIT ABOUT CANCER RESEARCH UK
Cancer Research UK

WHO WE ARE

– We the largest fund-raising medical research charity in the world
– We are the largest funder of cancer research in Europe

WHAT WE SPEND

– We spent £332m on research in 2011/12
– The money we raise is spent on
  • research
  • information
  • advocacy and public policy
Cancer Research UK

WHERE WE WORK

– Cancer Research UK supports over 500 research groups
– We support research in about 40 towns and cities across the UK
– We support five Institutes:
  • London
  • Oxford
  • Cambridge
  • Manchester
  • Glasgow
Our finances

£332 million

Research spend in 2011/12:

- £42m Breast
- £34m Includes cervical...*
- £23m Bowel
- £20m Prostate
- £18m Leukaemia
- £15m Skin
- £12m Leukaemia
- £12m Lung
- £7m Ovarian
- £7m Non-Hodgkin Lymphoma
- £5m Oesophageal
- £4m Brain
- £4m Bladder

Research that underpins all types of cancer
CRUK STRATIFIED MEDICINE – PHASE 1
CRUK Stratified Medicine Programme – In a Nutshell

• The CRUK Stratified Medicine Programme is a collaborative initiative to undertake large volume genetic testing within the UK

• Aim to test approximately 9000 patients across the UK in a 2 year programme
CRUK Stratified Medicine Programme – Key Metrics

• 34,375 gene tests
• 10,512 patients consented
• 7,962 samples sent for testing (93% of target)
• 26 feeder hospitals
• 8 clinical hubs
• 6 indications
• 3 technology hubs
• 1 network!
10512 patients consented and 7962 samples sent for testing
A range of markers is tested for across six tumour types

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Phase 1 was Driven by Genetic Service Challenges Matched with Research Challenges

Issues with service delivery of tests

- Slow uptake of new tests and geographic variation
- Test quality can reduce as volumes increase
- Funding tests is difficult in NHS

Issues with evidence for research

- Large patient numbers required to get any of the rarer types
- Not enough clinical data to use our genetic understanding
- Profit motive focuses companies on new, expensive drugs
Stratified Medicine Requires Basic Research, Clinical Trials and Service Delivery

- Basic and translational science
- Clinical trials
- Deliver the treatment
Stratified Medicine Programme is Supported by Pharma, the Government, Diagnostic and IT Companies

- CR-UK, Pfizer and AZ fund the clinical and tech. hubs
- TSB and grantees develop new IT and panel tests
- DH CMO & NHS
- Additional partners, BMS and Roche provide funding for additional tests and Oracle provide analytics platform

TSB grantees, £5.6m
Additional partners, £1.4m
£5.5m
£5.6m
The CRUK Stratified Medicine Programme was designed to demonstrate how cancer gene testing can be done on a large scale.

![Diagram showing the service delivery component and research infrastructure.](image)

- **Central data repository (ECRiC)**
- **Clinical Hubs (Hospitals):**
  - RMH ICR
  - B’ham
  - Leeds
  - Man.
  - Edin.
  - Glas.
  - Camb.
  - Card.
- **Genetic Technology Hubs (Labs):**
  - RMH ICR
  - B’ham
  - Cardiff
- **Anonymised Data** flow to Researchers Partners NHS
- **9,000 Cancer Patients**
The Programme is operating through 3 Technology Hubs, 8 Clinical Hubs and 26 Feeder Hospitals.
Operational Collaboration is Key

- Over 150 multi-disciplinary staff working together across 26 hospitals and 3 technology Hubs

- Facilitated collaboration between research labs and regional genetic testing labs – shared protocols, shared expertise and development of new assays and validation of novel technologies

- Brought together people working in the informatics fields across Scotland, Wales and England to share issues on data collection and to increase the quality of data generated

- Enabled close working between hospitals and labs to discuss sample standards, sharing of samples for validation and QA assessment

- Utilised the UK’s co-ordinated clinical network to effectively screen significant numbers of patients
Operational Excellence

- Facilitated shared learning’s on consent pathways
- Developed key partnerships with Pharma- which has enabled close working on a site specific basis
- We have worked with DoH to share our lessons learned and contributed to the development of the 100,000 WGS project
- We have created an electronic network across the eight ECMC’s to enable a standardised messaging system
New Partnerships Have Also Been Built During the Programme

• We are working with UK NEQAS to monitor the quality of the testing
• Our data repository is hosted by the Eastern Cancer Registry and Information Centre and we are working with Oracle to set up an analytics portal for the data
• We have set up partnerships with Roche and Bristol Meyers-Squibb to pre-screen patients for clinical trials
• We are working with the Department of Health around a new structure for commissioning and delivering molecular testing for cancer patients
We Have Identified A Number of Key Barriers to a National System

(1) Establishing routine consent of data and samples for research

(2) Achieving clinically relevant turnaround times

(3) Data Issues /challenges

(4) Establishing standards for sample handling, preparation and processing*

(*For detail see Dr Emily Shaw’s presentation on Wednesday pm)
Ongoing Challenges Which Represent a Barrier to a National System - Consent

• **Ongoing Educational Need Among Consent Staff:**
  The ability to explain the difference between somatic mutations which are a defining feature of cancer and may be present in tumour only, compared to rare germline mutations that may contribute to earlier onset of cancer as part of hereditary predisposition syndromes

• **Addressing Public Concerns about Genetic Testing and Data:**
  • Within our (non-commercial) programme, consent rate has exceeded 95%, however there is some anxiety about the extent of genetic analysis performed, subsequent use of genetic data and clinical implications of detected abnormalities (especially the link to germline mutations)
Ongoing Challenges Which Represent a Barrier to a National System – Turn-Around-Times

• Turn-around-times are influenced by a complex range of related issues:
  • Failure rates – partial, versus whole gene failure
  • Sample quality, concentration, sample availability
  • “Research” genes versus clinically validated genes
  • Reporting process
  • Different Technologies
  • Patient’s status in their clinical pathway
Ongoing Challenges Which Represent a Barrier to a National System – Data Issues

- Automated extraction of data from existing hospital systems is difficult to achieve
- Specific key data items are not consistently recorded by cancer MDTs (i.e. Incomplete data sets)
- Lack of implementation of current versions of clinical coding systems (i.e. Inconsistent)
- Cross-border issues
Ongoing Challenges Which Represent a Barrier to a National System – Sample Handling

• Logistics - Consistent and stable sample flow is essential for management of workflows and ultimately sample TAT’s

• Variability in sample handling represents a challenge.

  Sources of variation:
  • Sample collection
  • Sample fixation, tissue processing, sectioning etc.
  • Almost endless variation all of which can affect the quality of the DNA that can be extracted and therefore the success of subsequent mutation analysis
Ongoing Challenges Which Represent a Barrier to a National System – Sample Handling (2)

• In a changing environment where complex genetic (and non-genetic) testing panels will soon become the norm
• A clear shifting to multiplexed testing panels to inform clinical intervention
• To support this, clear and robust guidelines around sample collection, processing and handling need not just to be generated, but need to be broadly implemented to support the molecular revolution that is coming
• Pathology data systems need to be equipped to support the changing landscape with appropriate intra-operability
Key Success Factors

• Willingness to work truly collaboratively
  • Treating each other as equals
  • Sharing expertise
  • Playing to our strengths/ acknowledging our weaknesses
• An acceptance that things will go wrong sometimes- it’s about how we deal with these situations that matters
Key Success Factors

• What is clear, is that nucleating the network around a single focus and within the constraints of the programme has provided exceptional collaborative working and enabled progress, change and improvement that would otherwise would not have happened