

Advanced biobanking and good management

Martin Yuille
2nd Annual National Biobanking Symposium
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Contents of talk

- To understand why advanced biobanking needs good management, we need to go back to first principles...
- For translational research to succeed, we require changes in practice and culture by universities, hospitals and industry.
- Biobanking networks are one of the most effective ways of enabling those changes – if the networks have standards that can reach across universities, hospitals and industry.
- A network quality management system can be an effective tool to drive the changes required for a biobanking network to function.

Pre-translational research

Basic
research

- addresses
'scientific good'

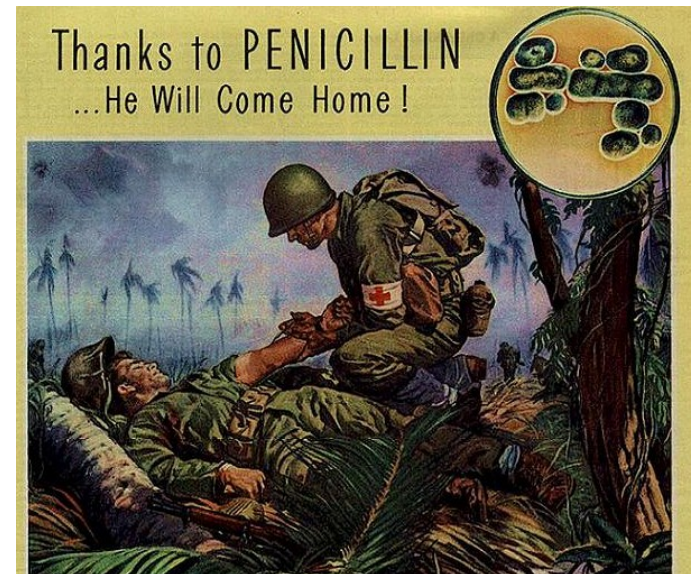


Applied
research

- addresses
'public good'



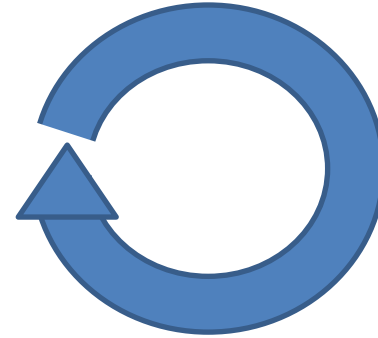
*Physicist Leo Szilard (with tie) and fellow Phage Group members
Max Delbruck, Alan Garen, James Watson*



Pre-translational research

Basic
research

- reflexive culture



Applied
research

- linear culture



Pre-translational research organisation

Basic
research



Applied
research



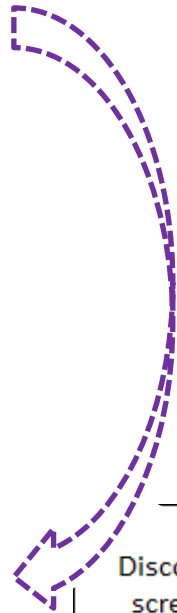
Wartime penicillin culture facility at the University of Oxford

Translational research conception 2000

Basic
research

linear

Applied
research

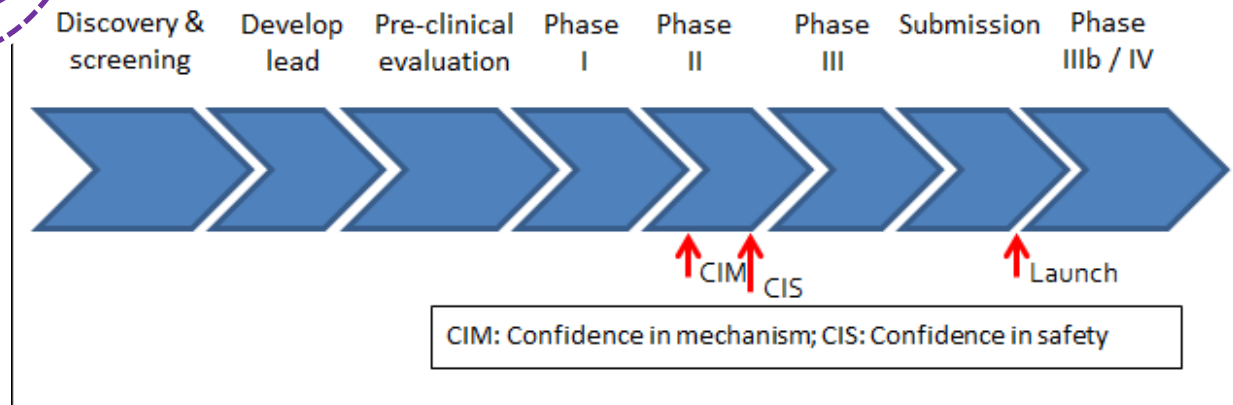


Big Biology is born



"We've sequenced the human genome!" say Blair and Clinton

Industry's linear process model

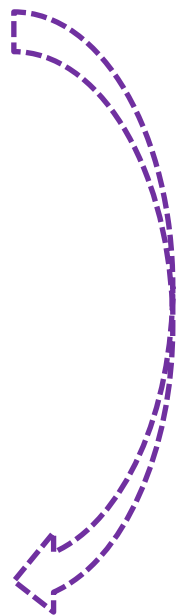


Translational research organisation 2000

Basic
research

linear

Applied
research



The Genome Campus, Hinxton, Cambridge UK



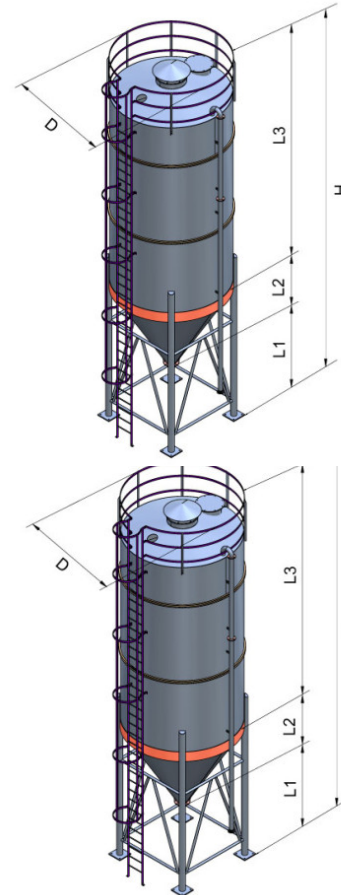
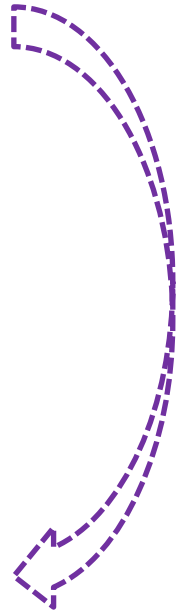
GSK campus, Stevenage, near Cambridge UK

Translational research organisation 2000

Basic
research

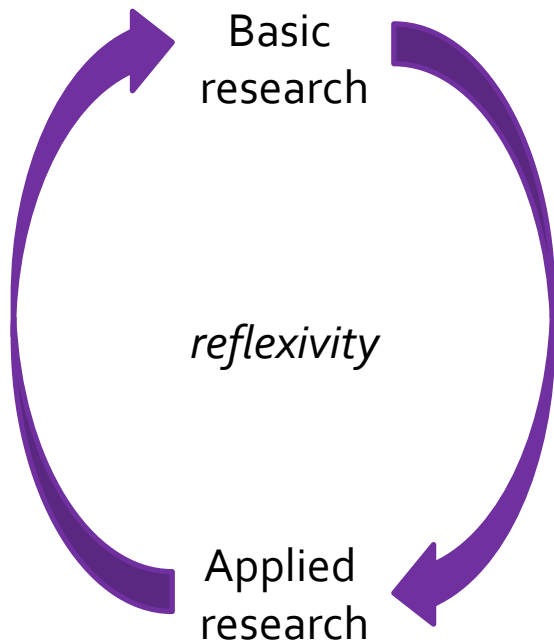
linear

Applied
research



Siloisation inhibits the 'community of academic and industrial scholars'

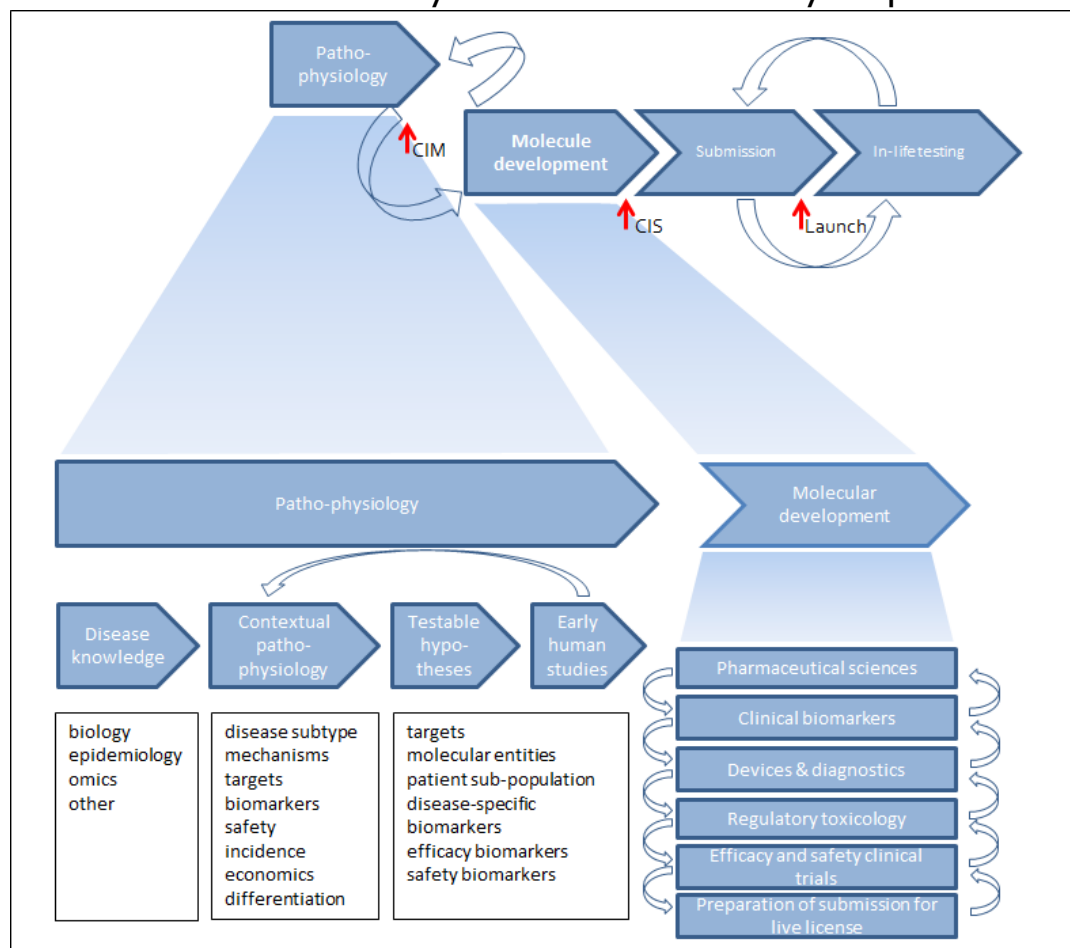
Translational research 2020



□ Translational research becomes Big

□ Translational research □
translational medicine =
stratified medicine =
“reflexive medicine”

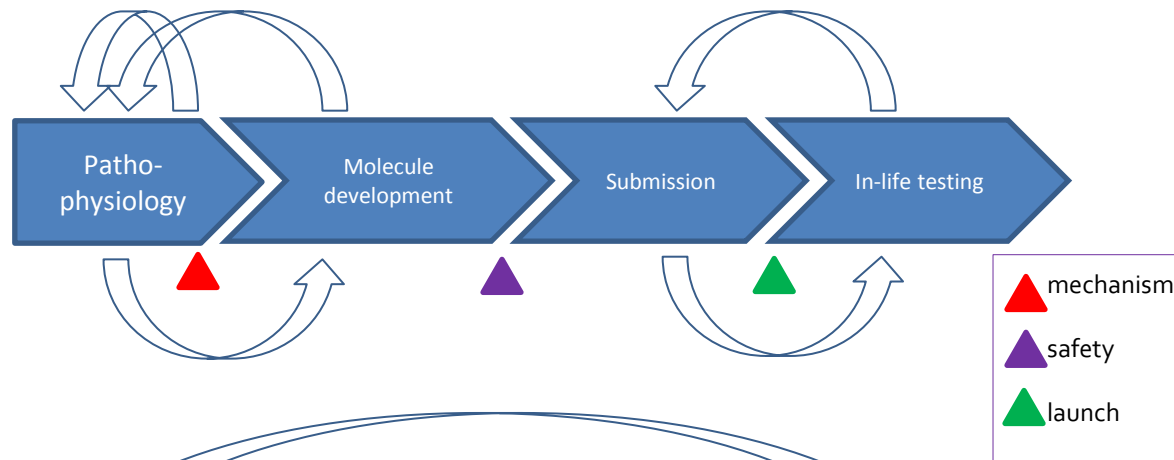
Industry abandons linearity of processes



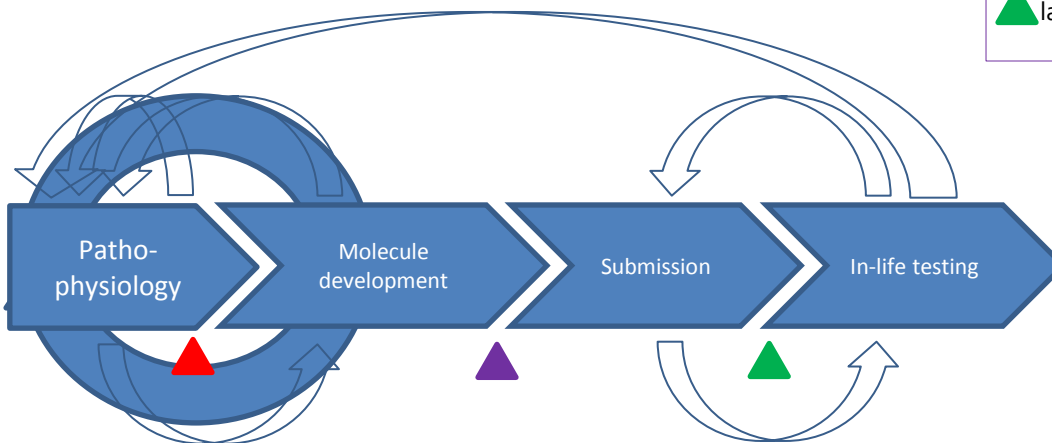
Pricewaterhouse Cooper: Pharma 2020 – The Vision.

Industry abandons linearity

- PwC identifies some reflexivity
 - iteration between steps in medicine development
 - iteration between industry, academia and clinicians

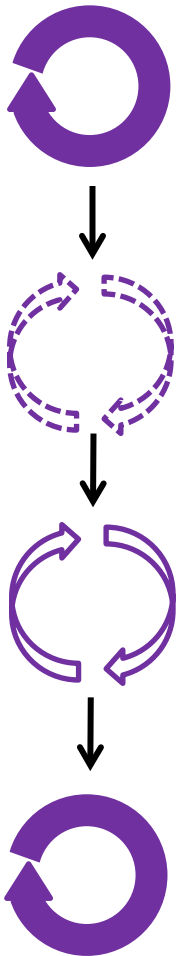


- In fact, reflexivity is complete
 - research has become medicine
 - the bench is in the bed



Translational research organisation 2013

An epigenetics community of scholars



*In 2020, they will be 7 years older. Some will have left. Some will join. But the network will probably live on.
Is its success best measured by the sum of its parts?*

From processes to organisational choices...

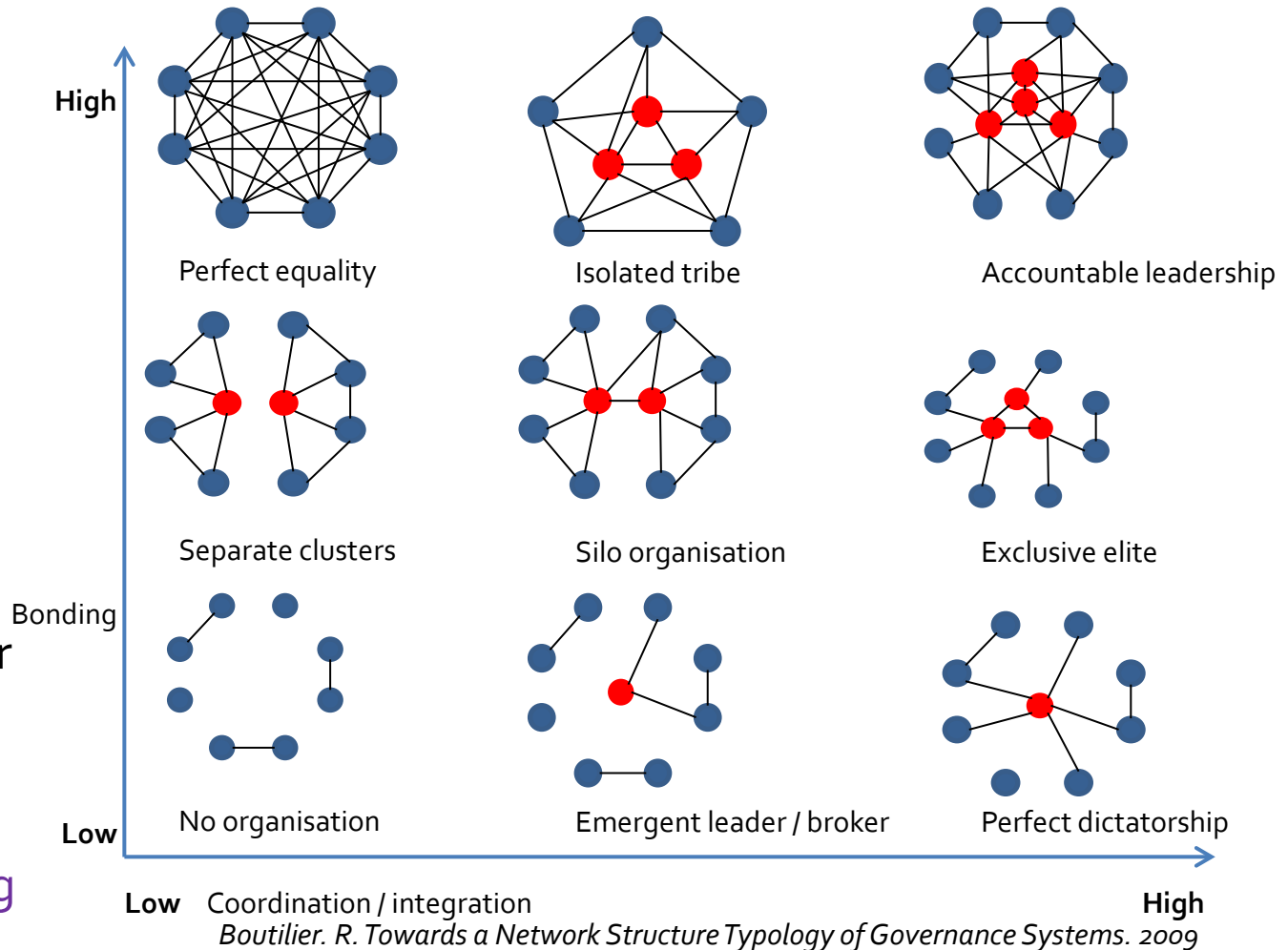
How should we organise ourselves?

Networks for things

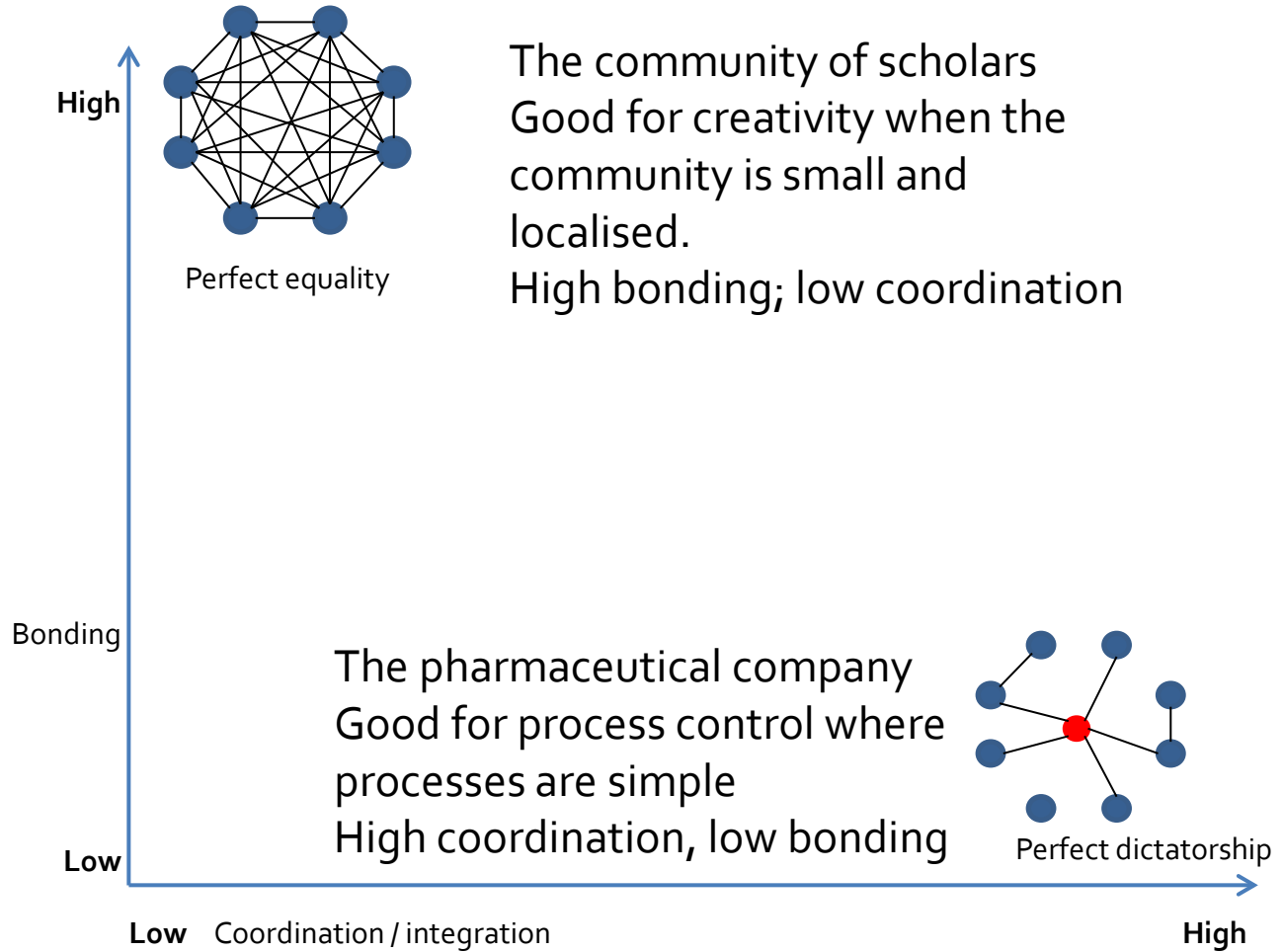
○ Hubs and nodes

Communities for people

○ I am not a node: I am a human being

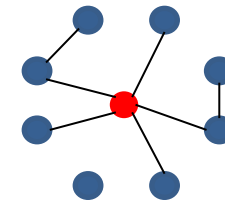
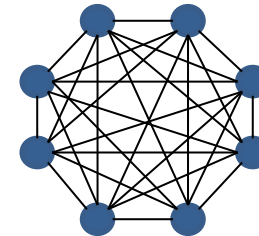
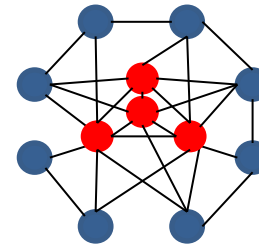


What organisational choices are best? Two simple examples...



Choices for organisation of data

- Data community
 - Accountable leadership?
 - Ontology development requires high bonding and coordination
- Data storage and transfer network
 - Perfect equality?
 - Perfect dictatorship?

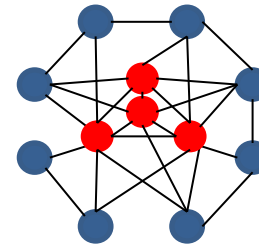


Choices for organisation of samples

Sample community

- Accountable leadership?

- Yes



Sample storage and transfer network

- Perfect equality?

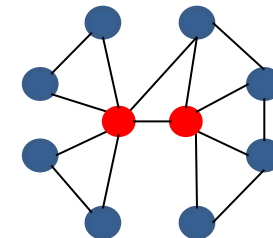
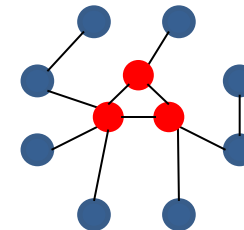
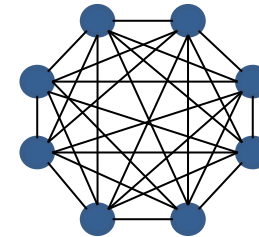
- No

- Exclusive elite?

- Regional centres

- Silo organisation?

- Liquids and solids



Choices for organisation of funding

Redacted

(Abgefaßt)

Problems of transparency and engagement

Stratified medicine: a smörgåsbord of research infrastructure

The menu:

1. Funders' network
2. Data network
3. Sample network
4. Basic research network
5. Clinical research network
6. Medicines development network
7. Population health network

There is no 'right' place to start:

- EU has started with (1 + 2); (1 + 3); (1 + 5); (1 + 6)
 - ELIXIR; BBMRI-ERIC; ECRIN; EATRIS and IMI
- UK is experimenting with 5; (2 + 4); (3+4)

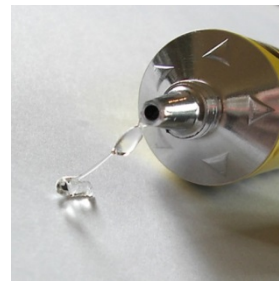


Creating the smörgåsbord: why biobanking is a good place to start

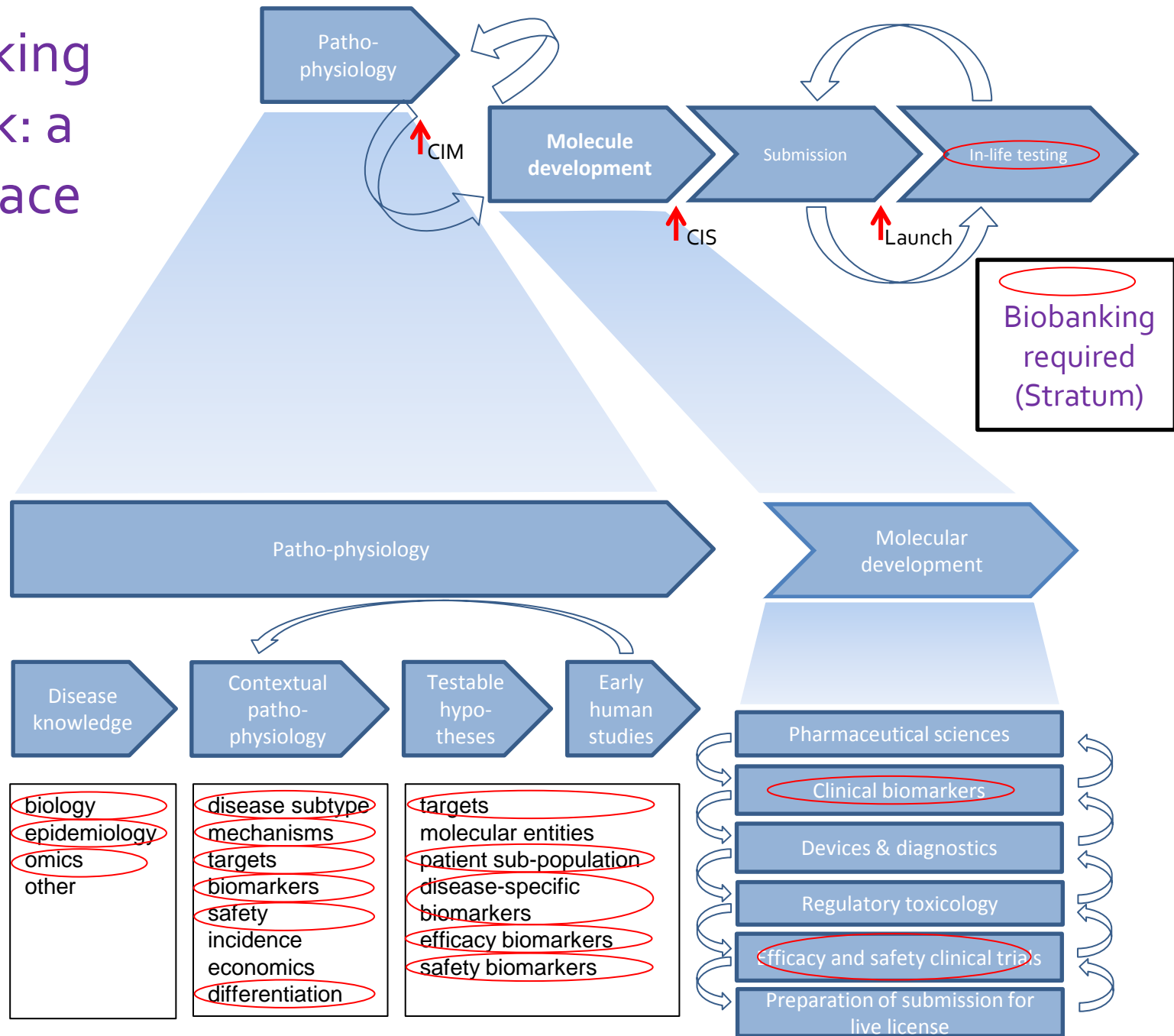
1. Funders' network
 2. Data network
 3. Basic research network
 4. Clinical research network
 5. Medicines development network
 6. Population health network
 7. Sample network
1. No research deliverables
 2. Semi-autonomous
 3. Too many silos
 4. Semi-autonomous
 5. Infancy
 6. Embryonic
 7. Yes

o A biobanking network

- Spans the 'value chain'
- Spans the specialisms
- Acts as community 'glue'
- Addresses the main bottleneck in today's translational research

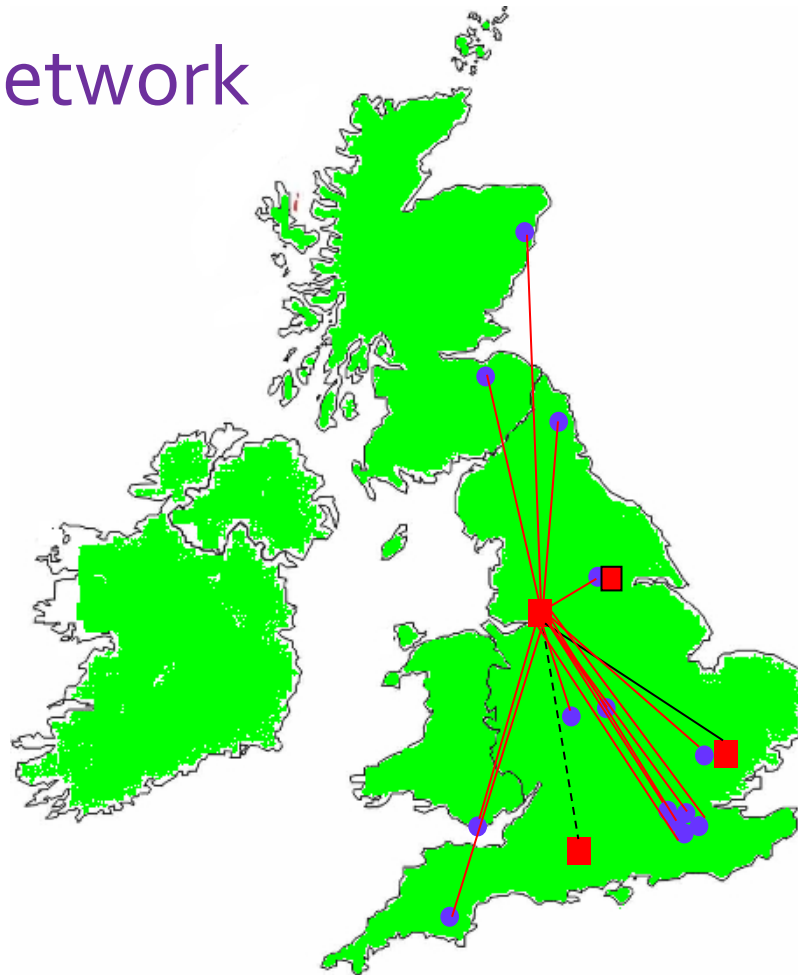


Biobanking network: a good place to start



No standards: no network

- The UK DNA Banking Network : a prototype biobank network
- Researchers' community + centralised biobanking
- UDBN needed a Quality Management System to provide 'glue' for acceptance of sample centralisation
- QMS demonstrated biobanking consistency
- we required a QMS to bind together a community – not to enable a samples network



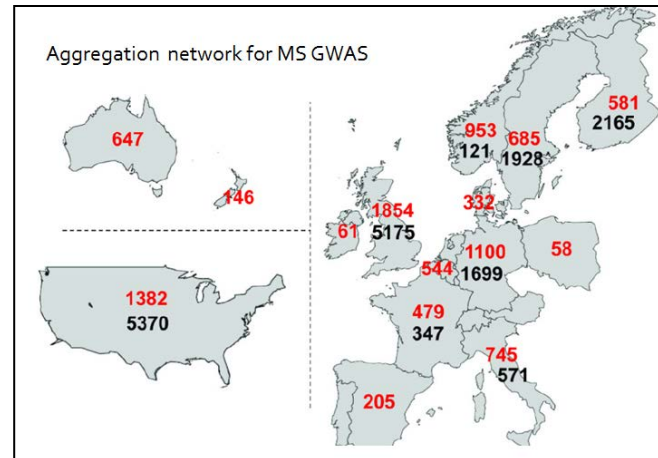
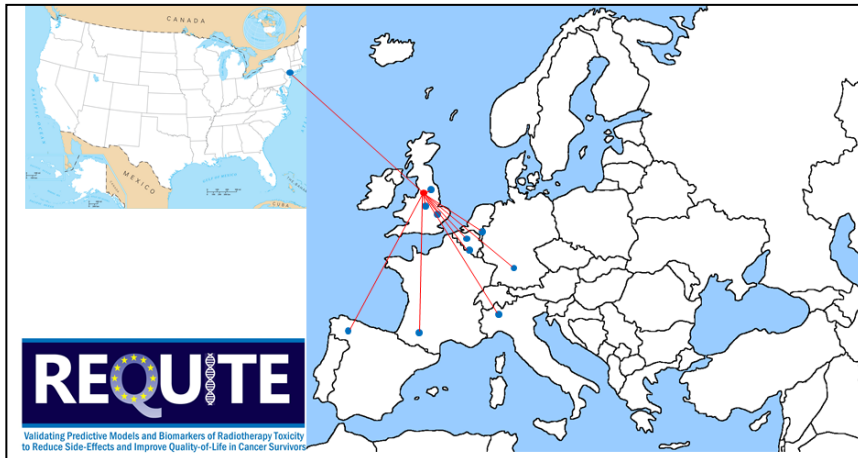
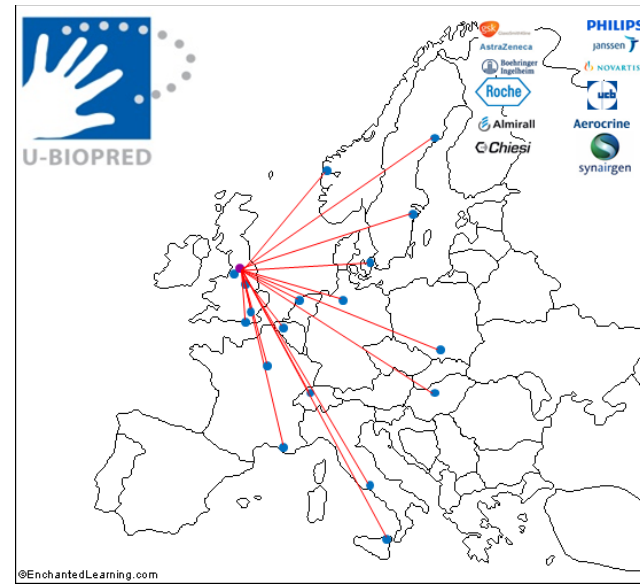
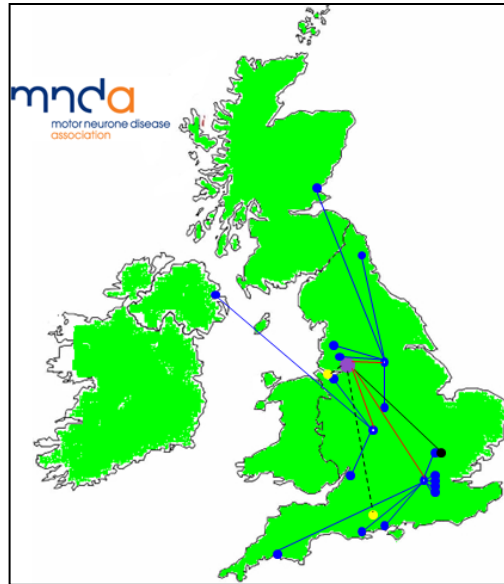
U Manchester
(EBI)
ECACC
U Leeds
PIs for collections

■ DNA, plasma, cells etc
■ Annotations archive
■ Transformation service
■ Research network hub
● Sample and phenotype data accrual

Standards become a tool for growth

Once we had a QMS, it became a tool for

- network support and development
- biobank sustainability



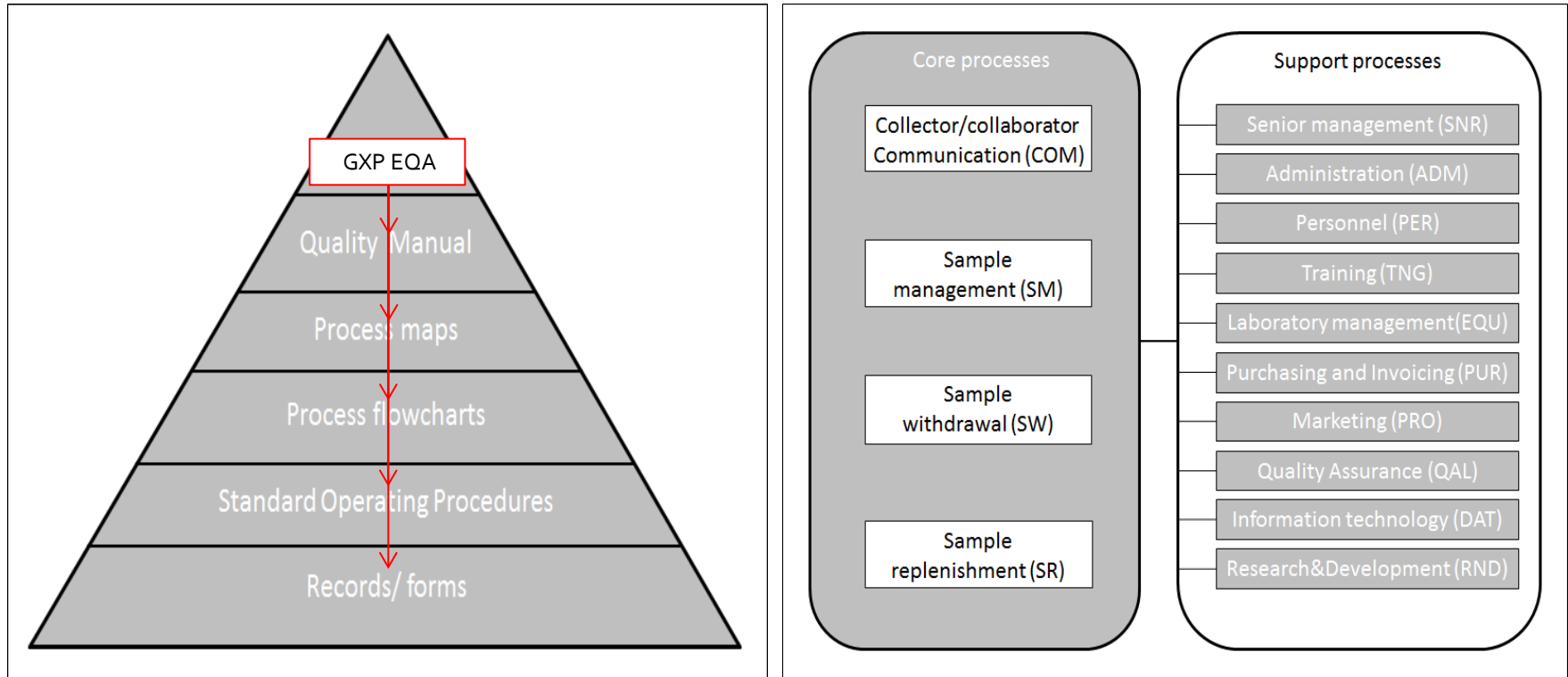
REQUIRE: an instance of reflexive medicine

How best to organise standards

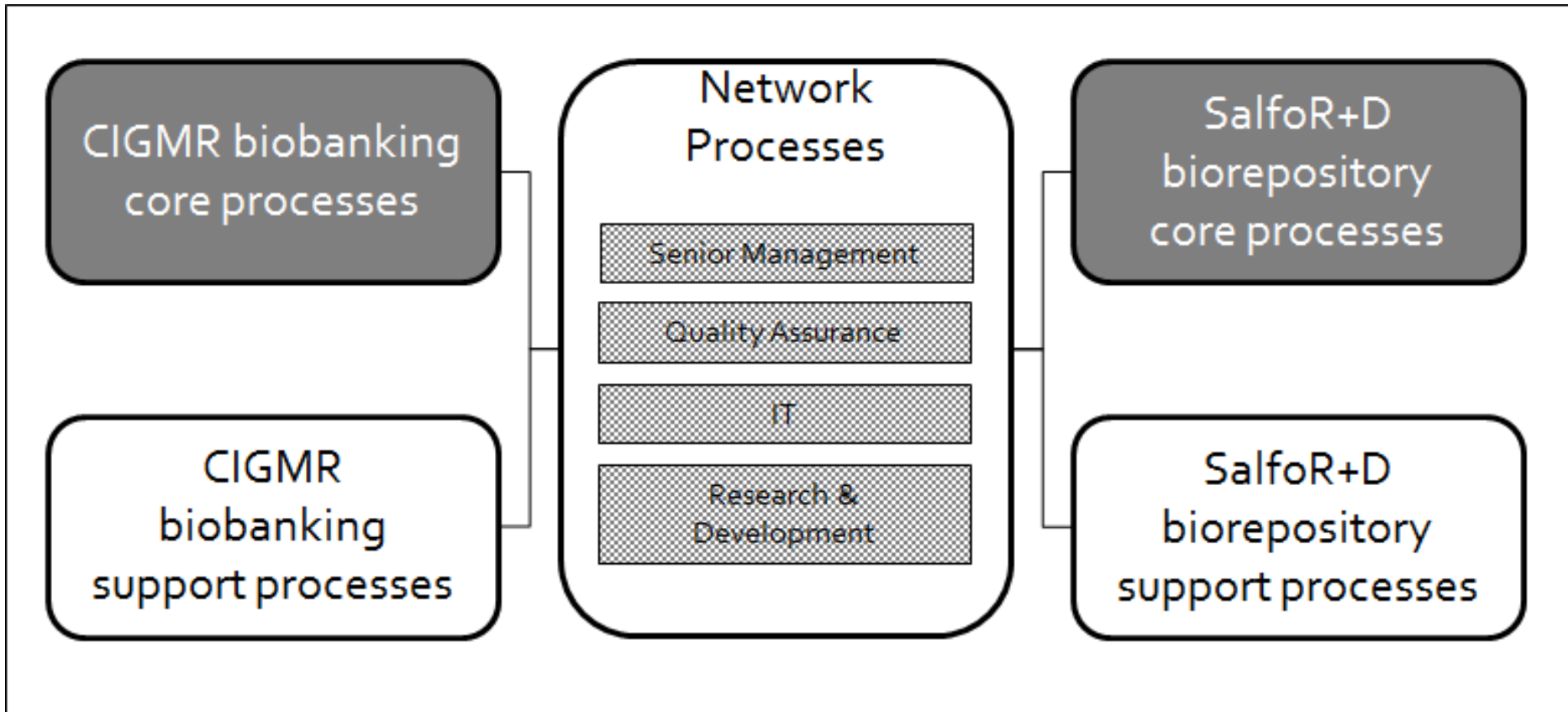
- CIGMR chose ISO9001 because it
 - Requires external certification.
 - This provides confidence that a claim of consistency is valid.
 - Is generic
 - Essential in a research setting to allow flexibility
 - Encourages good management in general plus highly focussed management
 - Requires continual action to improve
 - Informed by our errors and by our policy
 - Requires promotion standards by partners - upstream and downstream - so as to build a 'chain of quality'
 - Critical to moving samples in a network
 - Is harmonised with e.g. ISO27001 (data management)
 - Enables a multi-network quality environment



How ISO9001 works for us



Using one management system in two biobanks



The Network Quality Management System (NQMS) in Greater Manchester

A Network Quality Management System creates network efficiencies

- Accelerated experimental design
- Accelerated accrual of samples
- Increased resilience
 - second site storage; emergency staff cover; access to alternative equipment
- Capital used more efficiently
 - divisions of labour between biobanks
- Labour used more efficiently
 - sharing some administration, reducing staff with shared capabilities
- Overheads reduced
 - shared training, shared service contracts, shared consumables and shared dissemination

Conclusions

- Our area of science and practise has seen - and needs - increases in scale and changes in culture
 - “reflexive medicine” describes the full integration of medical practise and medical research
- People and processes are being - and need to be - reconfigured to create
 - communities that sustain values (scholarship, universal care, Hippocratic Oath)
 - networks that realise use value
- Networks realise use value by adopting standards
- A biobanking network acts
 - to glue together the components of this new organisation for reflexive medicine
 - to relieve a bottleneck
- Biobanking network standards are best achieved by adopting a networked quality management system

Thanks for your attention



We look forward to working with you all