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Making Clinical Trials More Patient-Friendly: Challenges & Opportunities

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Disclosure Information

Honoraria / Consultancies / Speaker (payable to employing institution):

- Astra Zeneca
- Bayer
- Bristol Myers Squibb
- Celgene
- Clovis
- Eisai
- Genentech
- Glaxo Smith Kline
- Immunova
- Jennerex / Transgene
- Nucana
- Karus Therapeutics (Scientific Advisory Board)
- MSD
- Otsuka
- Roche

Research Funding (payable to employing institution):

- Astra Zeneca
- Basilea
- Bayer
- Celgene
- MiNa Therapeutics
- Roche
- Pfizer
- Sierra
- Lilly
- Eisai
- Glaxo Smith Kline
- Novartis
- Bicycle Therapeutics
- Halozyme
- Johnson & Johnson
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- Vertex
- Plexxikon
- Boehringer
- Athinex
- Adaptimmune
- Bristol Myers Squibb
- MSD
- Medivir
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- Nucana
- Immnuocore
- Berg
- Beigene
- Iovance
- Modulate
- BiolinerX

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CAN WE MAKE CLINICAL TRIALS MORE PATIENT-FRIENDLY, MORE PATIENT-FOCUSED?

We Can….We Must

Challenges for Patients

we need to conduct trials safely……

- **Intensity of procedures & hospital visits**

  are they all necessary

  (long) distances to the trial centre (regulatory requirements)

  all labs, radiology, standardised & accredited in a public / national health care system

- **Availability of Trials & Equity of Access**

  geography – remote communities

  areas of (high) deprivation

  some (? most) trials only in highly specialised tertiary centres

  economic, health, and social costs of participation

Challenges for Patients

we need to conduct trials safely……

- **"Excluded" groups from trials**

  brain metastases; HIV, HBC, HVC; TYA, Elderly

- **Availability of Enabling Technologies**

  genomic & molecular profiling provision is patchy

  availability of expertise for interpretation of genomic medicine

Can we streamline and reduce the burden of trial participation for patients without compromising safety and scientific integrity?

Challenges for Investigators

that affect patients too

- **Regulatory Requirements**

  sponsors' fears of inspections, licensing requirements, fuels bureaucracy

- **Vendors**

  increase costs, bureaucracy

- **Investigators**

  workload & service pressures

  become disengaged from clinical research

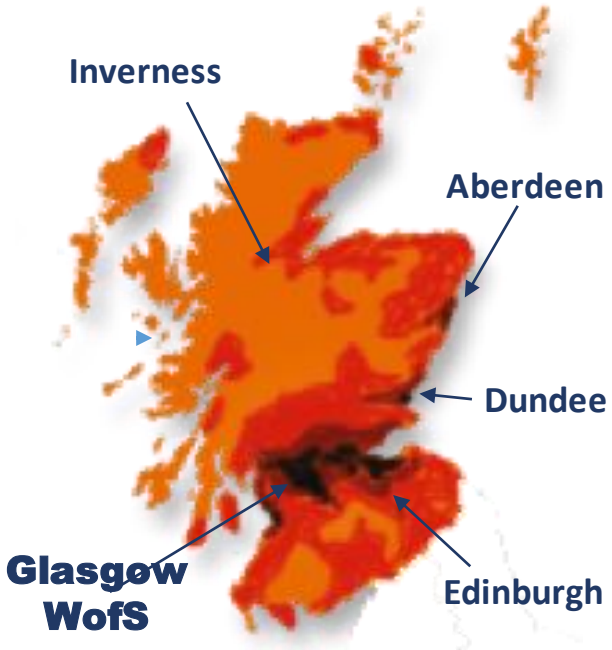
- **Support Staff**

  recruitment and retention; need better career structures & progression

All this slows down and hampers clinical research which is no longer patient-centred

A Pan-Scotland Approach

- **WoS Population: 2.5 million**
- **8,438 new patients per year**



- NHS Grampian
- NHS Highland
- NHS Orkney
- NHS Shetland

- **Beyond WoS (5.5 million)**

"whoever you are & wherever you live"

- **Access to early phase trials & experimental medicine for other Scottish Cancer Centres**
- **Equity of access for geographically–remote communities**
- **Inclusion of areas of high deprivation**

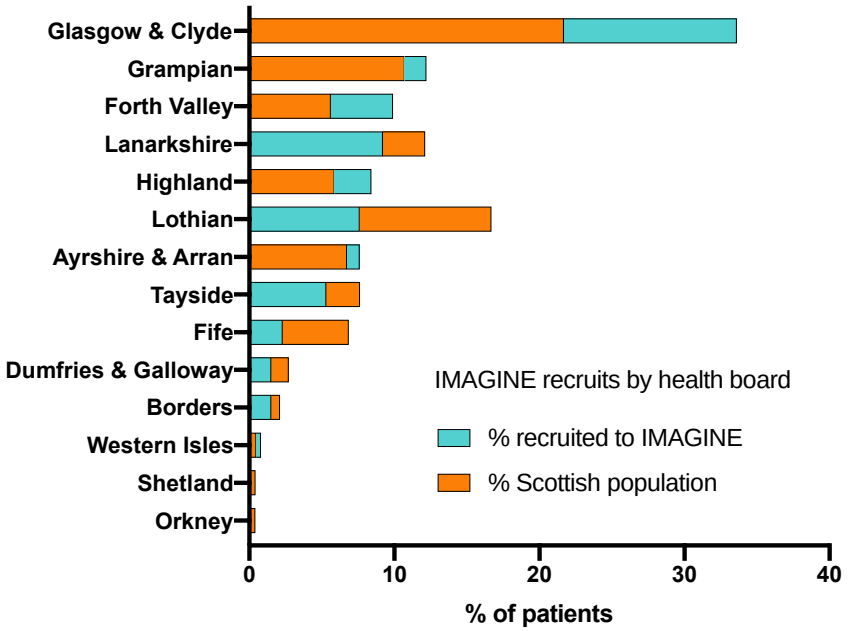
- NHS Greater Glasgow & Clyde
- NHS Ayrshire and Arran
- NHS Forth Valley
- NHS Lanarkshire
- NHS Western Isles

- NHS Lothian (Edinburgh)
- NHS Fife
- NHS Borders
- NHS Dumfries & Galloway
- (NHS Tayside)

Delivering Equitably to a Diverse Population

"whoever you are & wherever you live"

Inclusion across Scotland

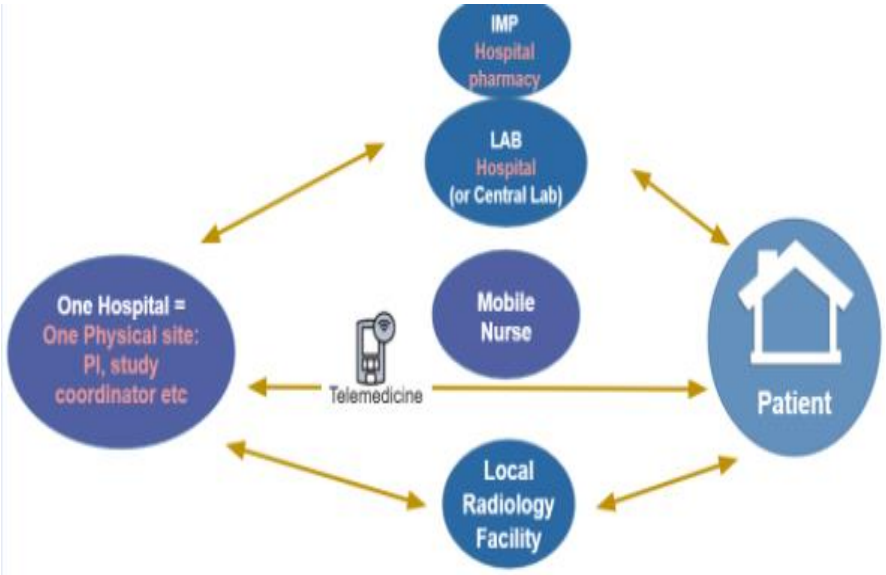


Across all Health Boards

Across all deprivation indices

Accelerating Activity

- "decentralised trials"
- apply lessons learned to TAPISTRY in Scotland



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“De-Centralised” Clinical Trials

- Brings the trial to the patient
- More efficient to recruit rare sub-populations
- Removes geographical constraints (and burden for patients etc)
- Better clinical resource utilisation
- Improves patient participation and retention

we need to convince stakeholders and ensure patient safety

A “De-Centralised” Clinical Trial

in “rare” populations

- near-patient trial activity
- remote (virtual) consultation with study centre & PI
- continued connection and engagement with local team
- less economic and travel burden for patients
- data integrity is maintained
- use of devices to collect remote data
- enhances participation – and of diverse populations
- inclusive of patients from rare populations (e.g. specific mutations)
- more equitable access
- better retention on study (and adherence to procedures)
- more efficient delivery
- ***better for patients***

Traditional Design vs De-Centralised Trials

"rare populations"

traditional approach to trials

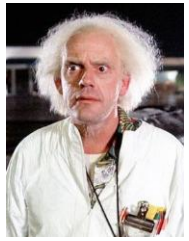
multiple sites, may not recruit many patients at each

multiple visits, for "standard" investigations and (oral) treatments

de-centralised approach to trials

patient reviewed at home by mobile (nursing) teams
PI and study teams via virtual consultations
specialised pharmacy courier services
local investigations & procedures
close working with local teams

De-Centralised Clinical Trials



one hospital for the UK

mobile Nurse

study teams

telemedicine

visit

continued support

central lab

CTs & other procedures

supply

local (radiology) facilities

IMP hospital pharmacy

patients (and their carers)

Challenges – Regulators & Sponsors

- **Study Oversight**
  - is it safe for patients
  - safety reporting requirements
  - GCP compliance & protocol adherence
- **Resources**
  - sponsors need to supply resource and infrastructure
  - mobile teams in many regions
  - training: GCP, Oncology, SACT, - with shortage of human resource
- **What happens if there is a problem?**
  - role and reimbursement of local teams
  - local R&D requirements

Challenges - Investigators

- **Study Oversight**

  can I do this safely?

  am I protected (indemnified)?

- **PI Responsibilities**

  how can I manage mobile teams not employed by my R&D?

- **Financial Reimbursement at local sites**

  up front negotations, or “just-in-time” response – mode?

- **How are patients identified** (and by whom)**?**
- **Academic credit** (publications; QQRs)
- **How best to liaise with the local teams?**

Traditional vs Just-in-Time Trials

- too much time spent on feasibility and opening unproductive sites
- redundant efforts in site activation and participation
- impairs early identification of rare patient groups
- multiple sites' IRBs, contracts, IT, delegation logs
- sites have too many trials, impairs studies that are harder to recruit

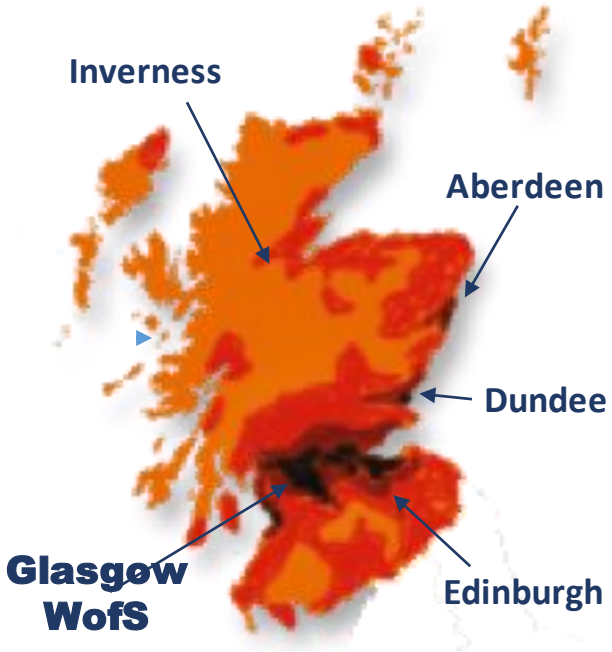
- only sites with eligible patients will enrol
- less redundancy of sites, activities
- maximise technology to identify patients
- maximise remote site support
- sites with less resource and more diverse patients can participate

Opportunities

- **WoS Population: 2.5 million**
- **8,438 new patients per year**

- **Beyond WoS (5.5 million)**

"whoever you are & wherever you live"



- apply lessons from COVID-19 studies
- use of devices, remote & virtual working
- engage patients & funders in new approach
- adapt for all trials (not just rare populations)

- one PI and multiple associate investigators
- devolve to include multiple labs, radiology
- treatment at study sites, assessments remotely or locally
- "nationalised" health care system

will need different regulatory frameworks, reimbursement models, working relationships & practices make trials patient-centred

Any Questions?