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Manchester BIOGEL

Dammy Olayanju

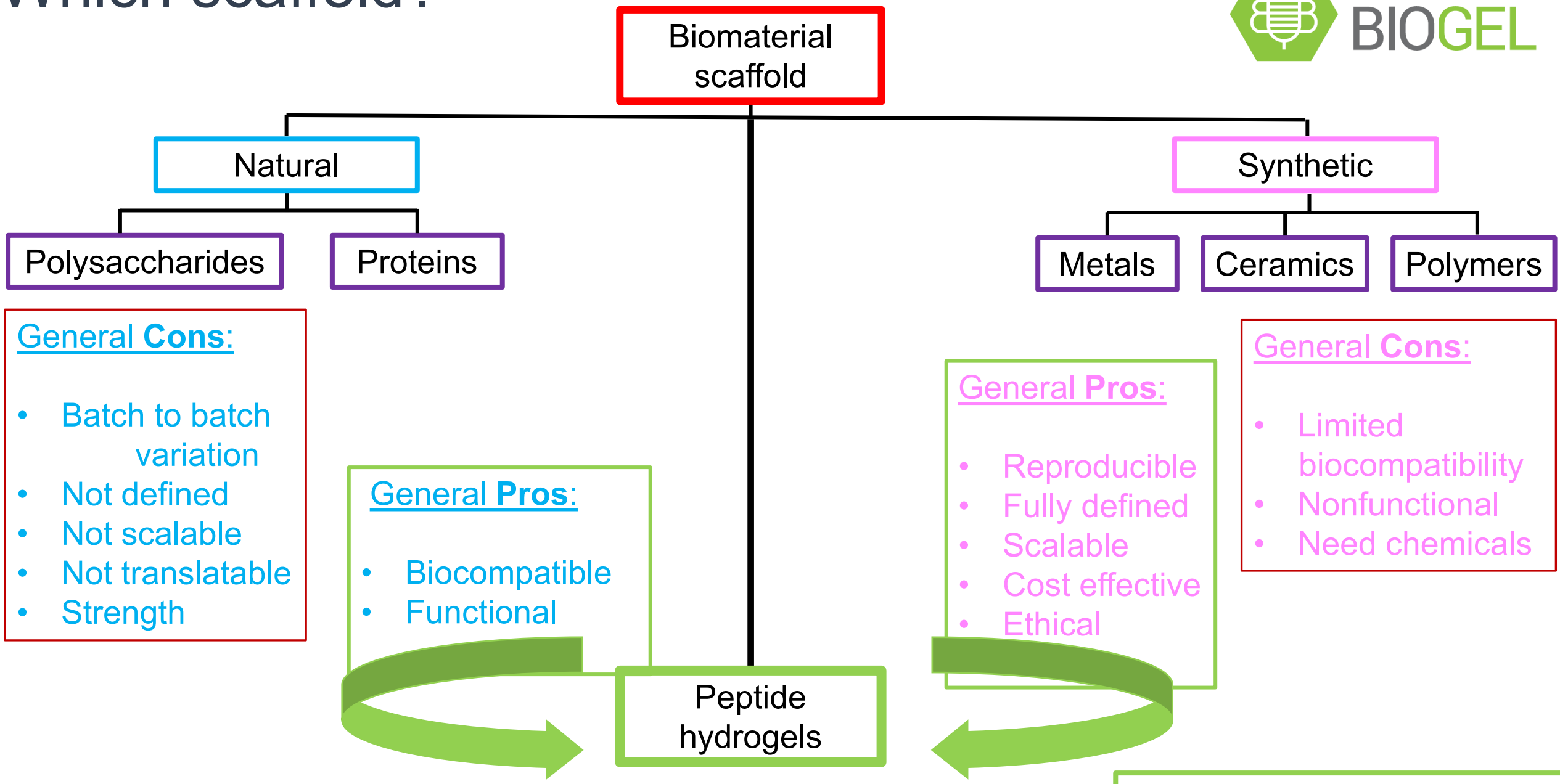
Animal-Free Tuneable Peptide hydrogels for Cell Culture

Dr. Dammy Olayanju
Principal Scientist

Manchester BIOGEL

Redefining Cell Culture for Life Science

Which scaffold?



a.olayanju@manchesterbiogel.com

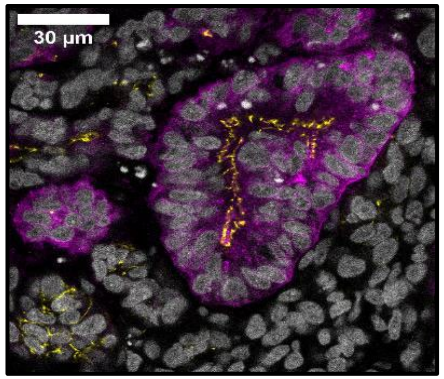
PeptiGels® for 3D cell culture

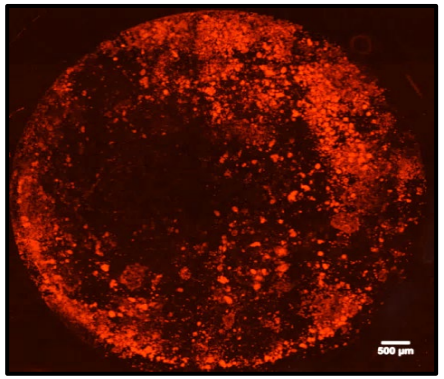
Manchester BIOGEL

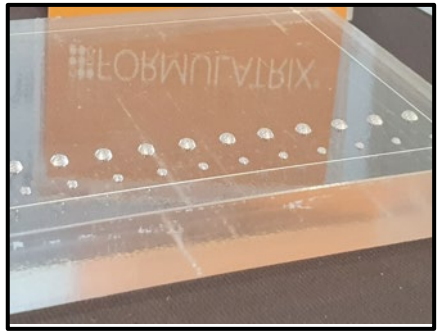
Fully synthetic peptide gels with tuneable stiffness and functionality to replicate all human tissues

a.olayanju@manchesterbiogel.com

Applications







Complex 3D models e.g. organoids

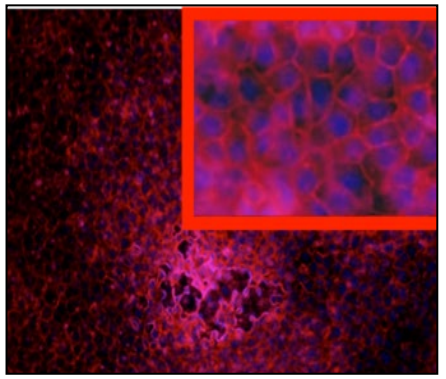
Drug discovery

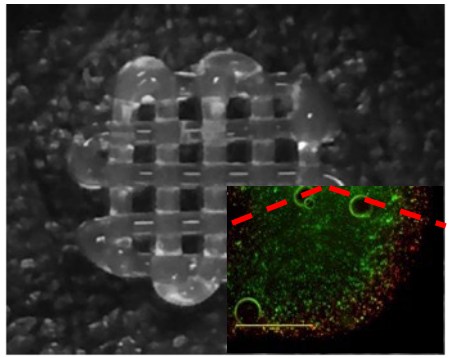
Liquid handling

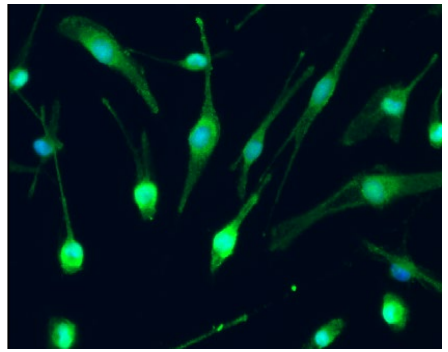
Disease modeling

Bioprinting

Regenerative Medicine







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Clinical Trials Sponsorship

Dr Mohammed Zubair


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Clinical Trials in Humans

Clinical academics and non-clinical academics are interested in seeing if drugs including advanced therapies and medical devices:

- **Safety**
- **Efficacy**

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Sponsorship Scope

- Why does the University of Manchester sponsor clinical trials?
- Legal responsibility
  - Finance
  - Indemnity
  - Management

Not just ethics or red-tape

- Regulations: GCP, GMP, ISO standards
- MHRA, EMA, FDA, HRA

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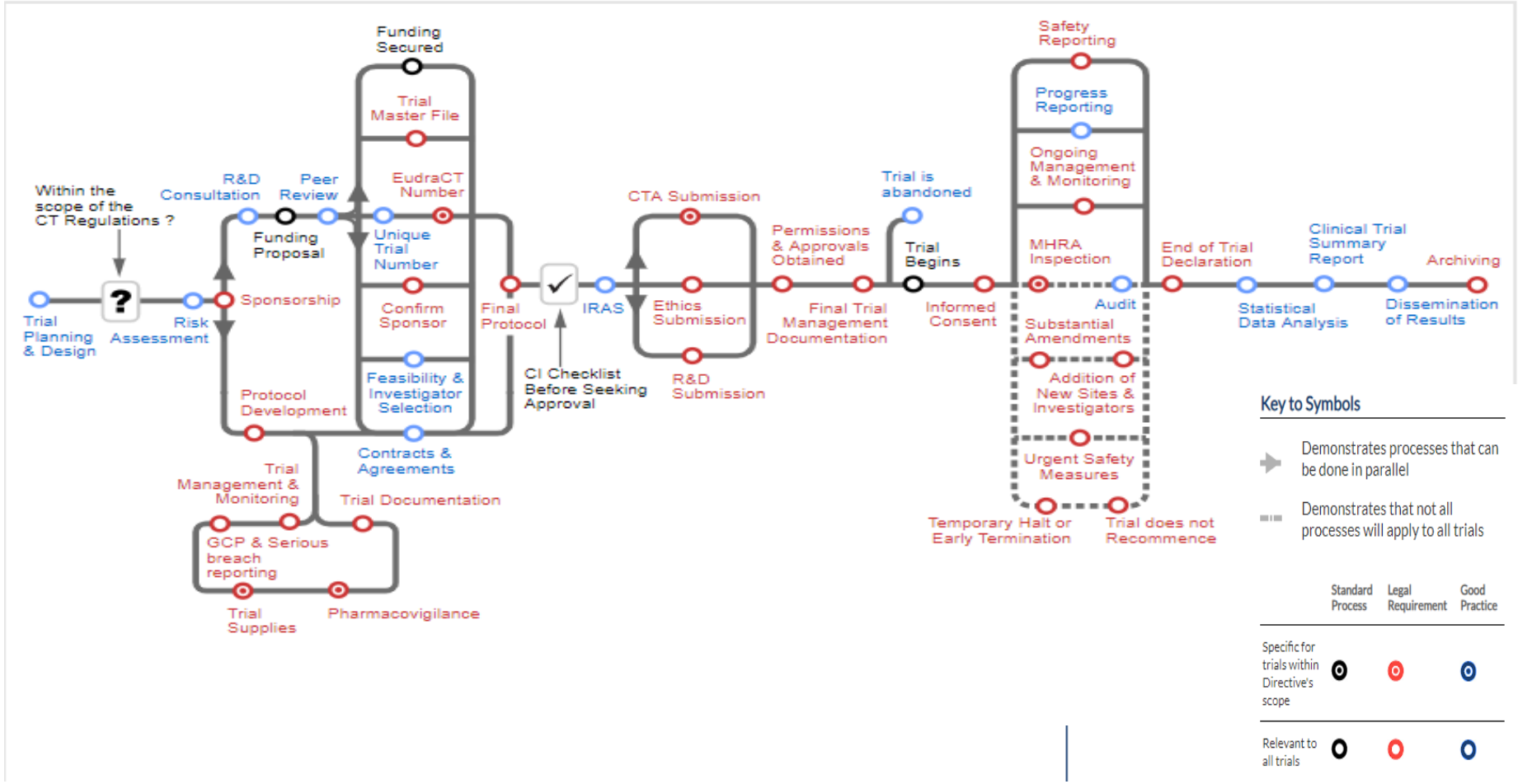

http://www.ct-toolkit.ac.uk/routemap/

UoM Clinical Trials Team - RBE

Specialists that provide oversight and support from application through to archiving

- **Medical Devices – All classes, including software**
- **Drug trials – CTIMPs and ATMPs**
- **Other trials – nIMPs, mechanistic trials and feasibility studies**
- **Clinical Trials Pharmacists – *IMP and ATMP Specialists***

Professional Services

- **Contracts – financial agreements, SLAs, service vendors (GCP and GMP)**
- **RSMs - Costs**
- **BE**
- **Insurance Office – Exclusions to UoM Clinical Trials Policy**

External

- **Sponsor Network - Russell Group Universities**
- **HRA and MHRA**

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Experience with Drug Trials

- Traditional CTIMPs
- Experimental Medicine
- Advanced Therapies (gene-modification therapies)
- Early (FIH) and late phase trials

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Experience with Clinical Investigation of a Medical Device (Sponsor and/or Manufacturer)

- Novel or off-label use Class I – self-certification
- Class IIA and IIB
- Class III – including first in human use.

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Collaboration and Support

- UoM has a strong reputation for research in basic science
- Our focus is to help colleagues understand the route to clinic through trials.

If your research may be clinically useful – drug, device or other clinical intervention thinking of or working on potential and/or you need to understand the regulatory strategy product into the clinic:

- Medicines
- New technologies – CRISPR; AAV or LV gene-modification
- New materials – Graphene or other nanomaterials

- Is there a plan to trial your product in humans?
- How valid is the pre-clinical data?
- Early Access Schemes?

- Speak with our sponsor team UoM:
- Medical device trials: medicaldevices@Manchester.ac.uk
- Drug trials or other: clinicaltrials@Manchester.ac.uk


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Bioxydyn Ltd

Prof John Waterton

CONSENSUS STATEMENT

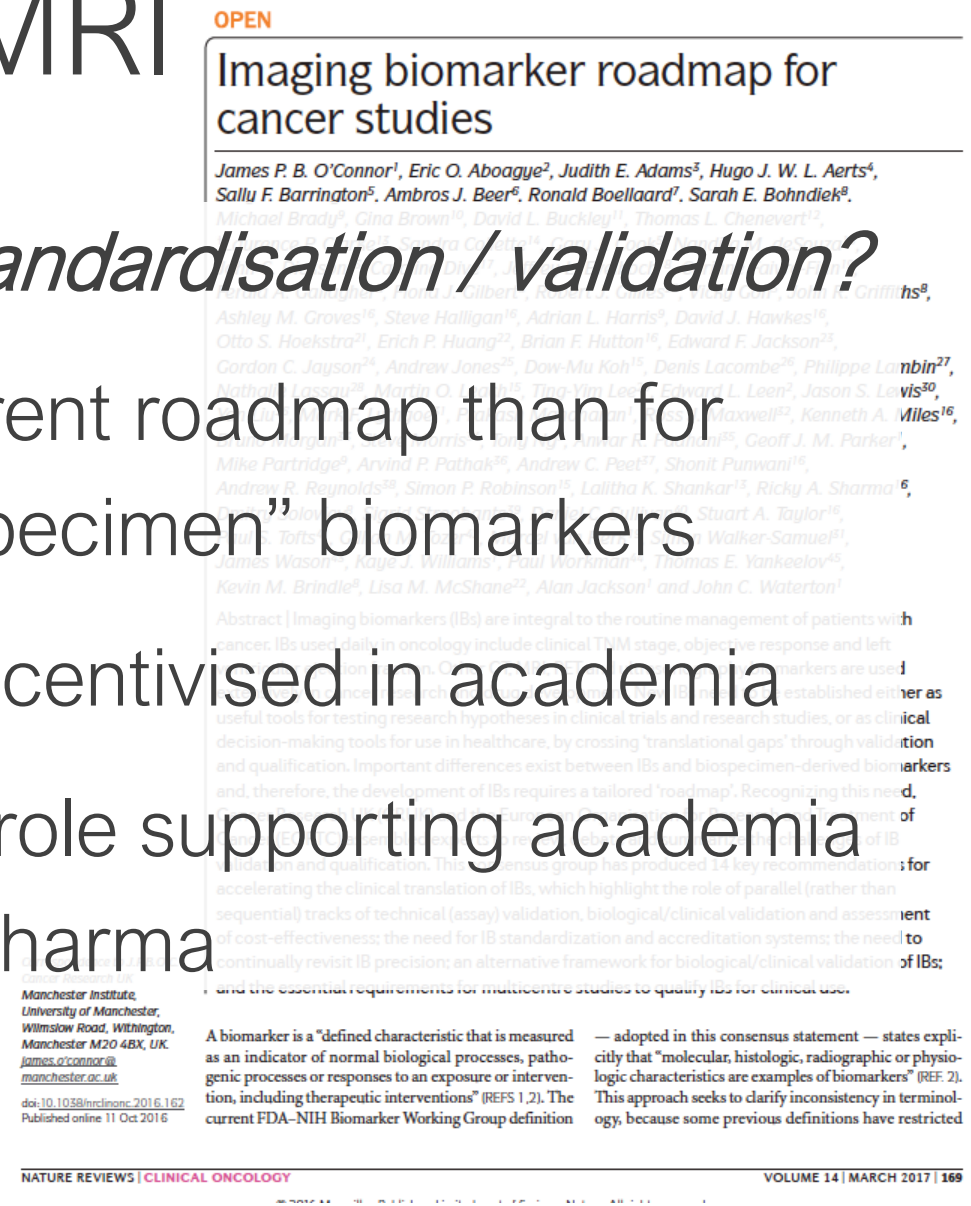
Imaging biomarkers e.g. MRI

Why?

- Good for focal disease
- Non-invasive and follow-up
- Same regulatory status as other biomarker modalities

But: standardisation / validation?

- Different roadmap than for "biospecimen" biomarkers
- Not incentivised in academia
- CRO role supporting academia and Pharma


OPEN

Imaging biomarker roadmap for cancer studies

James P. B. O'Connor[1], Eric O. Aboagye[2], Judith E. Adams[3], Hugo J. W. L. Aerts[4], Sally F. Barrington[5], Ambros J. Beer[6], Ronald Boellaard[7], Sarah E. Bohndiek[8], ...

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doi:10.1038/nrclinonc.2016.162
Published online 11 Oct 2016

A biomarker is a "defined characteristic that is measured as an indicator of normal biological processes, pathogenic processes or responses to an exposure or intervention, including therapeutic interventions" (REFS 1,2). The current FDA–NIH Biomarker Working Group definition — adopted in this consensus statement — states explicitly that "molecular, histologic, radiographic or physiologic characteristics are examples of biomarkers" (REF. 2). This approach seeks to clarify inconsistency in terminology, because some previous definitions have restricted

NATURE REVIEWS | CLINICAL ONCOLOGY VOLUME 14 | MARCH 2017 | 169

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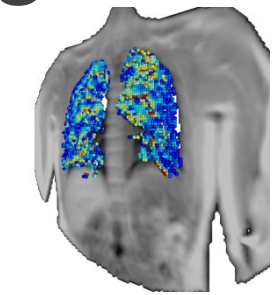
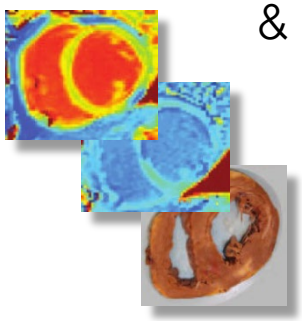
Example disease areas and imaging biomarkers – all quantitated

- **Pulmonary**: COPD, asthma, cystic fibrosis, NSCLC, ILD
- **Inflammation**: Rheumatoid arthritis, osteoarthritis, psoriatic arthritis, lupus, Sjögren's, IBD
- **Cardiovascular**: Heart failure, tissue quality
- **Hepatology**: Liver transporter function, perfusion, tissue quality
- **CNS**: Dementia, blood brain barrier, neurodegeneration
- **Oncology**: Hypoxia, angiogenesis, cellularity (proliferation & apoptosis)

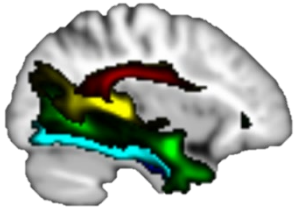


Ventilation & perfusion

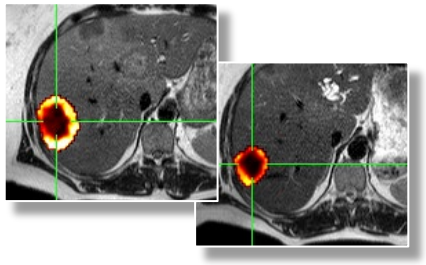
Inflammation



Tissue quality & function



Connectivity & tissue quality



DCE-MRI, OE-MRI

Morphology & BBB

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What can Bioxydyn do for you?

- Advice on choice of imaging biomarker
- Help justify in grant proposals / clinical development plans
- Acquire, analyse and report quantitative imaging biomarkers
  - QA single/multi-centre, GCP compliance, audit trail
  - QC site qualification, site training, data triage
  - Proprietary FDA 21 CFR Part 11 compliant VoxelFlow^{TM} platform
- Support publications and regulatory submissions

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Christabel Pankhurst Institute and Advanced Materials and Medicine

Prof Niels Peek

Our mission is to make positive change in health and care for all through multidisciplinary and collaborative development, evaluation and implementation of new health technologies

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@UoMPankhurst

EUROPEAN UNION
European Regional Development Fund

NORTHERN POWERHOUSE

Greater Manchester
Local Enterprise Partnership

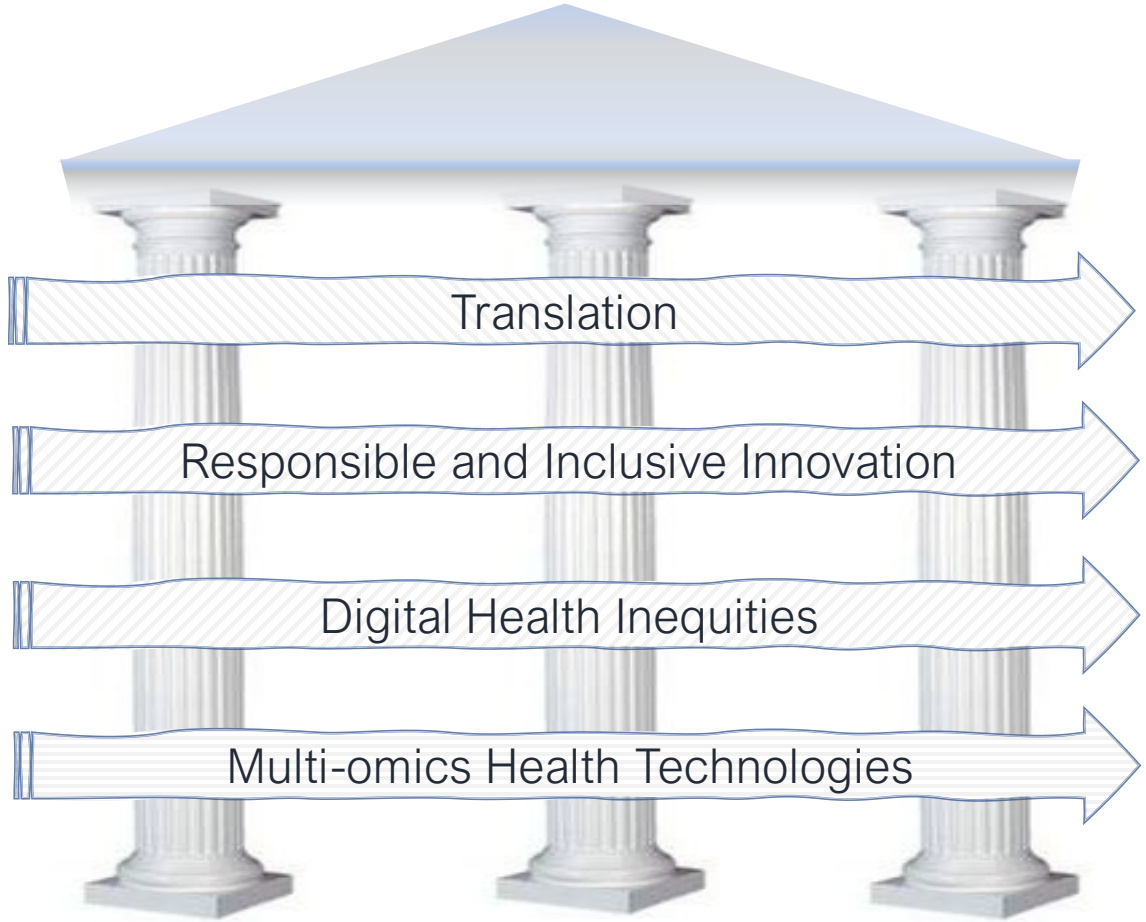
TECHNOLOGY AREAS AND CROSS-CUTTING THEMES

Claudia Lindner

Robert Meckin

Sabine van der Veer

Juhi Gupta



Niels Peek

Julie Gough

Samuel Kaski

TRANSLATION

Improve translation of health & care technology by making translational activities an integral part of health technology research.

Create and provide translational resources to support researchers from the early stages of development.

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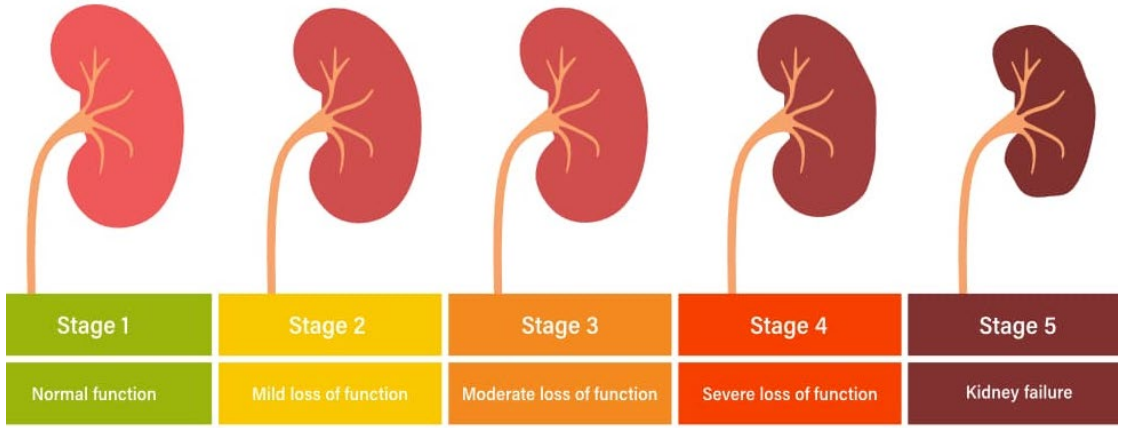
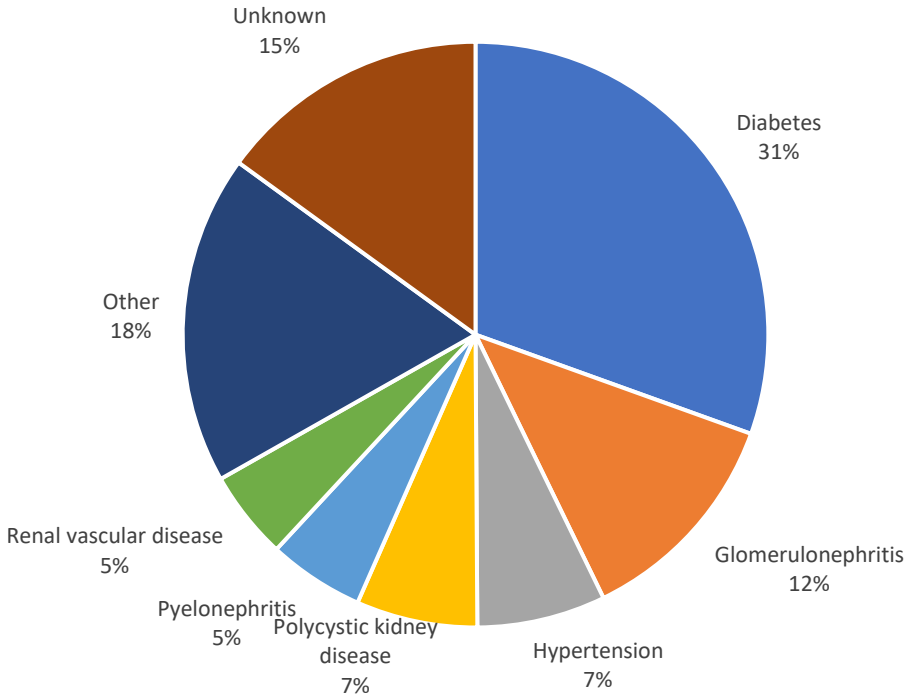
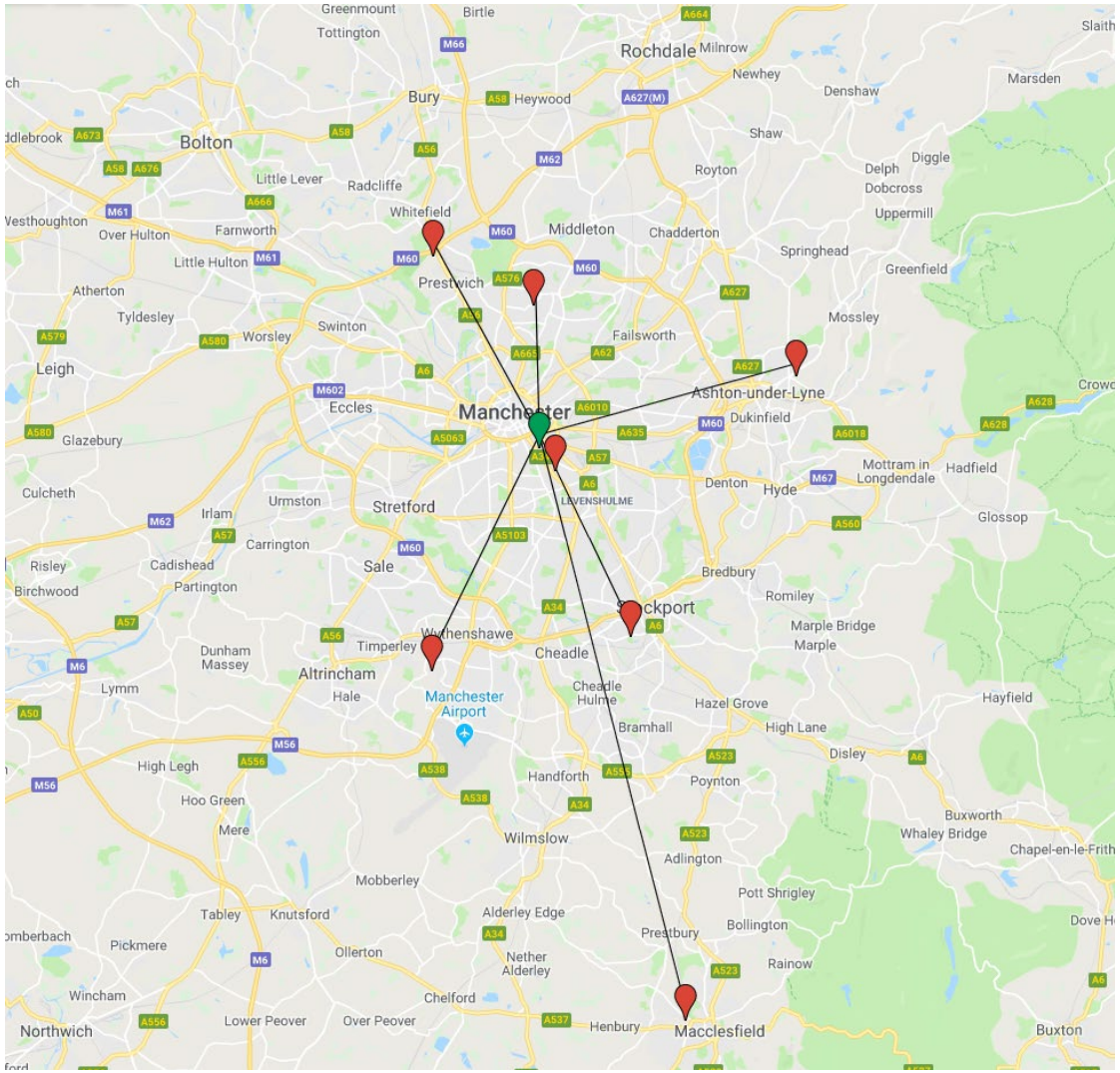
Manchester Renal Biobank at the Manchester Institute of Nephrology and Transplantation

Durga Kanigicherla







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NHS Foundation Trust

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Manchester Renal Biobank

Aims

- To develop resource for kidney disease research
- Advance precision medicine through innovative diagnostics & prognostication

Objectives

- Clinical repository for patients with kidney disease(s)
- Blood, Urine, Kidney tissue (fresh / frozen)

Processes & Sampling

- REC approved, MFT R&I Division
- 2016-2026
- 1000 patients
- Adults & Children
- Recruitment during natural history of kidney disease or renal replacement therapy
  - *Normal Healthy Volunteers*
- Genetics, Proteomics, Metabolomics
- Prospective collection & Serial sampling

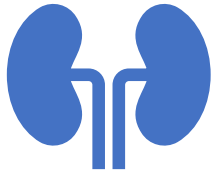
Manchester Renal Biobank

Partnerships & Access

Fundamental & Translational

Academic & Industrial research

Collaboration of scientists, clinicians & patient groups



Future & Ambitions

Recruit 1000 patients over 4 years

Non-Glomerular diseases like Polycystic kidney diseases, Unknown diseases, patients on dialysis

Contacts

Dr Patrick Hamilton

Dr Omar Ragy

Ms Ananya Saha

Prof Rachel Lennon

Dr Durga AK Kanigicherla

Prospective design, detailed clinical information, and stored biological specimens including kidney tissue

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Complex Wounds @ Manchester Biobank

Faith Phiri

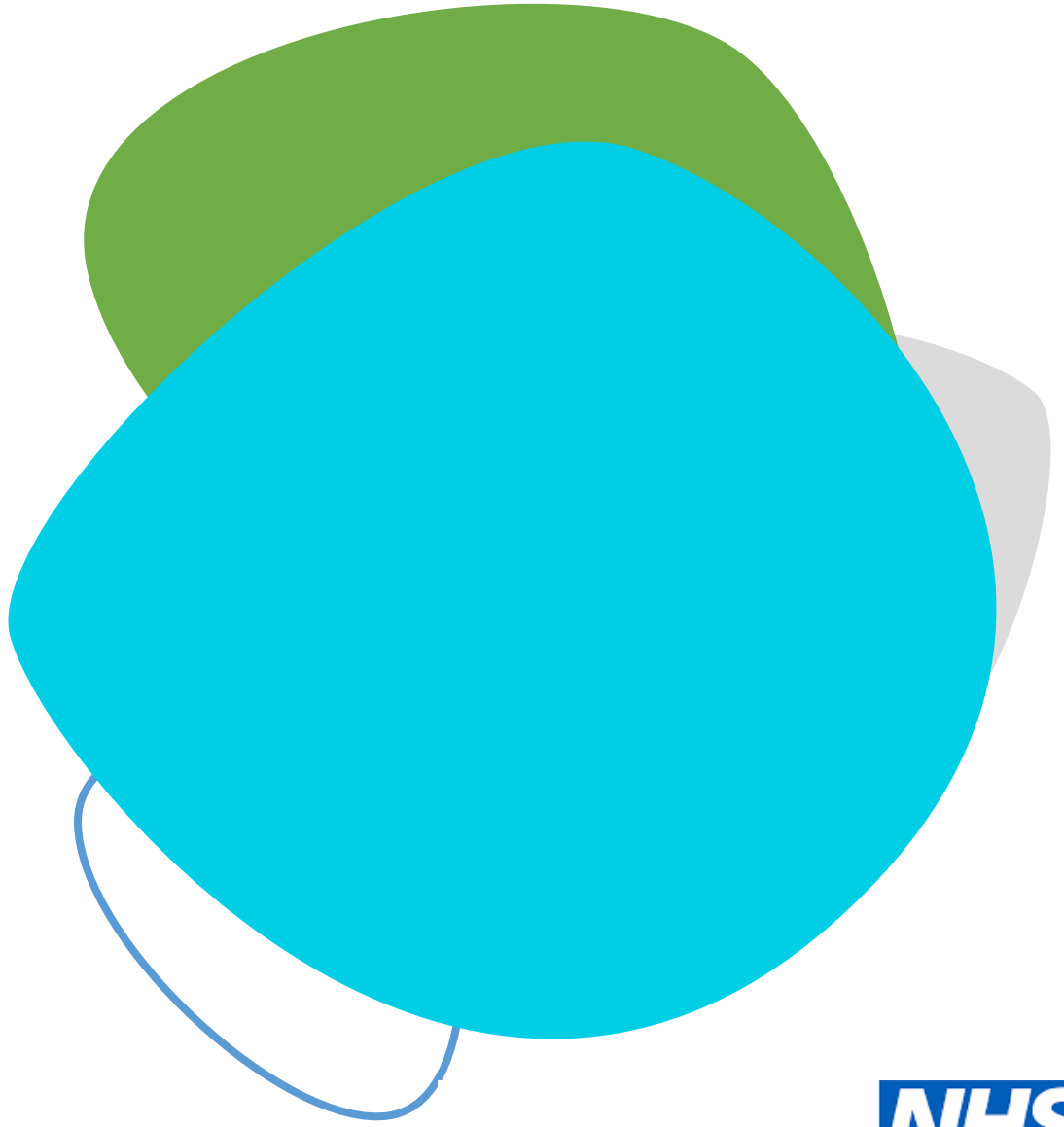
Complex Wounds Manchester Biobank

Faith Phiri

Clinical Research Practitioner

Burns & Plastics – Complex Wounds

ComplexWounds.BioBank@mft.nhs.uk



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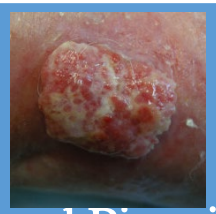
NHS
Manchester University
NHS Foundation Trust

Types Of Samples

Blood

Collected using a standard blood sampling needle and collection tube. The amount taken at any visit would not exceed 15ml.



Wound Biopsies

Additional wound biopsy during treatment period. These are taken from the wound and occasionally nearby healthy tissue.

Wound Fluid & Dressing

Dressing and wound material for analyses, that is usually discarded. These samples may be taken at any time during your treatments.

Wound Tissue

Removed from a wound as part of normal care e.g., during an operation.

Tissue such as skin, fascia, fat, tendon, muscle scar & adhesions etc.

Wound Swabs

Additional wound swabs during treatment period. The number of swabs taken will be dependent on the size and status of your wound.

Study Management

Assist biomedical research involved with preventing, diagnosing and treating a wide range of wounds with prolonged healing.

Applications are approved and accepted by the CWB Ethics Advisory Group

Compatible samples are taken prospectively to order - surplus wound samples are stored

Samples are application dependent/specific

Typically stored fresh frozen at -80oc at the MFT biobank ran by Jay Brown

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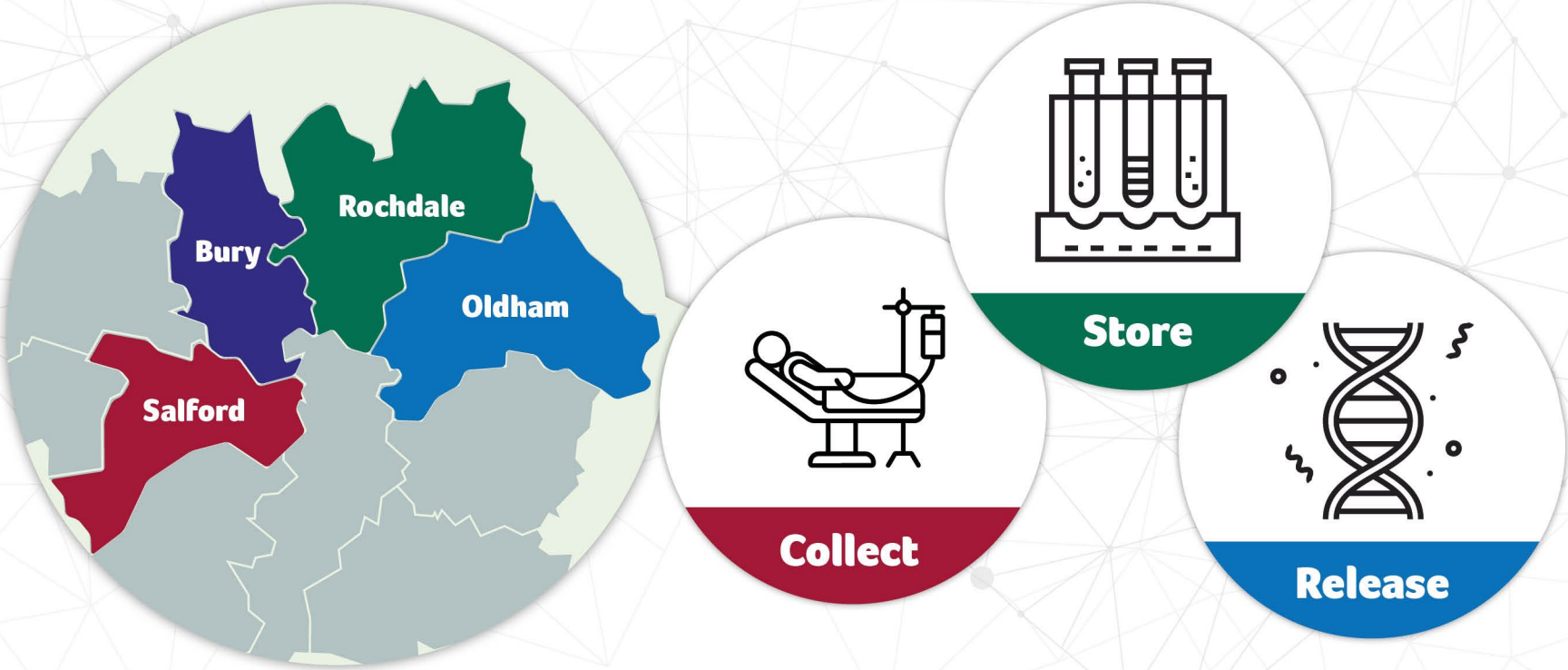
Northern Care Alliance Research Collection (NCARC)

Darren Green

Research & Innovation

NCARC
Northern Care Alliance Research Collection

NHS
Northern Care Alliance
NHS Foundation Trust



Saving lives, Improving lives

Collect

Collect

- Will samples hold research value
- Alligned to NHS or R&I objectives
- Funded or likely cost recovery
- Capacity / feasibility
- Regulatory implications i.e compliance and audit
- Appropriate number/type of samples and patient cohort
- Application to collect samples and review by the collection and access review panel (CARP)

Patients

- Potentially any disease area Living adults
- Can include patients with impaired capacity

Samples

- Any surplus clinical samples
- Additional minimally invasive
- Extra sample during a minor procedure

Store

Store

Salford Biorepository Facility

- Professional, safe and secure sample storage
- Access to staff and calibrated, serviced equipment
- Regulatory compliant (e.g., HTA PD, records, etc)
- Costs agreed with biorepository/NCARC

Release

Release

- Application to access samples and review by CARP
- Panel include patients, clinical staff, statisticians, R&I
- Applications circulated via email
- Justify sample request and value of research
- Cost recovery i.e type of partnership academic, commercial, charity etc

CARDIOVASCULAR RENAL METABOLIC

- Blood biomarkers in acute cardiovascular presentations
- Metabolic medicine and rare diseases
- Diabetes and endocrine collection
- Kidney Disease collection

SURGICAL SPECIALTIES

- Bloods and outcomes pre and post bariatric surgery
- Upper GI Cancer Biobank: tissue, bloods and other samples

NEUROSCIENCES

- Neuropathology biobank: tissue and fluid collection of neuroinflammatory and neurodegenerative disorders
- Tissue and fluid banking in idiopathic normal pressure hydrocephalus
- Idiopathic Inflammatory Myopathies (IIM), Myositis collection
- The Manchester Motor Neuron Disease Biobank (MNDB)
- Adult Spinal Muscular Atrophy (SMA) CSF and blood collection
- Myasthenia Gravis muscle biopsy and blood biobank
- Neurodegenerative collection

RESPIRATORY

- Salford Lung Cancer collection of pleural fluid and tissue samples
- Salford respiratory biobank of mixed biological samples
- COVID-19 tissue collection: blood, serum, saliva, sputum, nasal strips, nasopharyngeal & oropharyngeal swabs and pleural fluid

Contact

ncarc@nca.nhs.uk