The Wellcome Trust/HRB Clinical Research Facility at St. James' Hospital

Professor Michael Gill, Director

February 2015

Wellcome Trust - HRB
Clinical Research Facility
at St. James's Hospital

HRB
Health Research Board

Supported by
wellcome trust

Part of a Programme jointly funded by the Wellcome Trust and HRB

Components:

- Dublin Centre for Clinical Research (DCCR) Network involving TCD, RCSI, UCD and Molecular Medicine Ireland (2009 - 2015) – funded by HRB
- Development of the Clinical Research Facility at St. James's Hospital (2013). Building and equipment costs funded by the Wellcome Trust.
- Operation of the Clinical Research Facility (2012 – 2018) Funded by the HRB

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“It is our mission to improve health outcomes and quality of life by leading and enabling high quality, innovative translational clinical research”

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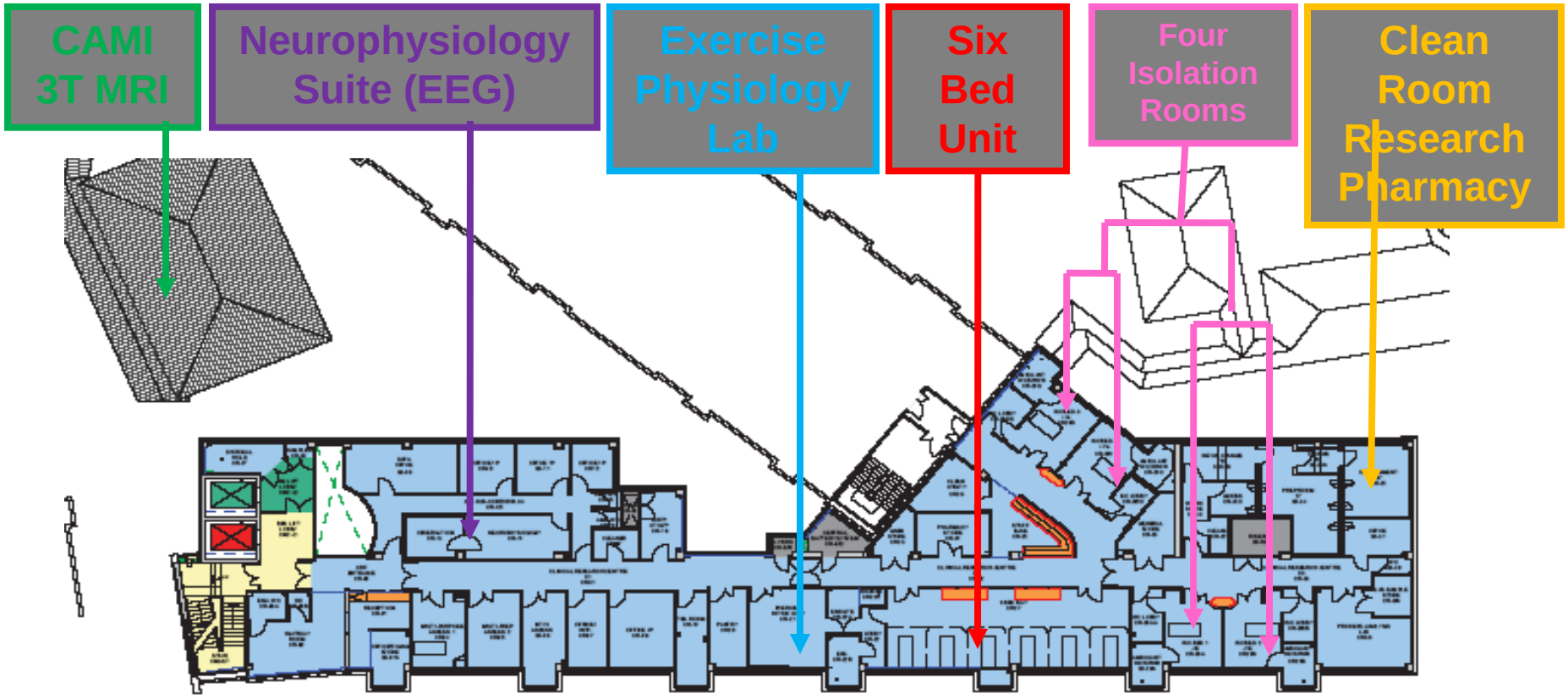
The Design



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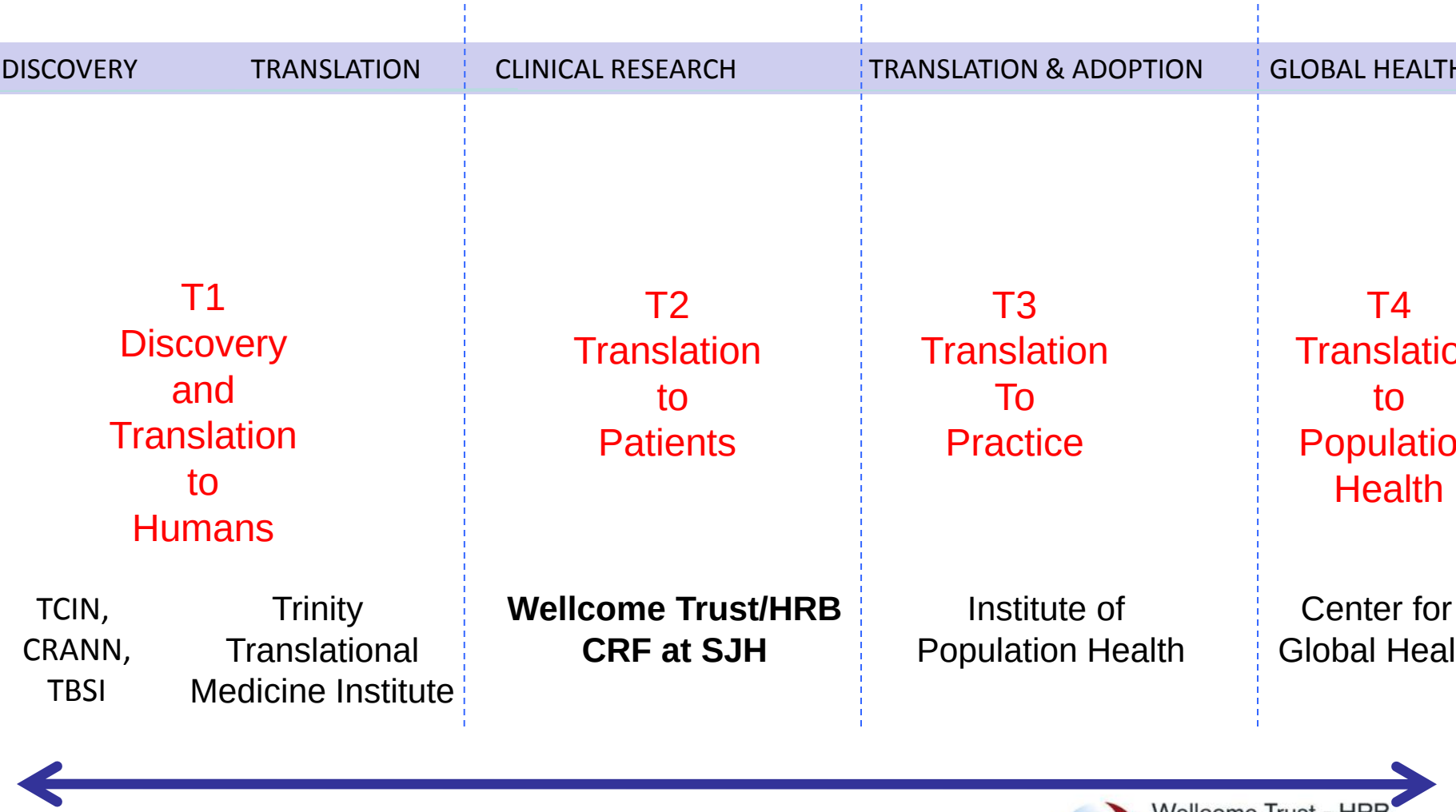
Trinity Translational Medicine Pathway



Courtesy: Professor Padraic Fallon

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Governance

CRF Governance

•Joint Governance between Hospital and University
•CRF staff are appointed by TCD but all have SJH staff appointments and/or staff numbers

Clinical Governance

•CRF is on the SJH Hospital Corridor – all subjects attending are patients of SJH and have a SJH Medical Registration Number (MRN).
•All Principle Investigators are SJH consultants or joint SJH/TCD academic clinicians (professor/consultant)
•The CRF is a designated entity under the Clinical Indemnity Scheme (January 2015)

The Spectrum of Studies supported

- Investigator led Clinical Research/Experimental Medicine/Advanced therapeutics studies.
- Investigator initiated Clinical Research/Clinical Trials (IMP or medical device)
- Pilot studies/clinical research/experimental medicine to obtain data to support future grant application
- Clinical Research/Clinical Trials – Industry Sponsored
- Health Services research – testing of treatment protocols
- Nursing Research Studies
- Studies by Allied Health Professionals including Bioengineering, Nutrition, Psychology, Pharmacy and Physiotherapy
- Studies involving healthy volunteers.

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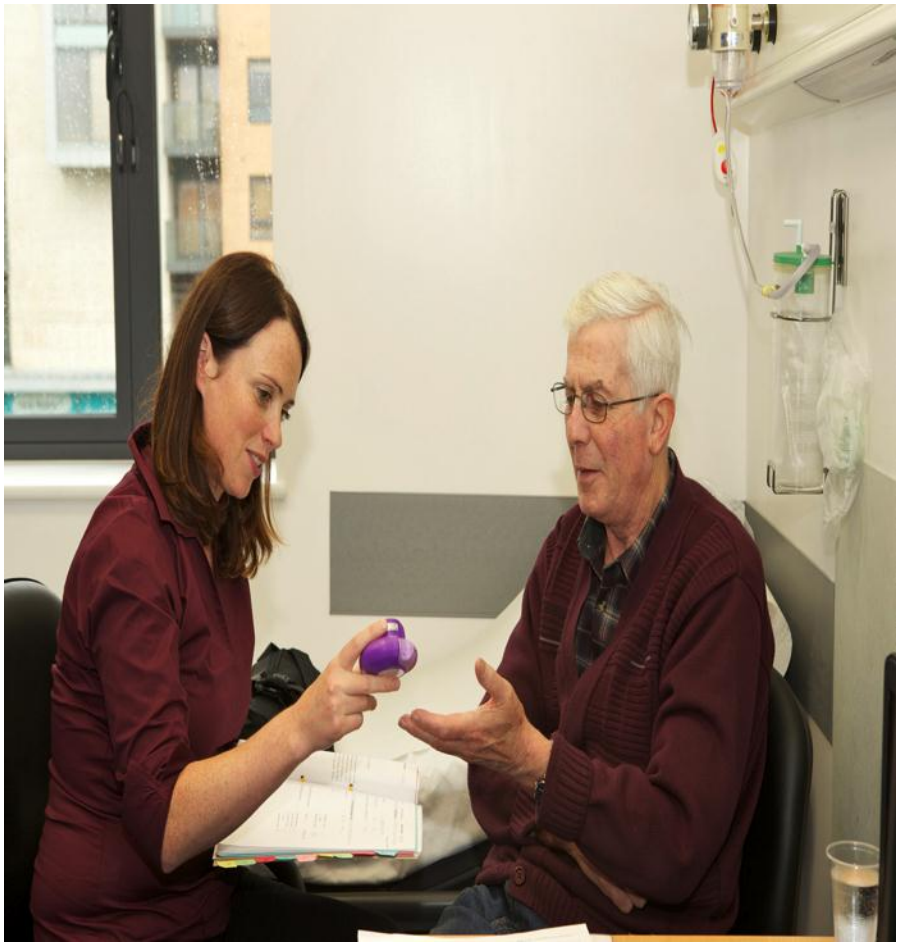
First Patient to Attend the CRF
– October 2013



- Prof. Richard Reilly, Bioengineering
- Prof. Richard Costello, Respiratory Physician
- DCCR Network Study
- WT/HRB CRF

Sally Couper, CRF

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CRF Activity during the first year of operation

- 56 applications
  - 4 applications rejected
  - 16 applications approved awaiting start
  - 10 studies active in CRF
  - 10 studies active outside CRF
  - 13 studies completed or closed

- 549 new subjects recruited
- 857 subject visits

- 26 Clinical Research, investigator led
- 8 Clinical Trials
  - 1 - medical device (investigator led)
  - 1 - Phase 1 (investigator led)
  - 2 - Phase 3 (commercial)
  - 4 - Phase 4 (commercial)

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Operational

- Service Level agreement between SJH and TCD
- Multidisciplinary Quality Framework
- Clear application and assessment procedure for new studies
- Emergency cover as part of the hospital – emergency trolley maintained by hospital
- All CRF studies have a named SJH consultant as PI and a named house doctor available for non urgent events
- All CRF vital systems and equipment procured and maintained by the hospital
- All CRF staff and study personnel are GCP trained

Quality & Regulatory Affairs

- Quality Management System implemented
  - Policies, SOPs, Work Instructions, Study Procedures
- Training Matrix developed:
  - Outlines training requirements per job role for CRF staff
- Staff training records implemented
- Regulatory Tracker set up:
  - Tracks regulatory and ethics submissions to ensure compliance with regulatory requirements
- Training courses developed for internal & external staff

CRF operations - Application process.

- Brief application form and study protocol submitted
- CRF staff meet with PI to complete detailed information on the study and requested CRF resources
- Completed application reviewed by Operational Management team and application approved or additional information required.
- Study feasibility and risk assessment completed
- Study start-up only when all documentation and regulatory requirements are in place and all study staff trained.

The Role of the CRF

- To provide experienced research staff
  - Assistance with protocol development
  - Assistance with Regulatory and Ethical Submissions
  - Conduct day-to-day research activities
- To provide Quality Assurance
  - Conduct internal audits
  - Ensure study/facility is inspection ready
  - Provide training
  - Implementation of standard procedures
- To promote high quality research which is in compliance with applicable regulations

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Development Plan, 2015

- Research and Development Hub – joint TCD/SJH initiative
- Access and support for other non medical clinical disciplines – nursing, physio, pharmacy
- Access and support for non clinical disciplines
- Participation in new HRB funded Irish Clinical Trials Research Network
- Clinical Trial Sponsorship by Trinity College

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St. James' Hospital - an Academic Medical Centre

Mercer's Institute for Successful Ageing

NCH
the new children's hospital

CAMI Centre for Advanced Medical Imaging

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