

Plans for implementation for ISO 20387 – Story so far

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National Irish COVID-19 Biobank

Background & Context:

- Funded by HRB at the request of Dept. of Health
- First Government investment in Biobanking
- Essential component in Ireland's response to Covid-19
- National asset to ensure Covid-19 samples and data are collected in a co-ordinated way
- Key driver for National and International collaboration



National Irish COVID-19 Biobank

- **National Irish COVID-19 Biobank (NICB):** collaboration between 6 academic institutions and 13 hospitals.
- **Co-Principal Investigators:** Prof Colm Bergin (TCD) and Prof Paddy Mallon (UCD)
- **Academic Partners:** NUI Galway, RCSI, TCD, UCC, UCD, UL.
- **Hospital Partners:**

Beaumont Hospital,	Children's Health Ireland,
Coombe Women's University Hospital,	Cork University Hospital,
Mater Misericordiae University Hospital,	National Maternity Hospital Holles Street,
St James' Hospital,	Sligo University Hospital,
St Vincent's University Hospital,	Tallaght University Hospital,
University Hospital Galway,	University Hospital Limerick,
Wexford General Hospital	
- **Coordinators:** Suzanne Bracken (TCD) and Tommy Bracken (UCD)

National Irish COVID-19 Biobank



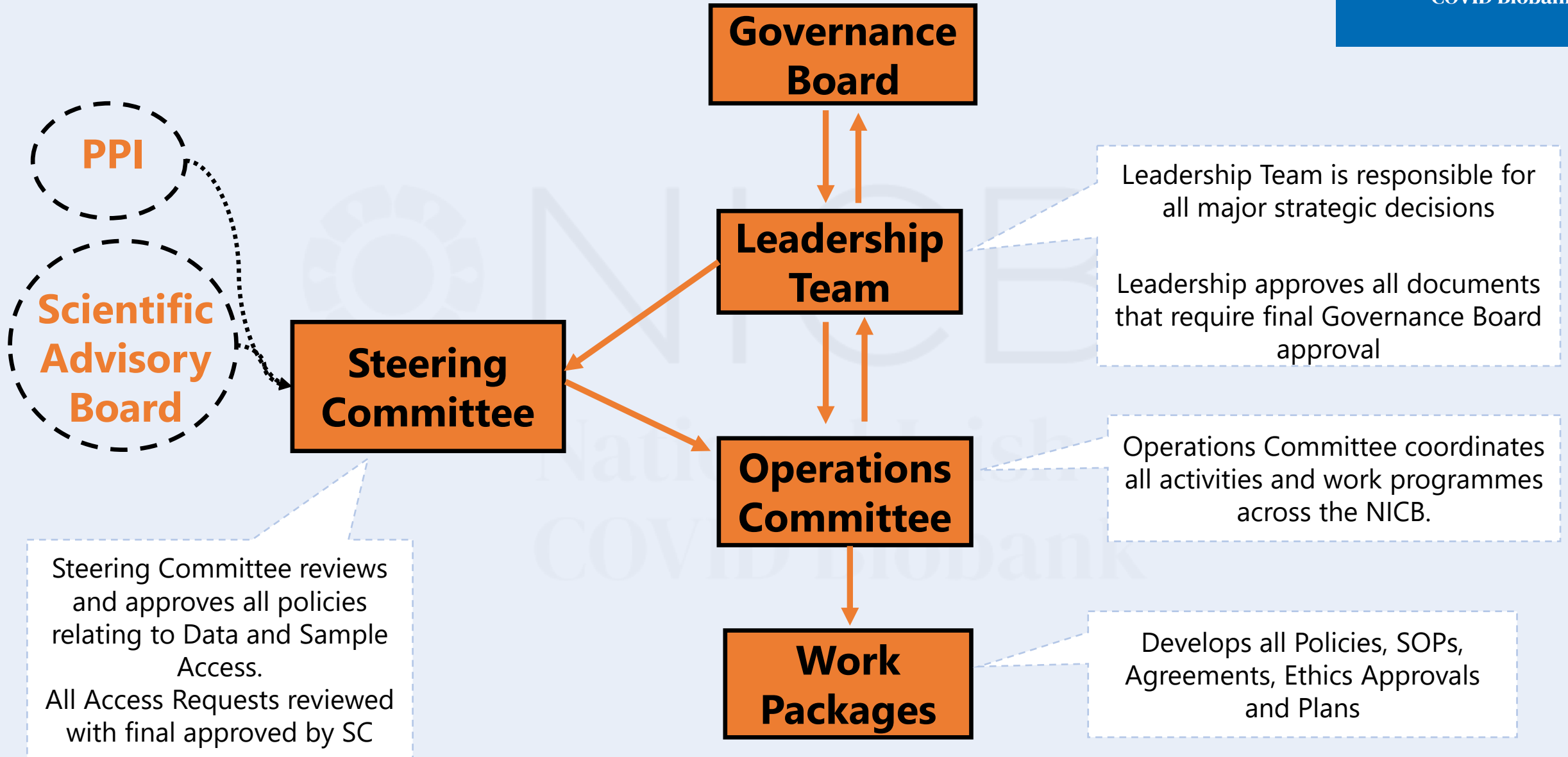
Mission: To compile an expansive, harmonised and integrated biorepository of biological samples and linked sociodemographic and clinical data from participants with COVID-19 and non-infected controls



Aims:

- Support high impact research into the causes, progression, diagnostics, treatment and consequences of COVID-19
- Adapt as new knowledge gaps emerge
- Better prepared for future emergencies
- Provide a roadmap for future integration of biobanking for other diseases e.g. cancer

Governance



Work Packages

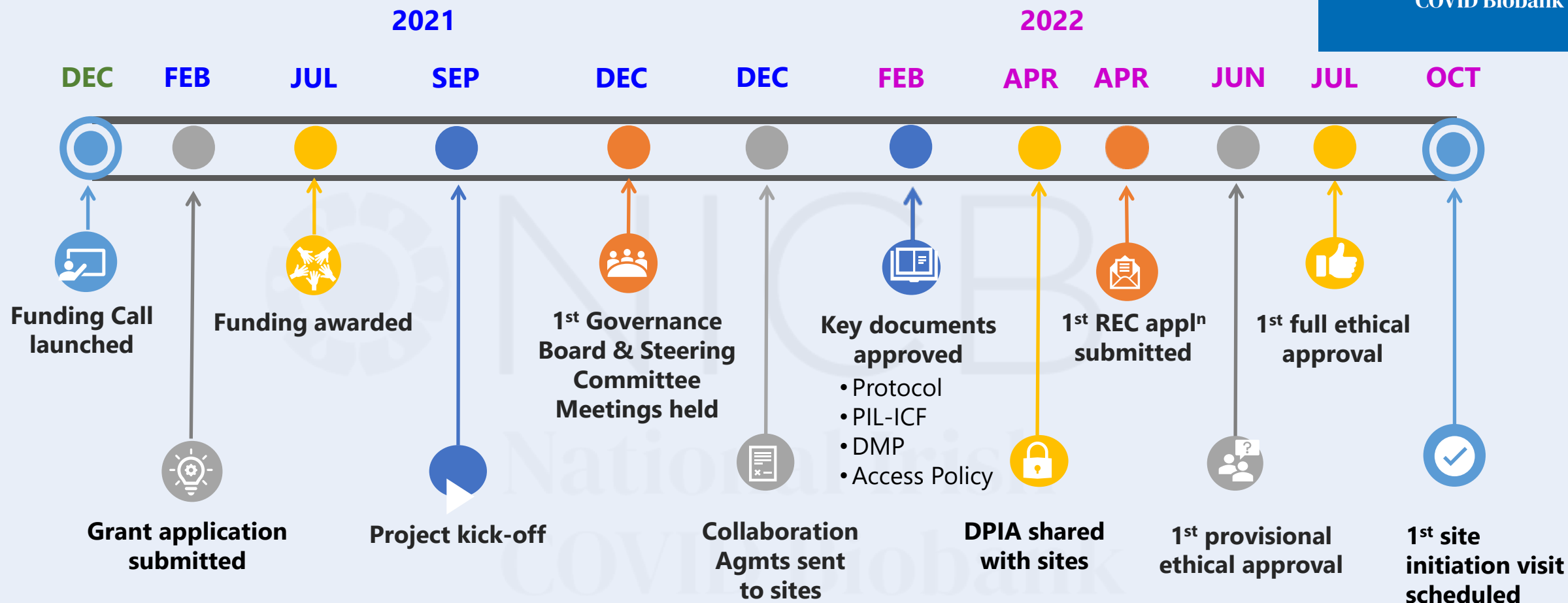
	Work-package	Leads
WP1	Coordination and Management	Colm Bergin (TCD) and Paddy Mallon (UCD)
WP2	Quality Management & Accreditation	Donal Brennan (NMH/UCD), Gianpiero Cavalleri (RCSI)
WP3	Data Standards	Cliona NiCheallaigh (SJH/TCD), Bairbre McNicholas (NUIG/UHG)
WP4	Site Assessment & Mobilisation	Aoife Cotter (MMUH/UCD), Paul McNally (CHI)
WP5	Sample Collection	Niall Conlon (SJH/TCD), Eoin Feeney (SVUH/UCD)
WP6	Collaboration and Dissemination	Mary Horgan (CUH/UCC), Cliona O'Farrelly (TCD)

Strategic Priority Research Areas

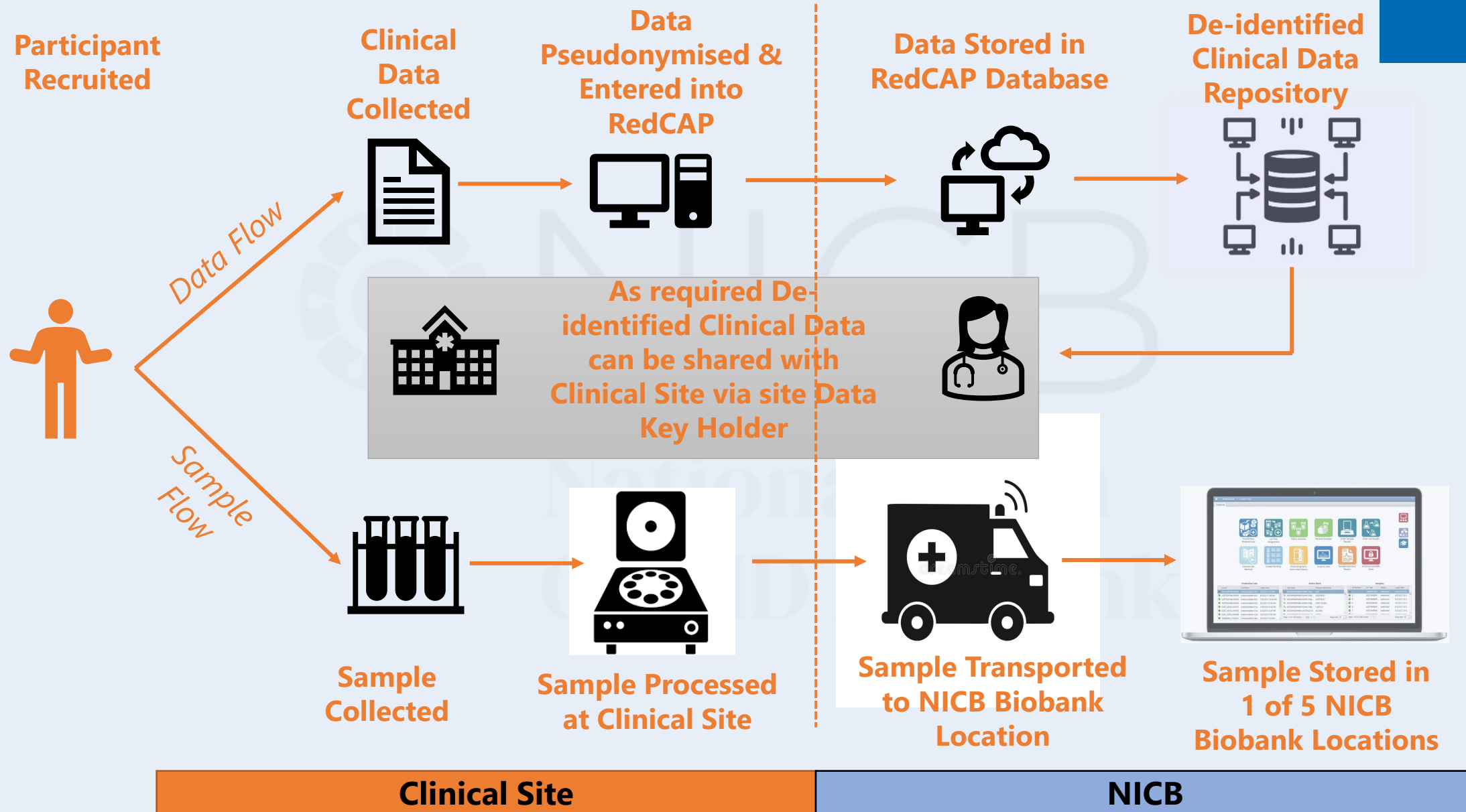
- Identified by Leadership Team with advice from Steering Committee, PPI Committee and Intl Scientific Advisory Board
- Used to develop data sets that collect data relevant to each area
- May change as time goes on, enabling NICB to respond rapidly to new challenges presented by the pandemic and maintain relevance of the biobank
- Strategic Priority Research Areas identified to date:
 - Long Covid
 - Therapeutics
 - Vaccine responses



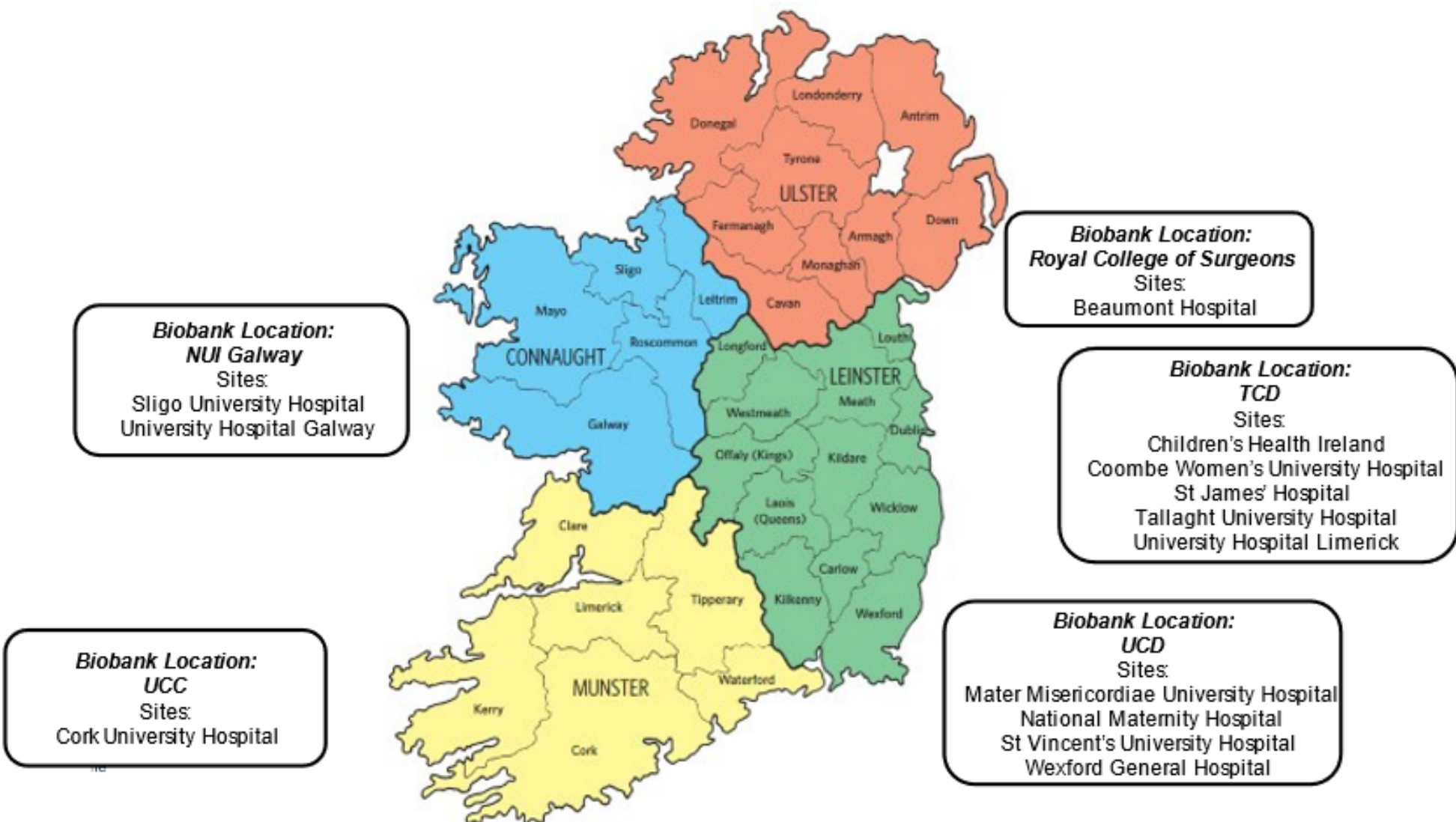
NICB Timeline: Milestones



Data and Sample Flow



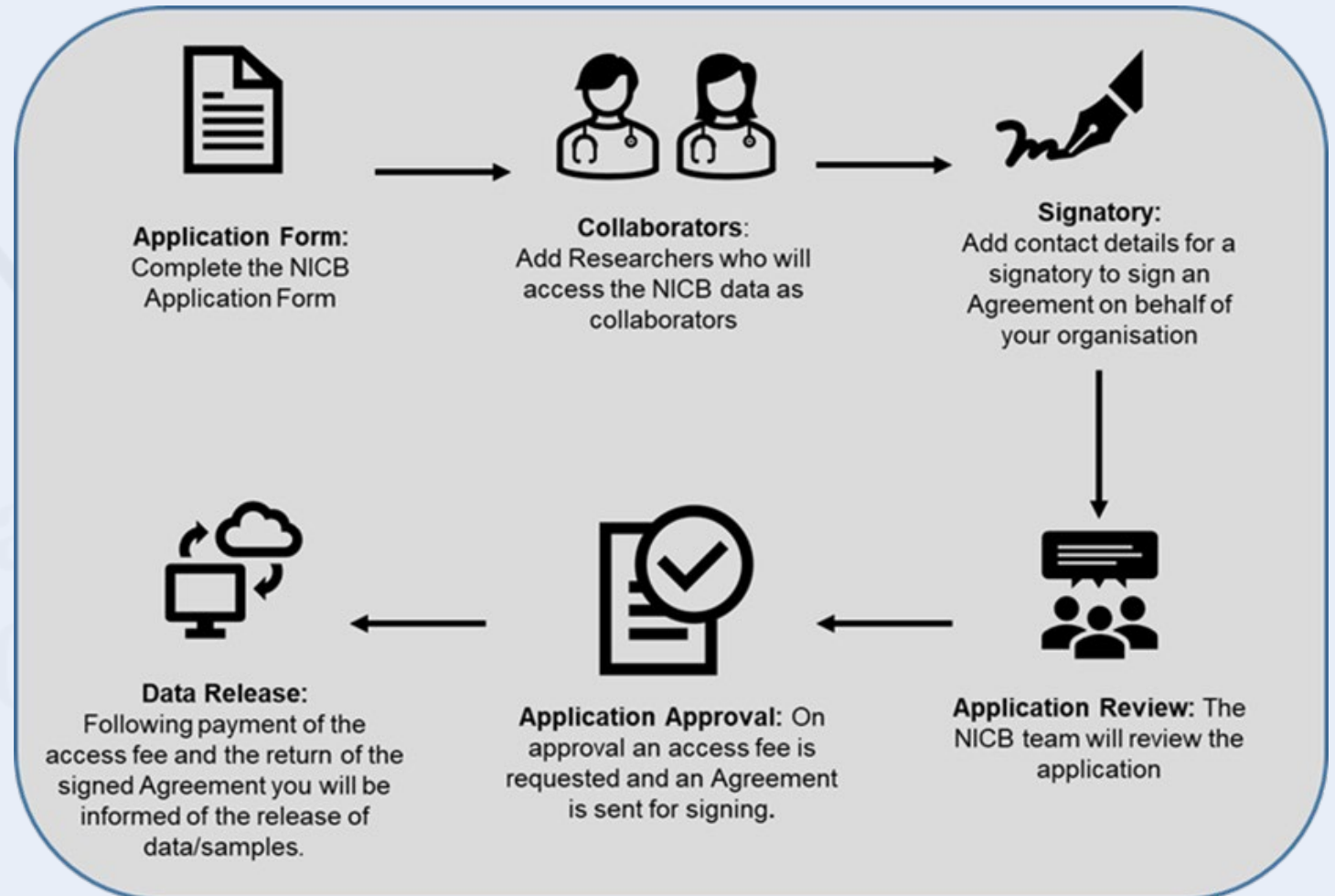
NICB Sample Storage Locations



Access Policy

In order to access coded data and/or samples in the NICB, researchers must:

1. Apply to NICB Steering Committee
2. Get ethical approval from independent research ethics committee
3. Sign and adhere to legal contract outlining how the NICB data and/or samples are to be used and kept confidential.



Moving towards ISO 20387....

- Quality considered at every step
- Convened a quality management subgroup – expertise in quality and biobanking within NICB partner institutions
- Plan to work with Emma Snapes as Consultant to help the NICB with guidance and recommendations for implementing ISO 20387

Steps so far

- Fitness for Purpose
- Document Control
- Process Workflow
- Training

Fitness for Intended Purpose

- Biobank will collect samples and associated data for future unknown Covid-19 research projects
- Research prioritisation exercise to focus on specific research themes
- Clinical database – extensive review and input from stakeholders to ensure clinical data collected meets their requirements
- Lab log will capture pre-analytical processing data – for user report
 - Cross-check ISO 20387 Annexes A&B
- QC plan with quality metrics for samples & proposed report to users – share with stakeholders/users for input & feedback – will be an iterative process
- Website will display data codebook and sample meta-data

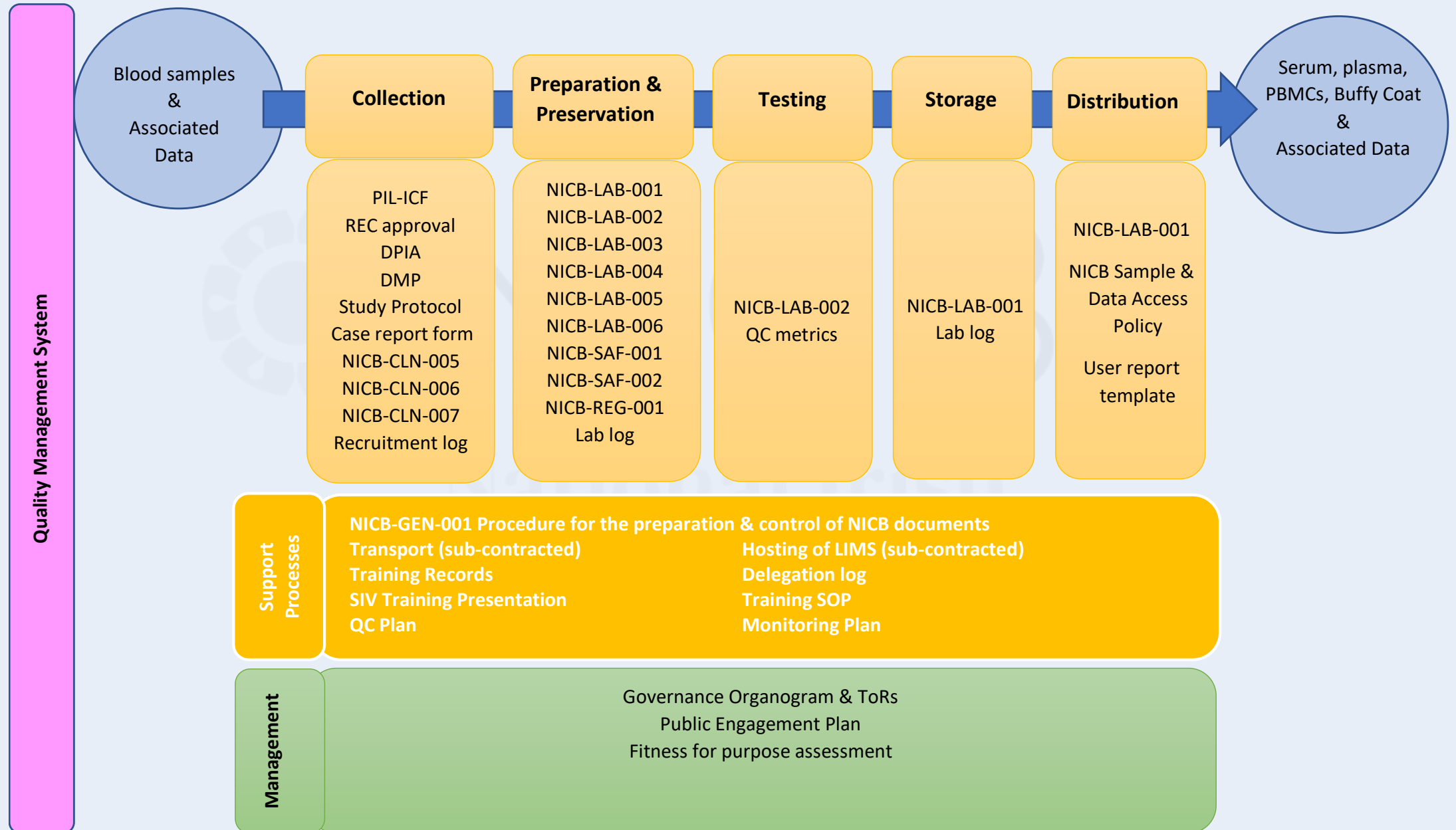
Document Control

- Overarching SOP: Procedure for the preparation and control of all NICB documents
 - SOPs (clinic, lab), Study Documents (PIL, Protocol, DPIA), training records
- Currently using MS Teams
- Researching document control system that can work across hospital sites and academic partners
 - LIMS may have capability
 - Complete QMS

Process Workflow

- Requirement for ISO 20387
- Consider the life-cycle stages of the samples & data within the NICB – detailed procedures describing the processes
- Separate workflow for different sample types – not all stages required for every sample type
- What stages are sub-contracted
- Capture workflow in a diagram – help everyone understand how the biobank functions

NICB Process Landscape – Blood Sample



Training

- Training Plan:
 - Site-by-site training needs assessment
 - Training to be given at Site Initiation Visits – hybrid of in-person and recorded presentations: general, quality, data protection, clinical processes, lab processes.
 - Training log for each staff member involved to include read/understood SOPs, attended SIV, and competent in tasks.
- Training and Quality Assurance SOP
 - induction of new staff member
 - updating training
 - identify who can sign off on training
 - Assessing competency via internal QC tests

Lessons Learned so far.....

01

Start with Quality
Management in
mind

03

"Pandemic readiness"
– roadmap for other
National biobanks

02

Realistic timelines -
takes time to set up
new structures

04

Sharing is caring!

Thank you for listening!

