

Research Development & Innovation at UHB

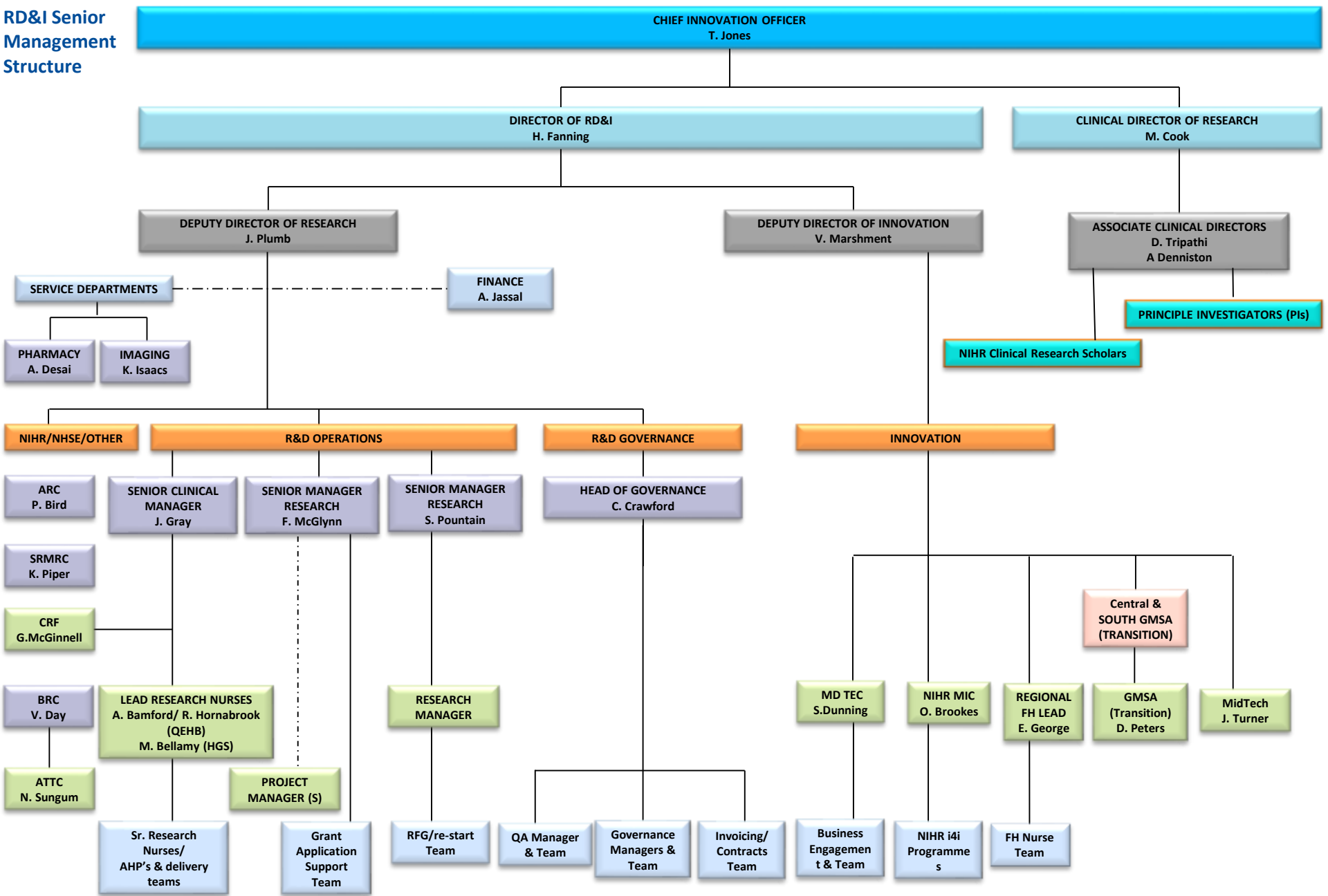
Webinar 5

25 March 2021

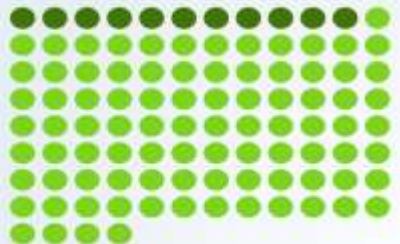
This webinar will provide...

- An update on our current position and context
- An update of the restart framework and how we can work together to maximise our capacity and activity
- An overview of the assess, arrange and confirm process
- An update on our and for our staff
- A brief video montage of vaccine FAQs
- Answers to your questions and seek feedback

RD&I Senior Management Structure



Open Studies



■ Remained Open Throughout (10.56%)
■ Opened after review following COVID 'Waves' (89.44%)

710 Studies Open



75 studies remained open to recruitment



635 open and in-followup following pauses

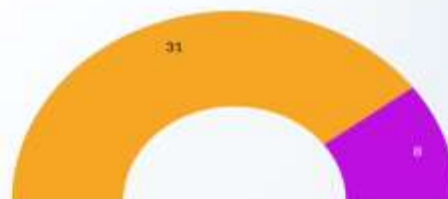


Across all sites & specialties



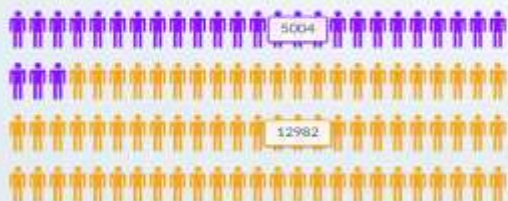
Supporting our patients to access the fullest range of treatments

39 COVID-19 Studies



■ Patient Studies (79.49%) ■ Healthy Volunteer (20.51%)

17,986 Recruits in COVID-19 Projects

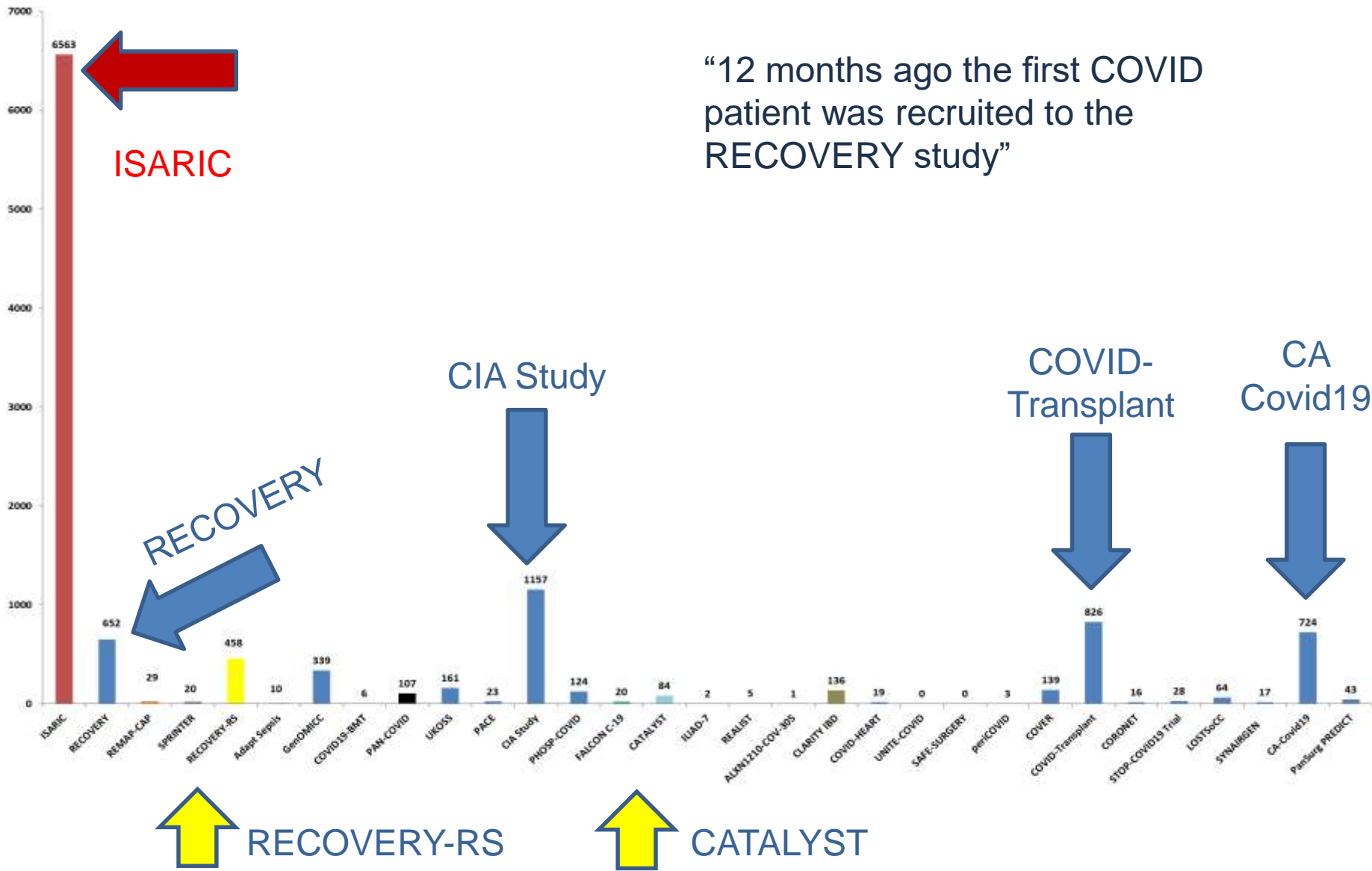


■ Healthy Volunteer Recruits (27.82%) ■ Patient Recruits (72.18%)

Urgent Public Health COVID-19 Set-Up



Source: NIHR Open Data Platform



Activity and Highlights

NON COVID

- Qtr 2-3 (2020) trial recruitment stands at approximately 1675, 183 of which are recruits to cancer trials.
- Qtr 4 (2021) 187 patients have been recruited, of which 34 are to cancer trials.

COVID

- Phosp-covid has been highest recruiter in Jan and Feb to tier 1 UHB
- Top recruiting site for Recovery RS & CATALYST
- HRH visit to recognise significant contribution to vaccine & COVID research at UHB
- Total recruitment to all Covid & Vaccine studies 17,318 participants
- 15,227 staff to NHSE Antibody testing
- 40% of all patients recruited to COMCOV were BAME
- Valneva FIM vaccine study recruitment target met in 36 hours

Recovery and restart

- UHB total covid19 +ve inpatients sitting at just over 12k, next closest Trust at 2/3 of this number
- Peak of 1067 inpatients covid19 +ve in January 2021, compared with 750 at the peak of the first wave
- 1500 staff redeployed at peak of this wave
- Recovery of our staff is paramount and will support the restart of services
- Prioritisation decisions being made in teams means full knowledge of opportunities and challenges
- Phased reservist repatriation plan commenced in March
- Trust workforce plan to release all staff back into R&D roles by 1April

Dec Jan Feb March April May.....

Paused to follow up (98)

Completely paused (280)

In set-up (41)

New Trials

Working together we can shift the timeline

Timeline shifts left as resource increases (staff return and study closure)

Prioritising studies for restart and start

Study provides an urgent treatment/intervention that could prevent harm to patients and/or would otherwise be unavailable
May provide additional patient benefit e.g. reduced hospitalisation/surgery
UHB is Chief Investigator Site (UHB or UoB sponsored)
UHB is Lead site and/or partner site with UoB for contracted Research Activity (i.e NIHR, Innovate UK, MRC/UKRI, Charity funded)NIHR/Innovation UK/Charity/Other contract associated with study
NIHR Portfolio Adopted Essential study providing evidence for pandemic management/Badged as Urgent Public Health by the NIHR/Chief Medical Office
Study provides an income necessary to support recurrent workforce costs.

Journey to fewer externally set factors

Teams identifying their own priorities

Keeping an eye on income to teams and balancing commercial and non-commercial

Edge in place to support prioritisation and decision-making when studies underway

Assess, Arrange and Confirm (AAC)

Trust-wide Research Facilitation Group (RFG) to be replaced by Assess Arrange and Confirm procedure:

- Virtual review as baseline
- Utilising digital platform (Edge)
- All reviews in parallel

Assess (informal review)

- Triggered by:
 - Anything the sponsor provides short of a full doc set
- Key Events:
 - Registration of study
 - Discuss between PI and Delivery Team
 - Discussion with Sponsor
- Key Players:
 - Specialty Research Facilitation Groups
 - Principal Investigator
 - Delivery Teams

Request to participate

Arrange

- Triggered by:
 - Full document Set
- Key Events
 - Submission of PI questionnaire to RFG
 - Formal review of all study aspects:
 - Funding
 - Delivery Team Resource
 - Contracts
 - Etc
- Key Players:
 - Contracts Team
 - Pharmacy
 - Delivery Teams
 - Imaging
- Results in approval for **all UHB Sites**

Confirm

- Triggered by:
 - Arrange Review Completion
- Key Events:
 - UHB signs the contract**
- Key Players:
 - Research Governance Team
- Delivery teams await Green Light From Sponsor

4 Weeks OR
7 days for UPH studies

Edge Monthly Reports

- Full list of studies
 - Recruitment, cumulative in financial year.
 - Recruitment targets
 - #Months left
 - Set up, closing out, open recruiting, open in follow up
 - Real time dashboard reports via Edge
 - PI's access to Edge system
 - All B7 leads now trained and have access

Pharmacy Update:

- Team redeployed to main pharmacy service during 1st wave
 - Small core team to deliver COVID-19 CTIMPs and portfolio which remained open
 - Staff repatriated but have provided additional support to core pharmacy service: through 3rd wave and Vaccine Hubs
 - COVID-19 Vaccine trials
- Pharmacy have been supporting (on EDGE) :
 - RAP review/approval for portfolio restart after 1st wave
 - RFG review/approval for new studies
 - Review/approval of amendments
 - Site feasibilities for proposed new studies
 - Cross-site review of studies impacted by service reconfiguration
- Pharmacy Aseptic Unit capacity and capability



Imaging Update:

- Imaging have been supporting:
 - Studies that have remained open
 - Reassessment of 400 studies for RAP review/approval

Moving forwards for Restart:

- Imaging will continue to support all levels of research
- Research capacity must be balanced with clinical service and any service reconfiguration across all sites
- Accurate and full completion of the PI Questionnaire is critical to enable a remote assessment
- Communication with your Consultant Radiologist colleagues is essential for study support and reporting
- Our assessments will be recorded on EDGE
- Consider your study's complexity and delivery timeframe at feasibility as this may not be compatible with our capability and capacity



Our successes

- Significant contribution to the pandemic and the non Covid portfolio
- Translational research to prevent disease and improve mortality and patient outcomes (5 approved Covid19 treatments and 5 vaccine trials)
- Delivery collaborations forged across all site speciality teams
- Studies remained opened for safety follow up
- New knowledge and clinical skills e.g. MAB training
- Embedding research into clinical service and building relationships with front line services
- Research in real time to treat patients for an unknown disease i.e Dexamethasone, Tocilizumab

“



THE CONVERSATION Follow

Less than a year to develop a COVID vaccine – here's why you shouldn't be alarmed

Vaccines are being touted as taking seven to ten years to develop. But you shouldn't be worried that COVID vaccine will take a year.

By Mark Toshne
Biomedical Research
Cambridge)
25 November 2020



BBC NEWS

BBC NEWS - 4-MIN READ
Covid vaccine: First 'milestone' vaccine offers 90% protection



METRO

Follow

UK:

Debunking the myths and conspiracy theories around the Covid vaccine

By Sean O'Keefe
3 December 2020 at 16:14 · 8 min read

History was made this week when the UK became the first country in the world to approve a coronavirus vaccine.

And the first doses of the Pfizer and BioNTech jab, made in Germany, are set to arrive in Britain anytime today and will be sent to 50 hospitals in the



The Telegraph

TELEGRAPH.CO.UK
Largest hospital trust is first with no Covid

CLINICAL RESEARCH NURSING

University Hospitals Birmingham
NHS Foundation Trust and NIHR
UK CRF Network

Development of the UKCRFN study intensity tool

Nursing Times Awards



The Live Guardian

THEGUARDIAN.COM
UK coronavirus live: Oxford University coronavirus vaccine safe and induces imm...

NIHR | National Institute for Health Research



100,000
PEOPLE

Join the NHS COVID-19 vaccine research registry today:
nhs.uk/researchcontact



Prince Charles County news

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Prince Charles: Country owes NHS 'debt of gratitude'

By 17 February

Coronavirus updates



The Prince of Wales and the Duchess of Cornwall visited the hospital just a week after getting their Covid-19 vaccine.

The Prince of Wales has told NHS staff the country owes them "an enormous debt of gratitude" for their efforts in the coronavirus pandemic.

Top Stories

EU leaders to discuss boosting vaccine supplies
 Leaders will also review plans to curb exports of 170,000 vaccines, which could affect supply to the UK.
 2 hours ago

North Korea fires two ballistic missiles
 5 hours ago

Papa could ask to see vaccine passports - PM
 1 hour ago

Features



The bus journey that saved hundreds of thousands of lives



Our Staff - workforce allocation

Require a flexible approach to balance non Covid and Covid activity

Keeping treatment options for our patients

Staff to deliver covid studies

Staff to deliver non-covid studies

Staff moving to support increase in covid patients

Non-covid studies

Covid studies



Recruitment COVID/Vaccine & Non COVID portfolios

Build resilience for potential wave 4



Hybrid role across research portfolios



Our Staff



Our Staff

