Department of Health & Social Care

Life Sciences Industry Webinar

Thursday 21 May – 09:00-10:00

Strategic Approach

Professor Jonathan Van-Tam, *Deputy Chief Medical Officer, Department of Health and Social Care*

Strategic approach to therapeutics

- We are using well-established UK-wide channels to review, prioritise and resource clinical trials, but making the end-to-end system faster and more responsive. These include the nationally prioritised platforms and a single NIHR/ UKRI funding gateway. **This work is coordinated through a DHSC-led Therapeutics Taskforce.**

- We have **focused initially on exploring the effectiveness of drugs that are already licensed**, as these are able to be used in large scale clinical trials now (subject to the usual processes on ethics, safety and oversight). **Convalescent plasma** has been added to the REMAP-CAP trial and is planned for inclusion in the RECOVERY trial in due course.

- We are also **developing a "pipeline" of more experimental drugs** that may be promising but have not yet been trialled extensively (or at all). These are being prioritised so that we explore those that show most promise on review of known data and expert literature first, whilst continuing to search for other possible candidates. Through the **ACCORD platform**, these drugs will be considered for smaller, phase II trials (eg 20-40 people) but with the ability to roll them into larger trials at pace if there are strong positive results.

Therapeutics Taskforce

Charlotte Taylor, *Deputy Director Therapeutics Taskforce Team, Department of Health and Social Care*

Therapeutics Taskforce overview

- The Taskforce will provide a collective end to end overview of therapeutic development, manufacture and supply.

- Taskforce membership will include a broad range of individuals from across government (including regional representatives), academia and industry. They will bring their expertise and interests from the organisations that they represent to work together to ensure patients in the UK have access to safe and effective therapeutics as soon as possible. The Taskforce will work to:

  - Share information and expertise on external and internal factors that may impact the development of COVID-19 therapeutics, their manufacture and supply, both for trials and potential future scale up, including emerging issues within their organisation.

  - Act as a conduit for information, bringing feedback from, and reporting back to, their respective organisations and members.

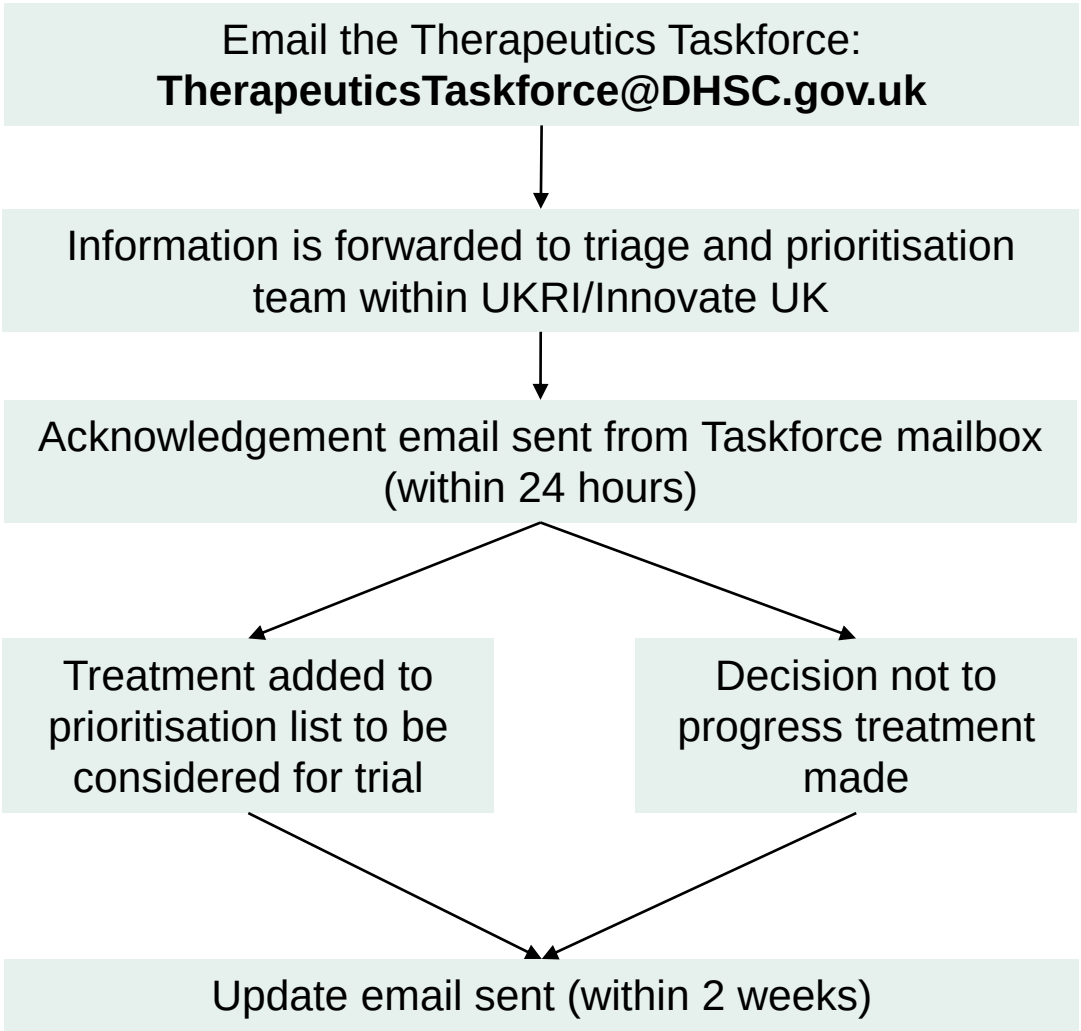
  - Ensure their respective organisations are supportive of, and carry out, decisions made by the taskforce.

  - Escalate current issues and blockages in the development of COVID-19 therapeutics and identify potential future blockages

  - Problem solve issues as they arise using the expertise of all members.

Contacting the Therapeutics Taskforce

- The Therapeutics Taskforce inbox is in operation and is monitored by the Therapeutics Taskforce secretariat.
- This necessary channel ensures that all activity is recorded, as well as ensuring that the secretariat are informed and up to date on any progress relevant to therapeutics.
- The Therapeutics Taskforce welcome updates on supply, demand and manufacture of potential treatments via the mailbox and will work with relevant colleagues to provide support in this area.



National Platform Phase III Trials

Dr Johnathan Sheffield, *National Institute of Health Research COVID-19 Research Operations Director*

Current national platform phase III trials

There are currently three phase III trials for therapeutics currently underway:

PRINCIPLE

373 Participants & 755 Active Sites (as of 20/05/2020)

Primary Care Setting

Drugs Included: Hydroxychloroquine, Azithromycin has been given approval but permissions pending.

UKRI-MRC/NIHR funded

RECOVERY

10,445 Participants & 176 Active Sites (as of 20/05/2020)

Secondary Care Setting

Drugs included: Lopinavir/ritonavir, dexamethasone, hydroxychloroquine, hydrocortisone, prednisolone, azithromycin and tocilizumab. If approved, convalescent plasma will be also added as an arm.

UKRI-MRC/NIHR funded

REMAP-CAP

320 UK participants & 111 active sites (as of 20/05/2020)

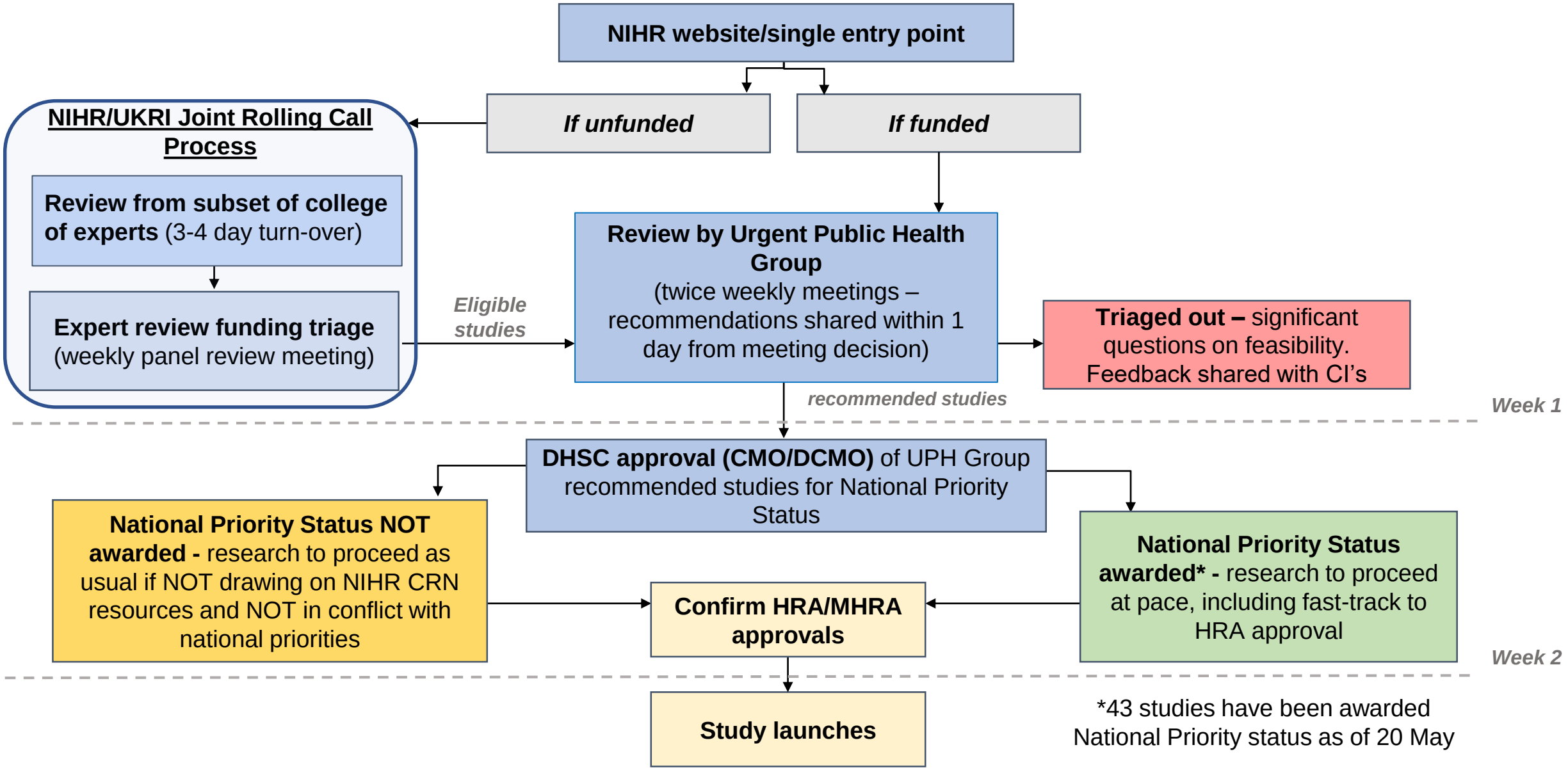
Intensive Care Setting: Patients with Severe Community Acquired Pneumonia (CAP)

Tests multiple drugs at once: Lopinavir/ritonavir, cortisteroids, interon beta, hydroxychloroquine, anakinra, tocilizumab & sarilumab. Convalescent plasma has also been added as a trial arm

Results dependent on randomisation ratios (adaptive randomisation)

International funders supported by NIHR

COVID-19 Research Study Triage



Case study: Roche

27 DAYS SET-UP

66 PARTICIPANTS

T&T 12 DAYS

- Evaluating tocilizumab
- Global sample size 330
- UK Sample size: 36 - met in 12 days, UK continues to contribute to global target
- Close: 29 January 2021
- **8 sites open**

NIHR | National Institute for Health Research

*Updated 20 May

ACCORD Programme

Professor Sir Mark Walport, *Chief Executive, UK Research and Innovation*

Dr Glenn Wells*, Director of Strategy and Planning, Medical Research Council, UK Research and Innovation*

ACCORD programme aims

- To support the development of safe and effective treatments to a) improve the outcomes of people who develop serious symptoms as a result of COVID-19; and b) prevent those at point of hospital admissions from progressing to severe complications.

- To complement the national investment in Phase III studies for COVID-19, by identifying and testing newer therapeutics and assessing their potential efficacy through smaller (20-60 participants), Phase II trials, to get an early indication of potential drug treatments' effectiveness in treating COVID-19.
  - The programme aims to accelerate the development of new drugs for patients hospitalised with COVID-19 by reducing the time taken to set up clinical studies for new therapies from months to weeks.
  - The programme is building a pipeline of drugs that can be accelerated for use in phase III trials or directly into clinical use, prioritising those that appear to show the most potential on the basis of the available data.

*ACCORD = **Ac**celerating **CO**VID-19 **R**esearch and **D**evelopment

Accountability and governance

- ACCORD is funded by UK Research and Innovation (UKRI) and the Department of Health and Social Care (DHSC). It brings together a single, UK-wide clinical trial platform providing the clinical research company IQVIA, and the UK's leading research expertise through the National Institute for Heath Research (NIHR).

- In addition to providing direct funding, UKRI is responsible for the delivery of the programme. BEIS will provide oversight and strategic challenge. DHSC will ensure that the programme is a coherent part of the wider therapeutics action plan, as well as resolving obstacles to successful delivery of the programme.

- The SRO for the programme is Professor Sir Mark Walport (CEO, UKRI) who is supported by Dr Glenn Wells (Director of Strategy and Planning, Medical Research Council), who is leading the ACCORD programme for UKRI.

- Strategic coordination of the programme, ensuring high level support, is through an Oversight Group chaired by the Secretary of State for the Department of Business, Energy and Industrial Strategy, that is meeting regularly to update on progress and ensure that the work is being taken forward at pace and with ambition. This group will identify and address any potential barriers to progress.

End to end process

Proposals for potential therapeutic agents sent to Therapeutics Taskforce mailbox and direct to UKRI

Industry liaison begins

Sifting and triage conducted by UKRI, supported by LifeArc

UKRI Expert Prioritisation Panel review list and make recommendations for admittance onto programme

ACCORD Executive Group make final decision as to which new candidates should progress onto programme, also factoring in operational and portfolio considerations

Contact made with potential supplied and supplied linked to IQVIA

List of prioritised candidates passed onto Trial Steering Committee who confirm if compound suitable to enter ACCORD

ACCORD Programme proceeds

Phase III trial leads invited onto Trial Steering Committee to review data and make a recommendation about suitability for progression.

Trial Steering Committee report on success of trial

Green-rated compounds enter into Phase III trials or directly into clinic

Expert Prioritisation Panel

- The primary purpose of the Expert Prioritisation Panel is to advise on the selection of the most promising compounds to move into early phase trial. The Panel is chaired by Professor Patrick Chinnery, Clinical Director at the Medical Research Council (MRC), part of UKRI.

- Principles for drug selection:
  - The need for a balanced portfolio with complementary mechanisms of action, to include drugs with clinical evidence of anti-viral effects;
  - Prioritise drugs with well established safety/toxicity profile;
  - To include generic, repurposed and early clinical agents; and
  - Prioritise drugs not being trialled elsewhere.

- Drugs may be re-considered at any point, including to take into account new information e.g. data from clinical trials; further research; additional detail on the progression of the disease.

ACCORD-aligned platforms

- To ensure a co-ordinated national approach by the UK Government to the early phase development of potential new treatments for COVID-19, the ACCORD platform is working alongside other platforms to ensure a consistency of approach, data sharing and co-ordinated patient surveillance and recruitment.

- These ACCORD-aligned platforms include:
  - Mul**t**i-**A**rm Therapeuti**c** S**t**udy in Pre-**I**CU Patients Admitted with COVID-19 (TACTIC)
    - led by the Cambridge Clinical Trials Unit at the Cambridge University Hospitals NHS Foundation Trust but will recruit from a network of hospitals across the UK
    - Currently focused on drugs which target the immune response
    - First two trials are of Ravulizumab and Baricitinib
  - CATALYST
    - Designed by the Inflammation – Advanced and Cell Therapy Trials Team (I-ACT) at the University of Birmingham's Cancer Research UK Clinical Trials Unit
    - Aiming to test existing medicines for cancer and inflammatory diseases such as rheumatoid arthritis.

Q&A