



Prioritisation and evaluation of novel coronavirus diagnostic in the UK

15 July 2020





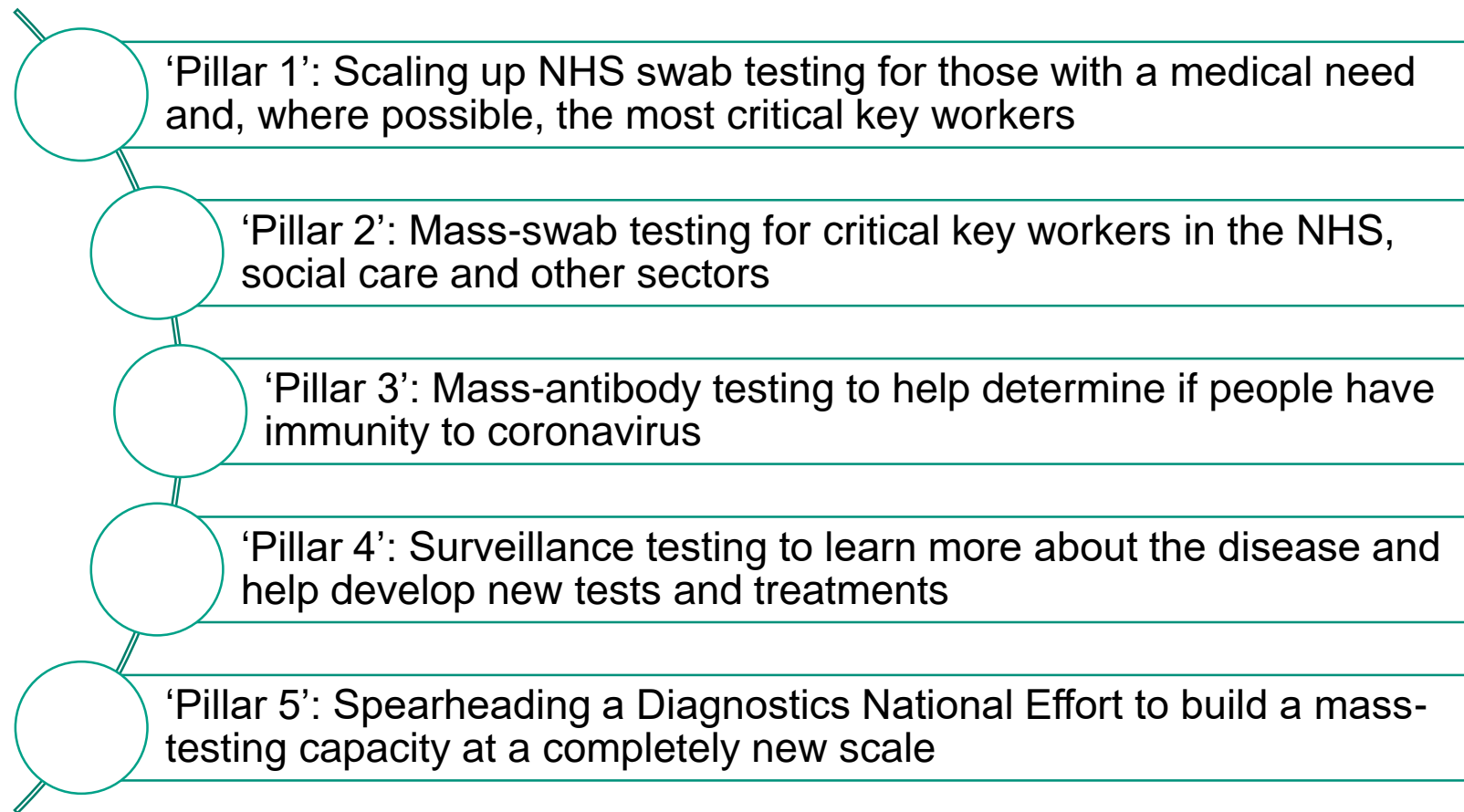
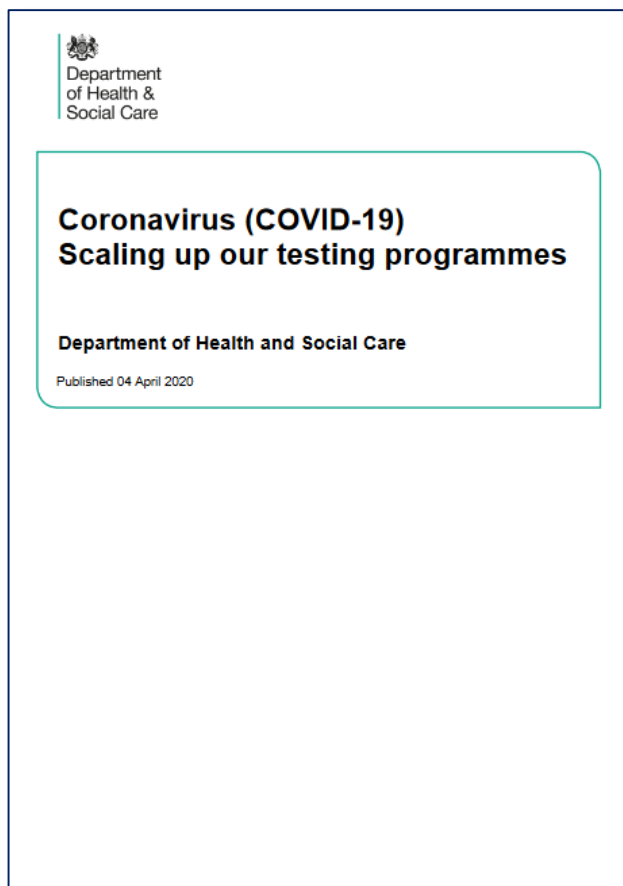
Department
of Health &
Social Care

COVID-19 New Test Triage and Evaluation System

Mike Messenger, Scientific Advisor to COVID-19 Testing Programme (New Tests)

13 07 2020

The five pillars of the national testing strategy announced by the Secretary of State on April 2 2020



Innovation priorities

In scope	Out of scope
<p>Point of care or rapid turn around time tests which:</p> <ul style="list-style-type: none">• Use a simple hand held or desktop-based (ie non lab based) machine to analyse samples AND/OR• Do not have a RNA extraction step or have an innovative approach to RNA extraction not demonstrated by products in the UK market AND/OR• Use an innovative and non-invasive sampling technique i.e. Saliva, sputum, urine, finger prick (capillary) blood, sweat, interstitial fluid, tears, breath AND/OR• Deliver a quick turnaround (e.g. <30 mins) AND/OR• Low cost and can be scaled to increase volume AND/OR• Multiplexes with other pathogens	<ul style="list-style-type: none">• The UK currently has a strong stock and supply chain of laboratory based RT-PCR

Potential use cases



Increase hospital lab capacity



A&E triage



Hospital admissions
(urgent and non urgent)



NHS staff testing

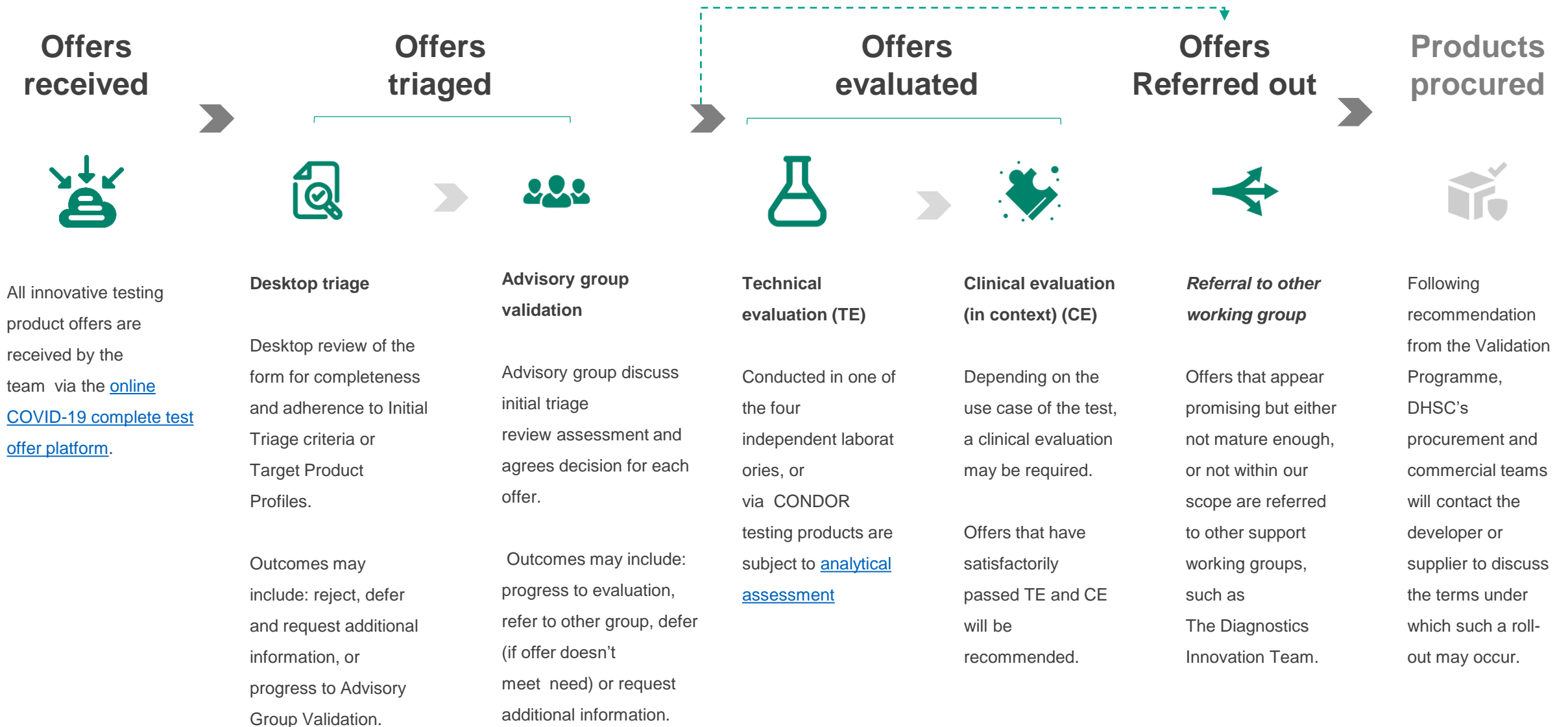


Out of hospital testing

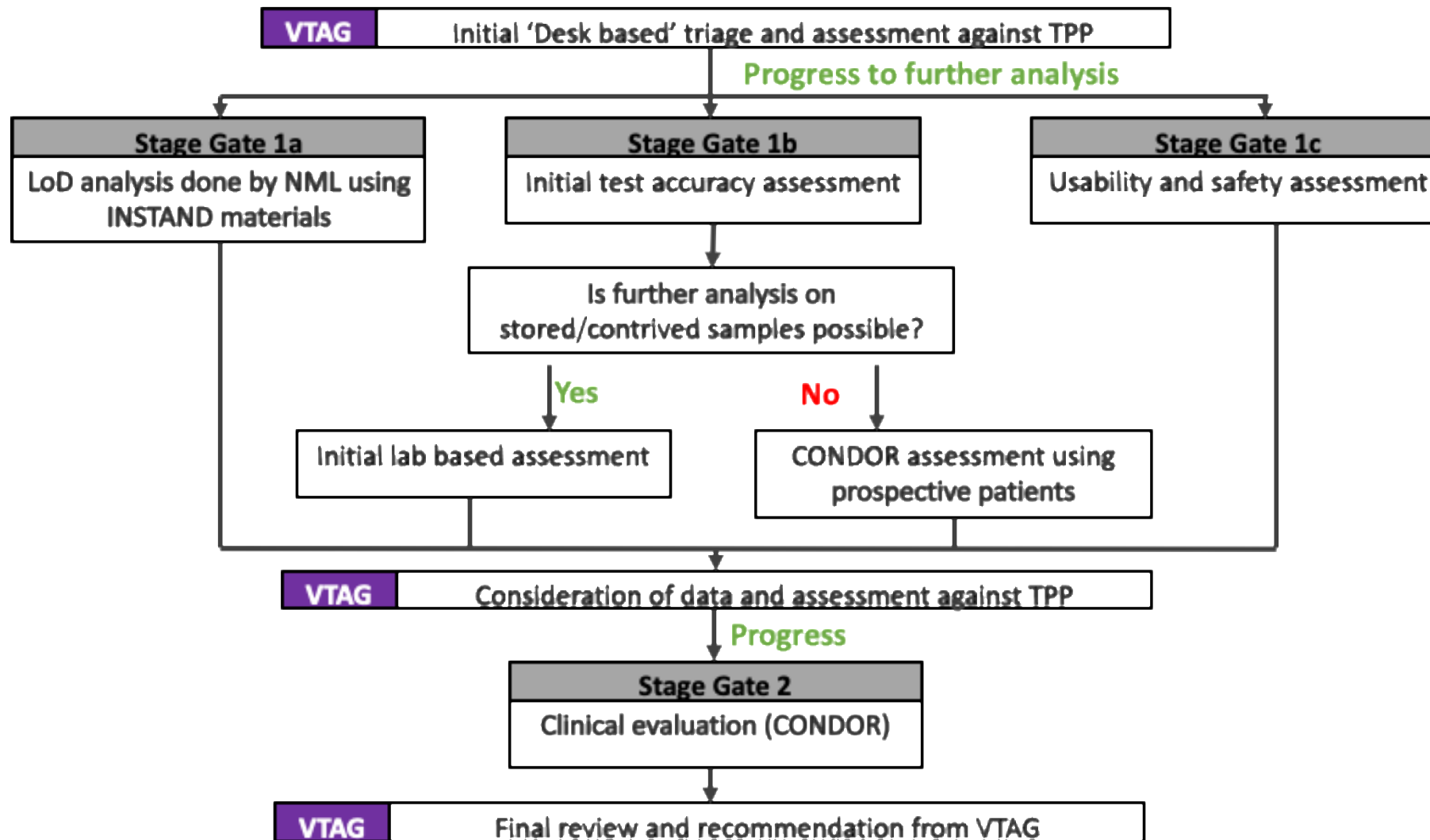


Test and trace

Validation process overview



Validation process for viral POC tests



Next steps and contacts for Industry

- Please read our guidance on helping the government increase testing: <https://www.gov.uk/guidance/help-the-government-increase-coronavirus-covid-19-testing-capacity#how-to-help>
- If you think you meet the TPP, or if your test does not match the specifications TPP but looks promising, please consider submitting your proposal via the DHSC portal: <https://consultations.dhsc.gov.uk/Full-Test-Kit-Covid19>
- If you have enquiries about the DHSC portal or process, please contact 0800 915 9965 or covid19triageservice@nhsbsa.nhs.uk.



NIHR | National Institute
for Health Research

CONDOR

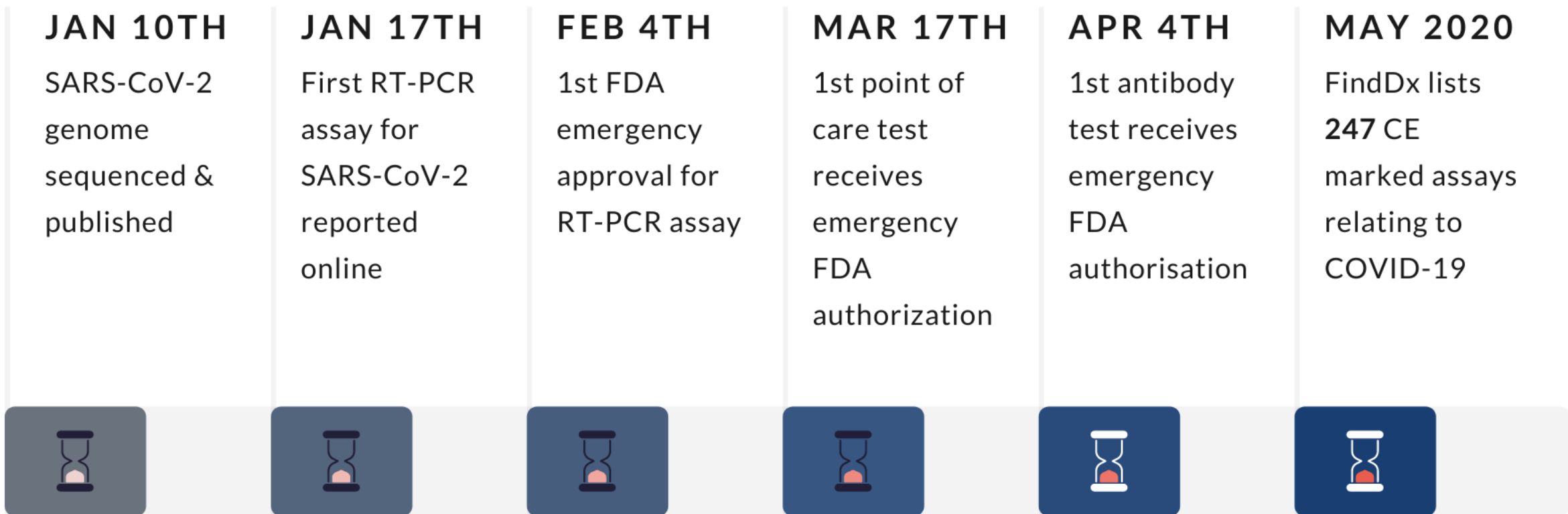
COVID-19 National Diagnostic
Evaluation & Research
Platform

PROF RICK BODY



DIAGNOSTIC PIPELINE

A timeline of the COVID-19 pandemic



NIHR | Community Healthcare
MedTech and In Vitro
Diagnostics Co-operative



NIHR | Leeds In Vitro
Diagnostics Co-operative

NIHR | London In Vitro
Diagnostics Co-operative



NIHR | Newcastle In Vitro
Diagnostics Co-operative



CONDOR

COVID-19 National Diagnostic Research
and Evaluation Platform



CARE PATHWAY ANALYSIS &
TARGET PRODUCT PROFILES



ANALYTICAL VALIDATION



IN-CONTEXT CLINICAL
VALIDATION



HUMAN FACTORS
EVALUATION

CONDOR PATHWAY



Test submitted using DHSC online portal

Referral made to CONDOR

Booking form completed. Call arranged

Steering committee identify evaluation needs

Evaluation completed

Feedback to DHSC, company, NICE, journals

SARS-CoV-2



Lateral flow test

RAPID RESULTS
SIMPLE TO USE
MAY BE LESS SENSITIVE



Self-testing



GP surgery



Airports



Bench top instrument

RAPID RESULTS

NEEDS SOME PROFESSIONAL EXPERTISE

RELATIVELY SLOW THROUGHPUT



Emergency
Departments



Care homes



Intensive Care Units



OTHER IMPORTANT CONSIDERATIONS

BIOSAFETY

INSTRUMENT
AVAILABILITY

USE CASE-SPECIFIC
TARGET PRODUCT PROFILES

WHY WORK WITH CONDOR?



Strong methodology

- Designed by an extensive national network of methodologists
- Subjected to robust peer review

National scale

- NIHR Urgent Public Health status
- Multiple sites
- Multiple contexts

One-stop shop

- Coherent approach with the DHSC, NICE, MHRA

FUNDED BY

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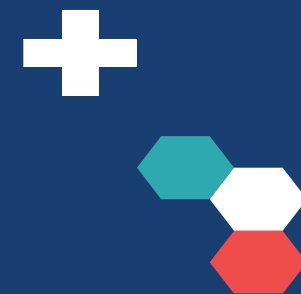


Testing is crucial to inform our emergence from the COVID-19 pandemic.

Our work will ensure that our testing strategy can be informed by the most rigorous science possible

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National Institute
for Health Research



Care Pathway Analysis

CONDOR Cross Cutting Workstream
The Methodology Subgroup

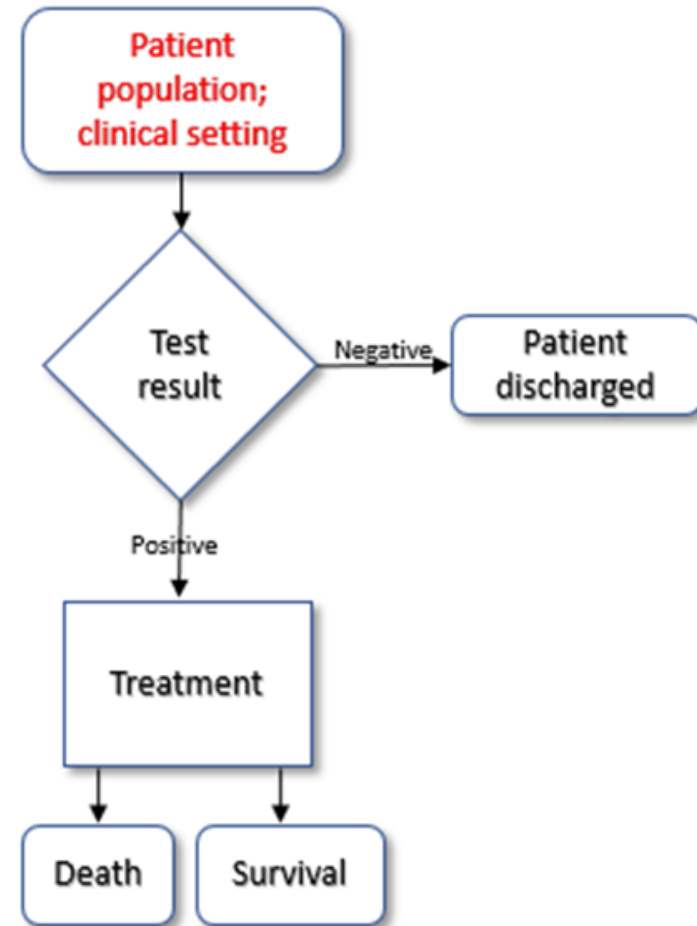


Care Pathway

The journey of patients with a certain medical condition during an episode of healthcare.

Care pathway analysis

- Allows visualisation of all clinical decisions
- Models the outcomes of the decisions
- Allows assessment of clinical needs
- Informs health economic modelling of the new technology



Workstream aims

- To characterise **unmet clinical need** and **optimal placement** for COVID-19 diagnostic tests
- To inform development of the MHRA **target product profiles** (TPPs)
- To inform the **appropriate design** of CONDOR clinical evaluations
- To inform **NICE economic modelling**
- To identify **evidence gaps**

Progress

National survey of health and social care professionals

- Prioritisation of clinical settings and use cases
- Identification of availability of testing and clinical needs

Care pathway analysis

- Interviews in hospitals and care homes
- Mapping of the pathways



Exploratory economic modelling of SARS-CoV-2 viral detection point of care tests and serology tests

Rebecca Albrow
Associate Director
Diagnostics Assessment Programme

Rationale for this project

To undertake exploratory economic modelling of hypothetical SARS-CoV-2 viral detection point-of-care (POC) tests and serology tests

- To identify the parameters that are most influential on cost-effectiveness modelling results
- Establish priorities for future research and highlight where data are absent
- Establish which use cases are likely to be cost-effective

Characteristics of tests modelled will be based on the **Medicines and Healthcare products Regulatory Agency's (MHRA) target product profiles**

2 decision questions

What is the clinical and cost-effectiveness of the point-of-care testing to help detect SARS-CoV-2?

What is the clinical and cost-effectiveness of antibody serology testing?

A range of use cases

Setting	Use cases
Hospital	A test for: <ul style="list-style-type: none">• Symptomatic patients presenting to a hospital• Symptomatic staff• In-patients who develop new clinical features of COVID-19 during their hospital stay
Care home	A test for: <ul style="list-style-type: none">• Newly admitted residents to prevent transmission to existing residents• Symptomatic care home residents• Symptomatic staff

Timelines

- Report for stakeholders on hospital and care home setting by October.
- Process designed to be responsive to changes in health system and government priorities.
- May be subject to change to allow NICE to respond as rapidly as possible.

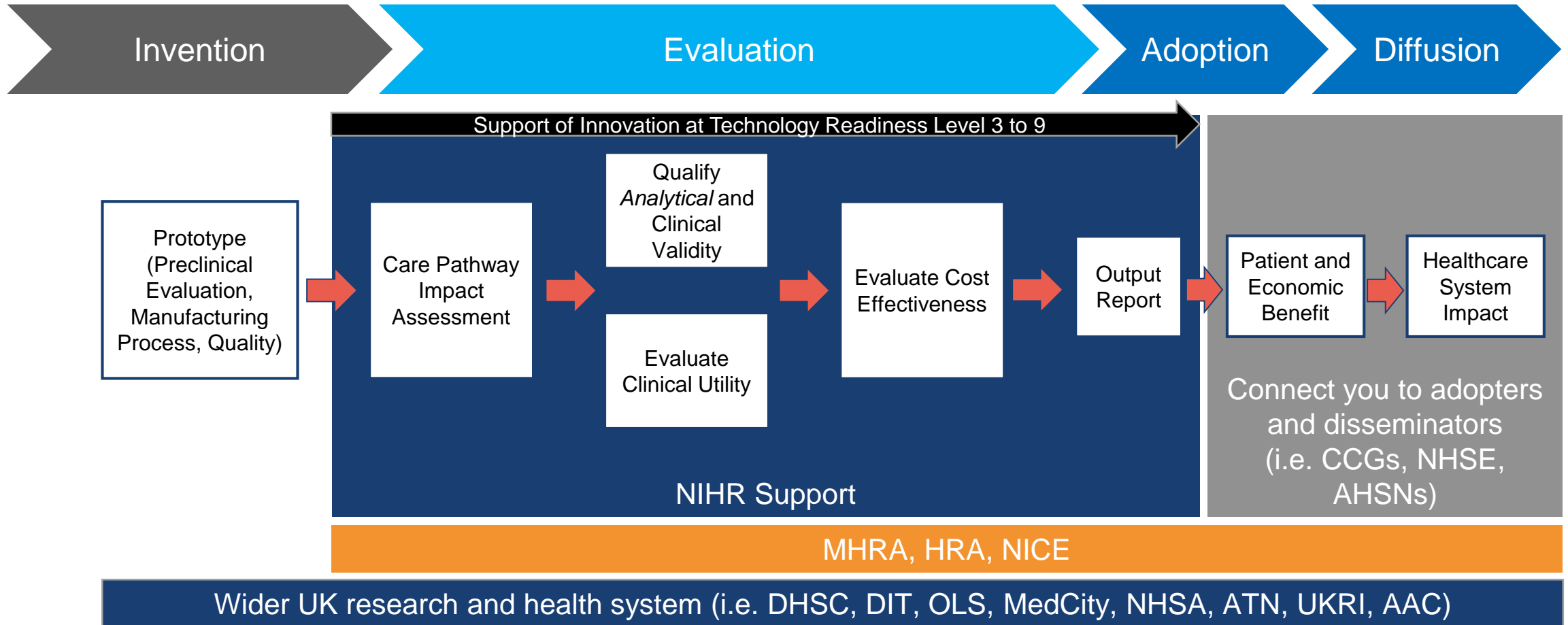
NIHR: Industry Offer

Dr Peter Sargent,
Head of Business Development, NOCRI
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July 2020



Supporting IVD down the road to market



NIHR Offer to Industry

- The NIHR supports life science companies **translate their new innovations into the clinic** and then onto market.
- We can provide a full range of offers to support innovators throughout their clinical pathway, from early stage translational research through to later stage clinical trials in the NHS and social care settings.
- Connect you to the wider UK infrastructure and Government (i.e. DHSC, OLS, DIT, Trade Associations and Clusters)

Free Service



Offers of Support:

CONDOR:

<https://consultations.dhsc.gov.uk/Full-Test-Kit-Covid19>



Broader Support:

NIHR Office for Clinical Research Infrastructure

nocri@nihr.ac.uk

www.nihr.ac.uk

