



HM Government

Webinar: Regulation, Research and the National Testing Programme – with an Update from Pillars 1&2



Our National Effort for Diagnostics

Lord Bethell of Romford

Parliamentary Under Secretary of State, Department of Health and Social Care

Today's Agenda

13:55- 14:10 Strategic Update and Forward Look	Update on Pillar 1 – David Wells, Head of Pathology, COVID-19 Testing Cell Update on Pillar 2 – Pillar 2 SRO Q&A
14:10-14:30 MHRA Update	MHRA Update - Janine Jolly, Devices Safety and Surveillance Group Manager Q&A
14:30-14:50 New National Research Programme	Introduction to a new National research programme to evaluate coronavirus tests in hospitals, GPs and care homes – Professor Rick Body, co-CI of CONDOR Q&A
14:50-15:05 Innovate UK and KTN	Introduction/General Information – Dr. Penny Wilson Innovate UK Funding – Dr. Karen Spink Support available from KTN- Dr. Terry O'Neill
15:05-15:15 Crowdicity Update and Close	Doris-Ann Williams, Chief Executive of BIVDA



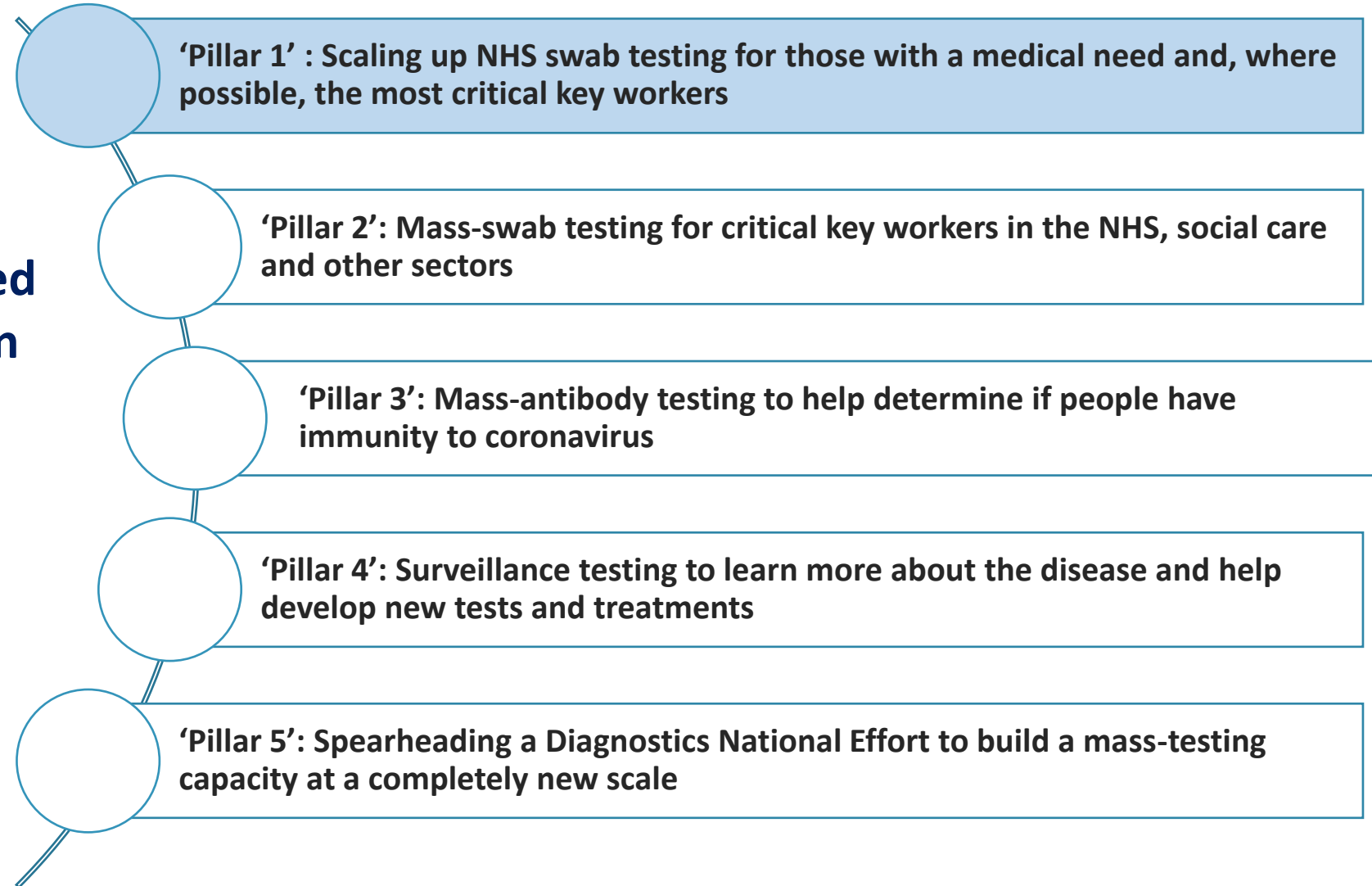
Update on the National Testing Programme: Pillar 1

David Wells

Head of Pathology, COVID-19 Testing Cell

Our National Testing Strategy - Update

The strategy was announced by the Secretary of State on 2nd April and has 5 key strands

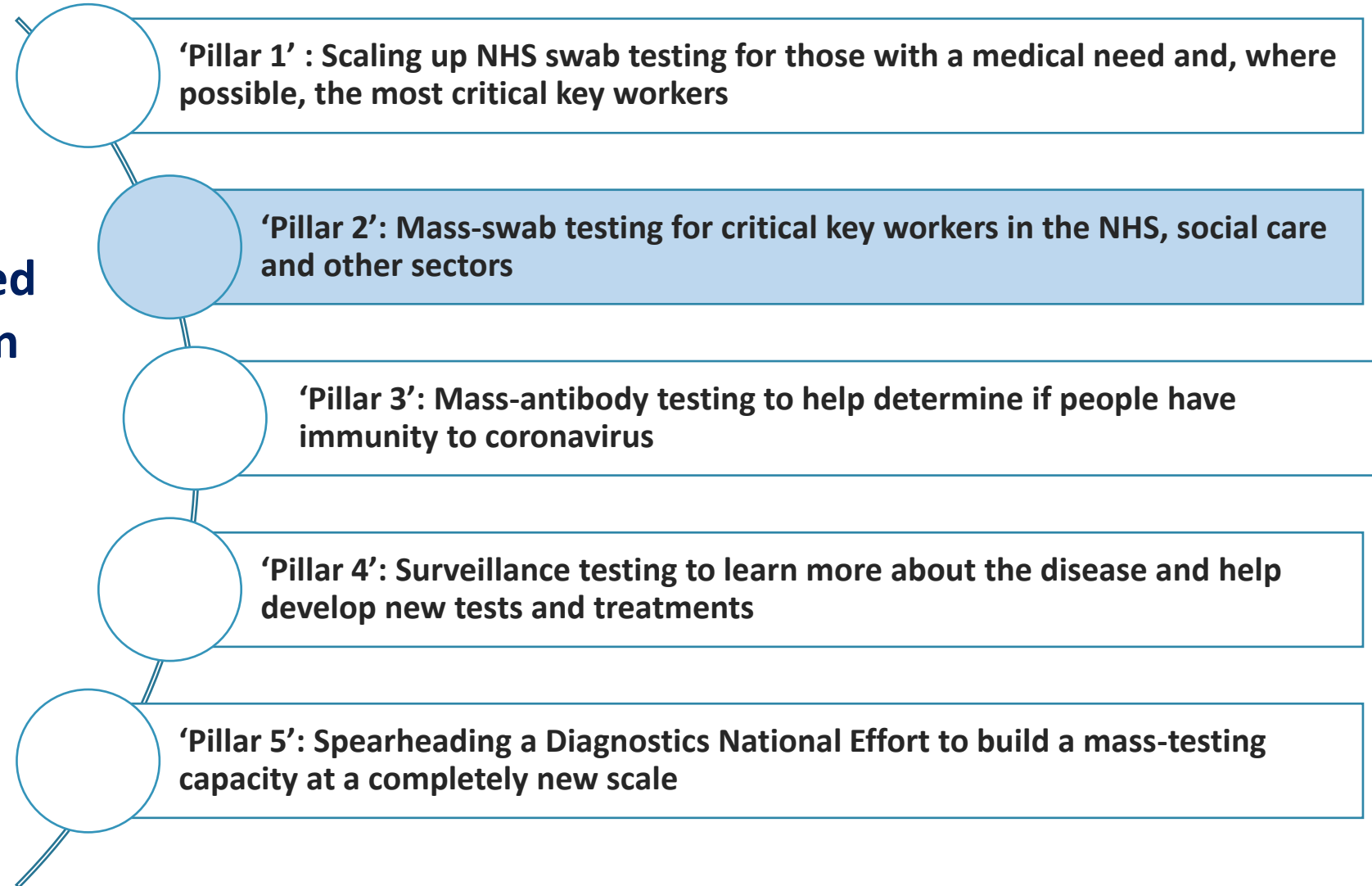


Update on the National Testing Programme: Pillar 2

Alex Cooper,
Pillar 2 SRO

Our National Testing Strategy - Update

The strategy was announced by the Secretary of State on 2nd April and has 5 key strands



Pillar 2

“World class testing at scale”

PURPOSE



Saving Lives
(rapid testing for anyone with symptoms)



Protecting the vulnerable
(screening of selected cohorts)



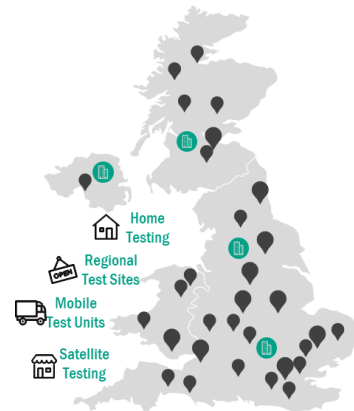
Containment
(Integral part of NHS Test and Trace)



Getting UK back to work
(testing available for all symptomatic citizens)



Understanding prevalence
(survey delivery)



WHAT WE HAVE ACHIEVED

Over 3.5 million **tests have been processed**

69 **regional test sites**

113 **mobile testing units** that can be deployed

Over 1 million test kits sent via **satellite model**

Over 700,000 **home test kits** sent out

OUTCOMES BY END OF AUGUST



Anyone who needs a test can get one



Except for postal, **results within 24 hours**



Service that you can rely on and trust



Testing that **protects your local community**



Testing that **supports wider contact tracing**

PRINCIPLES

EXCELLENT

- Quality (diagnostics, data, reliability)
- User experience
- Slick user journeys (speedy, effective, robust)

ACCESSIBLE

- Accessible for all not many
- Empowerment at local level
- Adaptable, agile and reactive delivery across the U.K.
- Better understanding of population's needs and behaviour

INTEGRATED

- NHS Test and Trace Programme and equivalents in Scotland, Wales and NI.
- Data analytics
- Wider HMG efforts & objectives
- Link into research - drive growth & support development

TRUSTED

- Public trust (privacy and quality)
- Reputation as a responsive, agile and accurate service
- Leads to action
- Transparent and accountable

FUTURE-PROOFED

- Develop capability for 2030, not just June 2020
- Resilient op model
- Long-term lab, workforce and infrastructure plan
- Capacity for worst-case scenario





Priority for June

24hr Turnaround Target

Test within 24 hours so
we can trace contacts
within 48 hours

Contact trace within 48
hours has a significant
impact on spread

RTS Process Step	Improvement initiatives
Digital Booking	Reduced the booking window for subjects to book test slots
	Text update on website – symptomatic subjects encouraged to get tested ASAP
Swabbing at RTS	Recent surveys confirm 90% at RTS within 30 mins. This is optimised.
Courier Delivers Sample to Lab	Multiple in-day courier collections from RTS
With Lab Processing	Reduce duplicate barcodes
	Improve communication between RTS and Labs

If we can get a test result within 24 hours of developing symptoms, then we can trace and contain contacts within 48 hours. This timeframe means that if contacts have been infected, they are identified and contained before they go on to spread the virus themselves.

We must all play our part to achieve this.



Q&A





MHRA Update

Janine Jolly –Group Manager, Devices Safety and Surveillance



Medicines & Healthcare products Regulatory Agency

Target Product Profiles (TPP)

Antibody tests to help determine if people have immunity to SARS-CoV-2

Issued by MHRA



Desired profile or characteristics of a target product



Designed to assist manufacturers



Lateral Flow Self-test



Lateral Flow POCT



EIA Lab test (unpublished)



Not Regulatory requirements



Working in partnership to consider a long-term home

Home Sampling (capillary blood)

Results from laboratory-based tests for COVID-19 antibodies using capillary blood sample collection kits may not be reliable (MDA/2020/015)

This covers issues with both laboratory based tests for COVID-19 antibodies (unvalidated sample type) and capillary blood sample collection kits (unvalidated for home use)

National Institute for Biological Standards and Control (NIBSC)



In development:

Secondary Standards

Verification Panel

Validation Panel

Blind panel of positive and negative samples for performance evaluation

Regulatory Flexibilities

flexible

[ˈfleksɪb(ə)l] 

ADJECTIVE

capable of bending easily without breaking.

"flexible rubber seals"

synonyms: pliable · supple · easily bent · bendable · pliant · malleable · mouldable · stretchable · workable · limber · ductile · tensile · plastic · elastic · whippy · springy · resilient · bendy · flexile

- able to be easily modified to respond to altered circumstances.

"small businesses which are dependent on flexible working hours"

synonyms: adaptable · adjustable · open-ended · open · open to change · changeable · variable · fluid · versatile

Expanding Horizons



DEROGATIONS



PERFORMANCE
STUDIES

Learning to date

Exceptional
challenge

Complex issues

Uncertain duration

No playbook

Creative thinking and
flexibilities

Critical decision
based on incomplete
or inconclusive
evidence

Principles of
transparency

Importance of regard
for patient safety

Q&A





CONDOR

COVID-19 National Diagnostic
Evaluation & Research Platform

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



NIHR | Leeds In Vitro
Diagnostics Co-operative

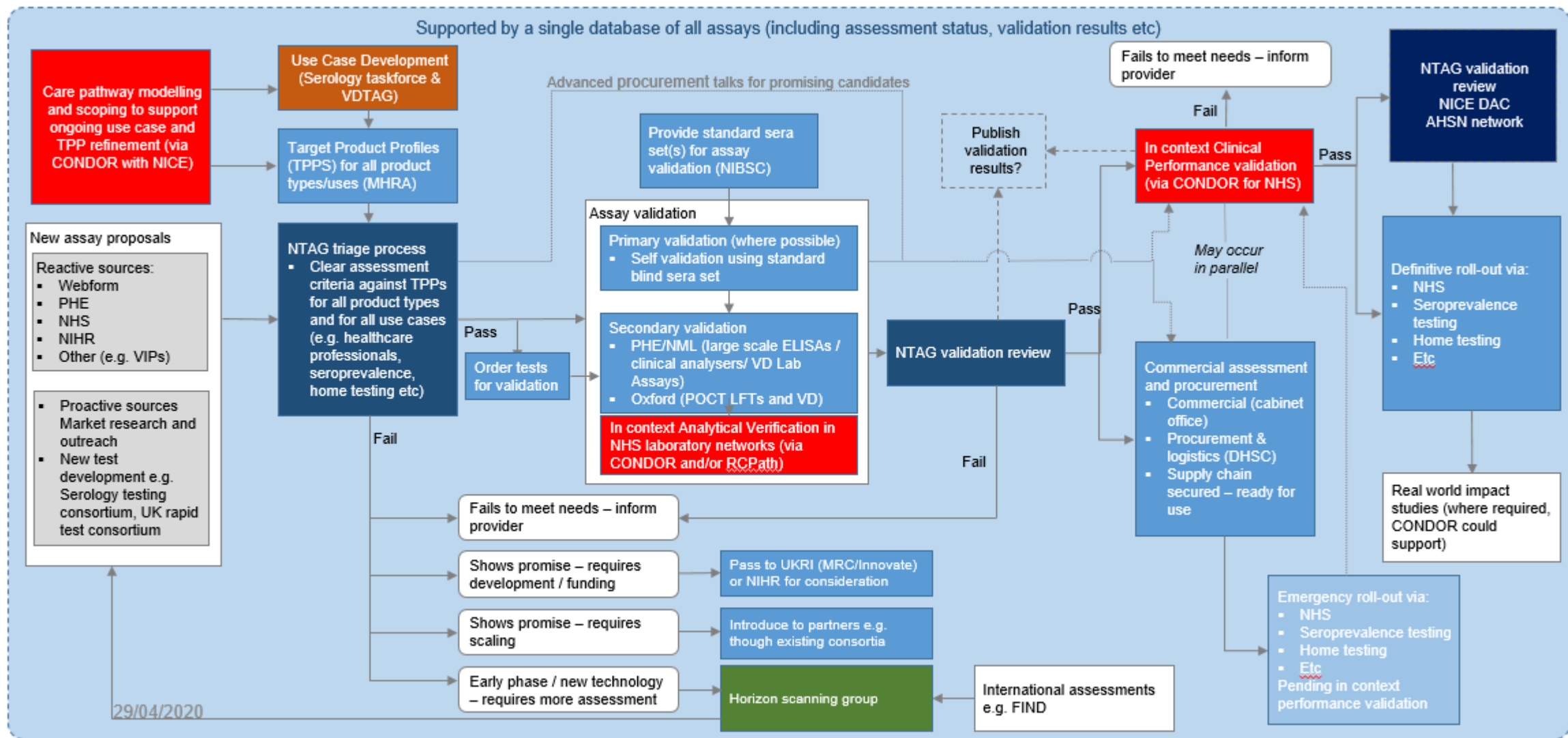
NIHR | London In Vitro
Diagnostics Co-operative



NIHR | Newcastle In Vitro
Diagnostics Co-operative



Assay validation and development pathways



UK Research
and Innovation

Structure

- CONDOR platform
 - Workstream 1: Analytical validation
 - Workstream 2: In-context clinical validation
 - FALCON (secondary care)
 - RAPTOR (primary care)
 - Cross cutting Workstream 3: Human factors
 - Cross cutting Workstream 4: Care Pathway analysis.



Process

- Tests prioritised by NTAG (New Tests Approvals Group) and VDTAG (Viral Detection Tests Approvals Group)
- Those prioritised for further evaluation are referred to CONDOR
- CONDOR steering group meets to decide most appropriate use case & design evaluation
- CONDOR liaise with company to arrange evaluation
- Clinical validation supported by IVD methodologists, powered to meet the requirements of the MHRA TPP (target product profile)
- Results to be fed back to NTAG & VDTAG to inform procurement; and to NICE.

Infrastructure

- Analytical validation
 - Supported by Leeds and Newcastle NIHR MICs, LGC National Measurement Laboratory & a network of laboratory experts.
- Clinical validation
 - Supported by the NIHR CRN as part of the Urgent Public Health portfolio
 - Care home network
 - Testing centres
 - GP surgeries
 - Approximately 30 hospital sites.



UK Research
and Innovation

Progress

- Funded
- UPH support confirmed
- REC & HRA approvals in place for both FALCON and RAPTOR
- Contracting being finalised
- First site opening this week, more to follow imminently
- Investigating potential to broaden scope
 - FIND evaluations
 - Validation in direct collaboration with pillar 2
- National survey to prioritise unmet clinical needs, inform NICE scoping and MHRA TPP development.

To find out more, please contact the NIHR Office for Clinical Research Infrastructure:

nocri@nihr.ac.uk

Plus, join us for our webinar:

Prioritisation and evaluation of novel coronavirus diagnostic in the UK

Wed 15 July, 9-10am



UK Research
and Innovation

Q&A



Innovate UK and the Knowledge Transfer Network Supporting our national efforts for COVID- 19 diagnostics

Dr Penny Wilson - Senior Specialist Diagnostics, Innovate UK

Dr Karen Spink - Innovation Lead - Precision Medicine, Innovate UK

Dr Terry O'Neill - Head of Health, Knowledge Transfer Network



Working across government and with industry to deliver clinically useful COVID-19 diagnostic solutions

- **As scientific knowledge increases, diagnostic opportunities will evolve and may include:**
 - Measurements to identify patients with immunity
 - Determination of host gene polymorphisms that correlate with disease severity and/or antibody dependent enhancement.
- **Already there are requests and discussions around:-**
 - Less invasive sampling with consideration for pediatrics
 - Differential diagnosis of COVID-19 and Flu at the point-of-care
 - Combined antigen and antibody testing

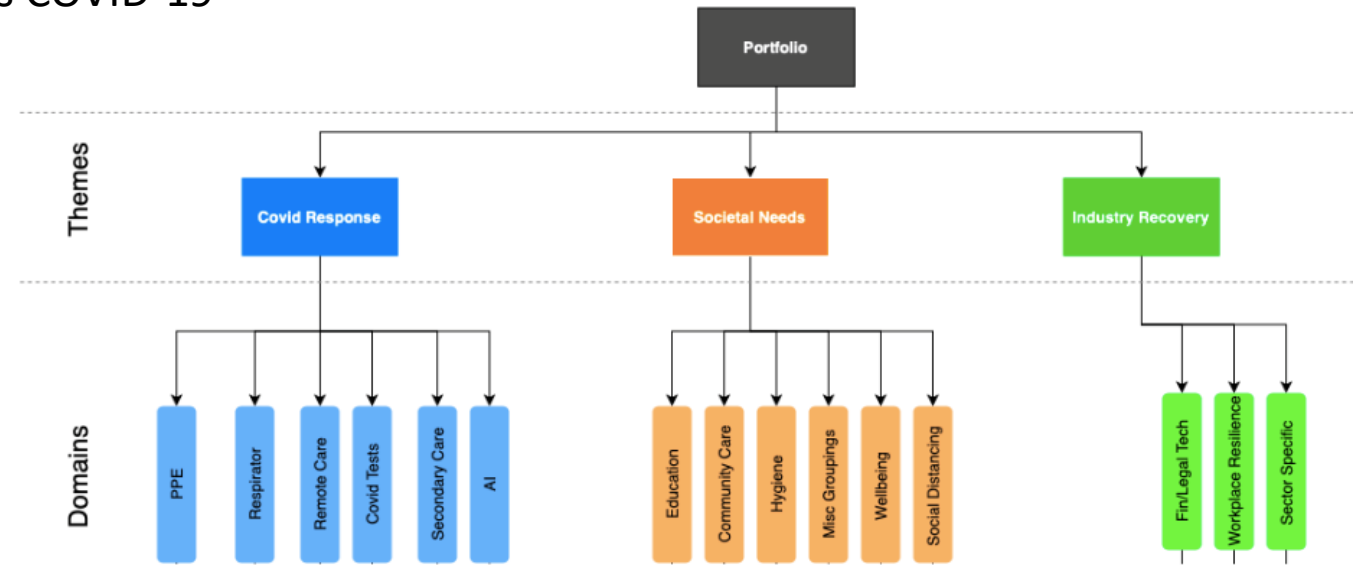
Extraordinary Times Demand New Energy in Supporting Businesses

Support for Existing Funding Portfolio

- Fast track 3 month no-cost project extensions
- Repurposing of existing projects to directly address COVID-19
- Continuity grant funding up to £250K
- Innovation continuity loans up to £1.6m

New Funding

- **Fast start** de minimus funding up to £50K
- **UKRI open call** for ideas that address COVID-19
- Further **bespoke COVID19 recovery funding** in development (pending announcement)
- **Biomedical Catalyst**
- **SMART competition** paused until August 2020



Fast Start - £40m Investment

- >8,000 applications
- >800 projects funded
- Delivered in 6 weeks!!!

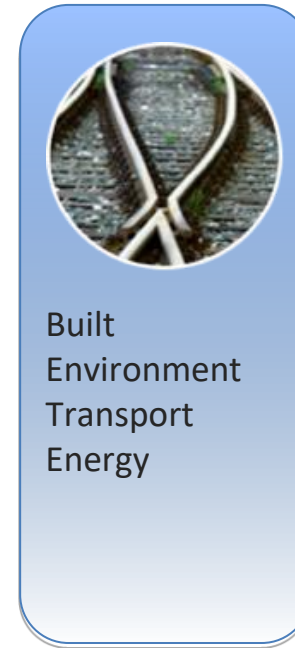
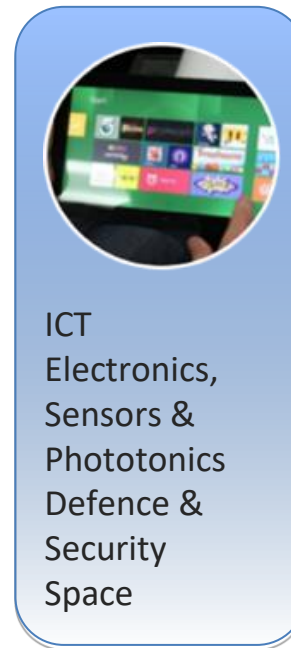
UKRI Open Call for ideas that address COVID-19

- Rolling open call with no specific budget
- Projects up to 18 months duration addressing and mitigating the health, social, economic, cultural and environmental impacts of the COVID-19 outbreak.
 - New research or innovation with a clear impact pathway that has potential to deliver a significant contribution to the response to, the COVID-19 pandemic.
 - Supports the manufacture and/or wide scale adoption of an intervention
 - Gathers critical data and resources quickly for future research use

The Biomedical Catalyst (BMC 2020 R1)

- Support for innovative solutions to health & care challenges
- Up to £30m available (early and late strands (ie. TRL 5-8))
- Project costs £250K to £4m, project duration 1-3 yrs
- Competition opens on 27th July 2020, closes 7th October 2020

Focus is on bringing together groups that would not normally meet



Sustainability, International, Access to Finance



KTN Reach

200,000

Network contacts

45,000

We have networked
with over 45,000
organisations

420
32,800

421 events with 32,867
delegates in
attendance

55,000

Over 55,000 active
subscribers to our
newsletter

SARS-CoV-2, COVID-19

KTN response has been quick and effective if a little responsive given the uncertainties of the pandemic and associated needs/drivers

- Ventilator Challenge
 - PPE
 - Vaccines Task Force
 - Therapeutics Task Force
- Over 28 separate COVID-19 funding calls including:
- Business led funding from Innovate UK
 - Rapid response UKRI call
- Over 325 engagements with businesses in a 3-month period

Thank you

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terry.oneill@ktn-uk.org



Q&A



Crowdicity Update

Doris-Ann Williams

Chief Executive of BIVDA

New challenge: COVID Plus: Multiplexing with other pathogens

As we move towards the winter flu season, we must consider how to include COVID 19 viral detection into the wider respiratory virus and/or gastrointestinal virus testing regimes. We are seeking testing kits that will deliver multiplexed or syndromic respiratory and/or gastrointestinal viral detection and that will operate on either existing rapid turnaround laboratory platforms, existing near patient care platforms, or new technologies that can be deployed into NHS and PHE testing laboratories.



These should be ready to deploy within four to six weeks.

Add your examples here: testingmethods.crowdicity.com

#TestingMethods2020

#Covid-19

Close

Doris-Ann Williams

Chief Executive of BIVDA

