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
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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 2\textsuperscript{nd} April and has 5 key strands

- **‘Pillar 1’:** Scaling up NHS swab testing for those with a medical need and, where possible, the most critical key workers
- **‘Pillar 2’:** Mass-swab testing for critical key workers in the NHS, social care and other sectors
- **‘Pillar 3’:** Mass-antibody testing to help determine if people have immunity to coronavirus
- **‘Pillar 4’:** Surveillance testing to learn more about the disease and help develop new tests and treatments
- **‘Pillar 5’:** Spearheading a Diagnostics National Effort to build a mass-testing capacity at a completely new scale
Update on the National Testing Programme: Pillar 2

Alex Cooper,
Pillar 2 SRO
The strategy was announced by the Secretary of State on 2\textsuperscript{nd} April and has 5 key strands:

- **Pillar 1**: Scaling up NHS swab testing for those with a medical need and, where possible, the most critical key workers.
- **Pillar 2**: Mass-swab testing for critical key workers in the NHS, social care and other sectors.
- **Pillar 3**: Mass-antibody testing to help determine if people have immunity to coronavirus.
- **Pillar 4**: Surveillance testing to learn more about the disease and help develop new tests and treatments.
- **Pillar 5**: Spearheading a Diagnostics National Effort to build a mass-testing capacity at a completely new scale.
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
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.
MHRA Update

Janine Jolly – Group Manager, Devices Safety and Surveillance
Target Product Profiles (TPP)

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

Issued by MHRA
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

WHO Project to develop International Standards for molecular and serological assays
CE Marked control materials for trend analysis for molecular and serological assays
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 · flexible

- 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
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.
• 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.
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
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

- Materials Chemistry Manufacturing
- Agri-Food Biosciences Medical Biotechnology Health
- ICT Electronics, Sensors & Phototonics Defence & Security Space
- Built Environment Transport Energy
- Creative Industries Digital Economy Design

Sustainability, International, Access to Finance
KTN Reach

Network contacts

We have networked with over 45,000 organisations

421 events with 32,867 delegates in attendance

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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karen.spink@innovateuk.ukri.org
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
#TestingMethods2020

We have a new challenge on the solutions sourcing platform

The nature of high-risk infections has necessarily generated more rigorous procedures which are likely to increase the detrimental environmental impact of testing.

How can we improve or minimise the impact going forwards?

Please share your ideas, solutions and examples that help to reduce the environmental impact of COVID-19 testing processes

testingmethods.crowdicity.com
Close

Doris-Ann Williams

Chief Executive of BIVDA