What can our community do to support the global effort on COVID-19?

BIA Webinar
BIA activity to support the national and global effort so far

Steve Bates
CEO
Bioindustry Association
BIA activity to support the national and global effort so far

Thus far the BIA has:

- Networked the UK medicines manufacturing community
- Participated in various sector-focused, government organised, coordination efforts
- Acted as an ad hoc facilitator for innovation exchange
- Used weekly Newscast to share latest sector focused information
- Contributed to a sector-focused conference call on the practicalities of continuing clinical trials during this period with the Department of Health and Social Care (DHSC) and the MHRA
- Briefed science and health media correspondents via the Science Media Centre
- Briefed Members of Parliament about what our sector is doing
- Held a call with CEPI on UK manufacturing capability – especially for innovative therapies
Agenda

• Early UK progress
• My structure for life science innovation in the COVID era
• Global situation report on our sector
• Engaging with the UK government
• Funding opportunities
• BIA Workstreams - updates
  • Scale up manufacturing – esp vaccines
  • Novel antibody approaches
  • Clinical Trials
• Digital Health – the moment of coming of age?
• Considerations for UK life science businesses
• Next steps
“There are decades where nothing happens; and there are weeks where decades happen.”

— Vladimir Ilyich Lenin
Synairgen to start trial of SNG001 in COVID-19 imminently

Southampton, UK – 18 March 2020: Synairgen plc (LSE: SNG), the respiratory drug discovery and development company, today announces that it has received expedited approvals from the Medicines and Healthcare products Regulatory Agency (MHRA) and Health Research Authority (HRA) to conduct a trial of SNG001 (inhaled formulation of interferon-beta-1a) in COVID-19 patients to potentially assist with the global outbreak of the virus.

COVID-19

COVID-19, caused by the SARS-CoV-2 virus, is a global threat and there is an urgent need to assess new treatments to prevent and effectively treat the severe lower respiratory tract illness that can occur with this disease. Older people and those with co-morbidities such as heart and lung complications or diabetes are at greatest risk of developing severe or fatal disease.
Where can innovation help? Getting us through

Public Health Measures – social distancing

Testing, Testing, Testing

Boosting Hospital capacity – especially ITU, Ventilators

Helping Health at home – The Digital Healthcare moment
Getting us beyond Defeating Coronavirus

1. Repurposed existing drugs

2. Vaccines: Discovery, trial, scale, delivery

3. Novel (anti body) approaches

4. Doing development differently in an internet and health at home way
Getting the global picture: Biocentury free

CORONAVIRUS ANALYSIS

In response to the urgent need for information about the coronavirus crisis, we are providing Biocentury's coverage of the policy developments, scientific advances, and progress on countermeasures for free. Our team is updating this collection frequently as research develops.

- A comprehensive list of the new vaccines and therapeutics in development against the coronavirus can be found here.

- The status of upcoming healthcare conferences can be found here.

- The status of upcoming regulatory meetings can be found here.

Please send suggestions for additional coverage to: mcov2019@biocentury.com. We are developing stories about the discovery, testing and deployment of medical countermeasures, and the response of the biomedical community to the outbreak.
Repurposing: trials timeline
# Vaccines in development – global as of March 4th

## NEW VACCINES AND THERAPIES AGAINST COVID-19

### Development programs for new COVID-19 vaccines

<table>
<thead>
<tr>
<th>Company/group</th>
<th>Technology</th>
<th>Organization type</th>
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# Novel therapeutics

## Development programs for new COVID-19 therapeutics

<table>
<thead>
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<th>Company/group</th>
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<td>National Institutes of Health</td>
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BIA co-ordination touchpoints with government and others – sharing the emerging wiring
I am contacting you as part of the Cabinet Office in relation COVID 19. I have been provided your contact details in regards to the below questions from Central Government and would really appreciate your assistance, I appreciate this is somewhat of a random request, so please do not hesitate to contact me directly or forward this email to the relevant department.

What are we doing?
We are doing some initial research on behalf of government on companies who may be able to provide large scale testing services to test for Covid-19.

Why are we doing this?
We are looking at how we increase capacity to undertake more testing.

What do we need to know?
• We need to know which companies in the UK can provide large-scale testing facilities and services to test for Covid-19.
• Who the contacts are in these companies for us to progress this?
• If this company is able to help, what would be the turnaround times?
• What form would any such testing be done - would these be testing kits that are posted?

If you can support with any of the above points, it would be appreciated. Please feel free to give me a call on my number below.

Janine Nuttall  Commercial Lead  Workplace Team - Buildings
Crown Commercial Service 9th Floor, The Capital, Old Hall Street, Liverpool, L3 9PP  Customer Service Centre: 0345 410 2222 Mobile: 07711909947
Janine.nuttall@crowncommercial.gov.uk
Other hotlines have also been set up for businesses to offer support

Vaccines – Nervtag@phe.gov.uk
Ventilators – 0300 456 3565 / ventilator.support@beis.gov.uk
Innovation/Tech – DNHSX@nhsx.nhs.uk

Increasing testing and diagnostic capacity: coviddiagnostics@phe.gov.uk

There is also a government dedicated web portal for ventilators and their components, where companies can detail their current offers.

The Department for Business, Energy and Industrial Strategy is looking for organisations who can support the supply of ventilators and ventilator components across the United Kingdom as part of the Government’s response to COVID-19. These questions aim to identify the suitability and readiness of organisations to be involved in the initiative.

There are three main sections
- Basic details and contact
- Supply chain experience
- Business capabilities

Basic details and contact
1. Add the name and contact details for your company.
Name of your organisation

This is moving fast……

• It’s not easy for UK SMEs to connect UK life science innovation into UK government effort at the moment
• But they have only gone to “war” footing this week
• We need to keep innovating and offering
• Some are using the media to get their message out – please share with us as we are discovering routes in daily – eg have put Thomas in touch with Janine
New Funding opportunities emerging

LIFEARC opening a £10M fund on COVID 19 this week
LifeArc has set up a £10 million fund for the development and testing of therapeutics that can be rapidly deployed to treat COVID-19. A call will be going out this week. Watch their website.

European Commission for startups and SMEs with technologies and innovations that could help in treating, testing, monitoring or other aspects of the Coronavirus outbreak to apply urgently for the next round of funding from the European Innovation Council. The deadline for applications to the EIC Accelerator was yesterday - **17:00 on Wednesday 18 March** (Brussels local time). With a budget of €164m, I know some UK SMEs and more information can be found here.
Key BIA workstreams

Mobilising the UK manufacturing ecosystem
Ian McCubbin
The BIA has networked the UK medicines manufacturing community and convened a consortium on emerging UK capacity to engage with government, supporting vaccine candidates reaching clinical trials scale and beyond.

Case study:

- BIA members rapidly (over a weekend) rallied to support the work of the Oxford Clinical Biomanufacturing Facility (CBF) at the University of Oxford to build a collaborative team to scale up manufacturing of a Chimpanzee adenovirus vaccine against COVID-19

- A team at Oxford led by Sandy Douglas, with Sarah Gilbert and the CBF, have put in a bid to UKRI in partnership with BIA members Pall, Fujifilm, Cobra, Cell and Gene Therapy Catapult and VMIC to develop rapid scale up of such a vaccine to a 1M dose scale by this summer
Objective:
1. **Short term**: find a way to create Xm doses of treatment, be that adenovirus vaccine, mRNA, or antibody.
2. **Long Term**: important to determine how to create a UK capability that can deliver 25m doses, within 25 weeks by 2025.

Actions:
1. Establish a small team based around BIA members within the UK who have the skills and capability to deliver the appropriate treatment.
2. Communicate through BIA channels to the wider community as needed.
COVID-19 Taskforce

**Work packages:** these will be based around the most likely treatment and follow a Discovery-Develop-Supply model.

- viral vaccines
- RNA vaccines
- Antibodies
- Fill Finish
- Supply Chain

**Underlining support groups:**
MHRA, UKRI, VMIC, KTN
Potential antibody approaches to novel therapeutics

Jane Osbourn
Antibodies and Biologics COVID-19 workstream

- Development of viral neutralizing antibodies as prophylactics to protect at risk groups and healthcare workers
- Development of protective antibodies/biologics as therapeutics for symptomatic individuals following acute exposure

**Workstream coordination:** Jane Osbourn (BIA Board & Alchemab), Paul Kellam (Kymab)
Approach and Next Steps

• Urgent need and impact requires a culture of putting commercial position to one side for this project

• We will look for opportunities for grant funding / philanthropic support, but we need to start work without this in place

• Additional teams will be created to develop work packages, provide mapping and co-ordination of capabilities, capacity, timing and availability

• We already have commitment from many of our members and the wider community (Kymab, Fujifilm, Alchemab, AbCam, Illumina, academic groups)

• If any members feel you can contribute to this effort in any way please email Eric Johnsson at the BIA at: ejohnsson@bioindustry.org

• Thank you for your leadership
Key BIA workstreams

Clinical trials – (dis)continuity
Emma Du Four
Clinical Trials Continuity (1/2)

• Where trials need to be temporarily halted due to COVID-19 related capacity or capability reasons, MHRA would not expect to be notified of trial halts. The trial master file should include a note that the trial was halted and the reason.

• However, if the halt is a result of a direct participant safety incident, particularly if this has potential to impact participants of other trials, or as a result of a medicines supply issue then MHRA should be informed in the normal way. This can be done via email to the MHRA helpline rather than via an amendment form.

• If the restart of the study does not involve any substantial changes to the Clinical Trial Authorisation (CTA), then a substantial amendment notification to MHRA will not be necessary. If changes do need to be made to protect participant safety moving forward, then this should be submitted as a substantial amendment in the normal way.

• Alternative arrangements for patient supply of investigational products e.g. posting of the medicine rather than clinic attendance, does not require prior notification to MHRA, however appropriate risk assessments should be in place.

• Remote monitoring is supported by MHRA where appropriate and practical.

• MHRA Clinical Trials Unit Helpline (clintrialhelpline@mhra.gov.uk or 020 3080 6456) will give inquiries relating to COVID-19 the highest priority, including the possibility for fast-tracking submissions.
Clinical Trials Continuity (2/2)

- Research studies may need to be paused and new studies delayed in starting, to free up clinical staff to help bolster the frontline response to COVID-19.

- All non-COVID NIHR funded studies in the set-up process will be suspended.

- This does not impact on MHRA/HRA approval processes – trials which have been approved will be paused and be ready to start as soon as possible after the pandemic.

- NIHR recognise the need to have a process combined with MHRA/HRA to approve COVID-19 clinical trials at national level. Guidance in consultation with Chris Witty, Chief Medical Officer (CMO) is being developed and will be issued soon. NHS is prioritising COVID studies approved by CMO.

References
MHRA Advice for Management of Clinical trials in relation to Coronavirus - link
DHSC guidance on the impact on COVID-19 on research funded or supported by NIHR – link
HRA Research in a public health emergency - link
ACRO’s Recommendations to support clinical trial monitoring oversight during COVID-19 – link
FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic - link
Key BIA workstreams

Digital health in the first internet era pandemic
Andy Richards
Questions?
Running a UK life science SME during this period, info and considerations

Assume your staff are **Key Workers** for government definition – us, ABPI, BIVDA, ABHI are checking with Government this morning, our sector has fallen within the definition when other governments have defined it

Can R+D tax credit system be used to provide an advance to keep innovative companies functioning- inputing to Treasury today
What do members need at the moment?

**COVID-19 Response Hub.** The Government’s Response Hub includes FAQs, travel advice and guidance for health professionals. This remains the key resource for the latest information and advice. The Government is now moving to the “Delay” phase of planning. Measures include staying at home for seven days if you have a new continuous cough or high temperature.

**Guidance for the general public.** The guidance issued for the general public includes a list of those ‘affected areas’ where it recommends that returning travellers stay indoors and ‘self-isolate’.

**Guidance for employers and businesses.** The Government has published guidance specifically to support employers and businesses with their preparations. BEIS has launched a dedicated business support helpline for advice on minimising and dealing with the impacts of coronavirus. They can be accessed at 0300 456 3565 Monday to Friday, 9am to 6pm, or email enquiries@businesssupporthelpline.org.
NEW: The MHRA have published a blog post, “Advice for Management of Clinical trials in relation to Coronavirus” MHRA is aware that there are challenges arising in relation to Coronavirus and the effect this is having on the conduct of clinical trials. They recognise the difficulties this creates for managing trials and would like to offer some advice.

NEW: The Health Research Authority has produced new guidance for sponsors, sites and researchers about the COVID-19 pandemic. The guidance covers the setup of new studies, amendments to existing studies and changes being made by sponsors at this time. The guidance will be updated regularly.

NEW: The DHSC has stood up the National Supply Disruption Response (NSDR) to monitor the supply situation and co-ordinate actions to address any incidents of supply disruption where normal procedures are unable to provide a resolution. Marketing Authorisation Holders will have received guidance directly from the Department today. They NSDR can be contacted at: 0191 283 6543 and at supplydisruptionservice@nhsbsa.nhs.uk.
NEW: The National Credentialing Register has published a list of statements from Hospital Trusts on policies restricting ‘external’ representatives visiting their sites. This includes the contacts at the trusts that enquiries need to be sent to.

NEW: DHSC issues guidance on the impact on COVID-19 on research funded or supported by NIHR. This will mean that many research studies funded by NIHR, or supported by NIHR (via the Clinical Research Network and other NIHR infrastructure) may need to be paused, to free up NIHR-funded staff to help bolster the frontline response to COVID-19.
More Guidance on web from members

Guidance on the legal aspects of COVID-19 by Simmons & Simmons

COVID-19: risks and opportunities
Remote working - signing legal documents using e-signatures
Government websites for country-specific COVID-19 guidance
The Coronavirus outbreak challenge
Coronavirus – impact on business contracts
Construction and the Coronavirus

Trusting the internet: An overview of anti-disinformation laws
Coronavirus (COVID-19) - the insurance issues
Managing Insolvency Risk and Financial Reporting
Coronavirus - impact on tax
COVID-19 and its potential impact on trade finance

Other publications
Next steps – external environment

Question and Answer on UK government’s approach to novel manufacturing in House of Lords today – we will watch with interest

BIA inputting UK content into US BIOs virtual conference on tackling COVID – planning stages at present
NIH is looking for volunteers who have recovered from COVID-19 to donate blood for studies on the immune system.

VOLUNTEERS NEEDED
The NIH Vaccine Research Center is looking for volunteers to donate blood for studies on the immune system.

You may qualify if you are:
- 18 years of age or older
- Fully recovered from confirmed COVID-19 infection
- Able and willing to complete the informed consent process

As these studies aim to further define and understand specific immune responses, the Vaccine Research Center is not evaluating or studying active or possible COVID-19 infections.

Participants will be compensated for their time and inconvenience. To volunteer, call 1-866-833-5433 (TTY 1-866-411-1010) or email vaccines@nih.gov.
Next steps – BIA activity

BIA webinar next Thursday – focus on managing life science business through COVID 19 and beyond – (rather than sector efforts on COVID 19)

BIA website COVID resource pages will be up and running in next few days

Manufacturing workstream webinar next week with CEPI’s Jim McMahon - Sustainable Manufacturing lead
Questions?
Contact us

Please send any questions or comments to:
BIAevents@bioindustry.org