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COVID-19 R&D TRACKER UPDATE: 6 AUGUST 2020

Monitoring COVID-19 R&D since January, the <u>COVID-19 R&D tracker</u> by Policy Cures Research seeks to help funders, policy makers, researchers and others understand the evolving COVID-19 R&D landscape. Below are some key takeaways around \$8.9 billion publicly announced funding for COVID-19 R&D and the product pipeline of at least 938 product candidates.

Several key candidates have received large funding commitments for both R&D and manufacturing

- As more candidates approach late-stage clinical trials, the focus of funding is shifting away from support for clinical development and towards preparing for the logistical challenges of large-scale manufacturing and distribution.
- The UK government has so far committed just over \$100 million to the clinical development of Oxford University's ChAdOx-1 COVID-19 vaccine, which is now one of the most advanced candidates in the pipeline.
- The US BARDA has pre-committed \$1.2 billion to British-Swedish multinational pharmaceutical company, AstraZeneca for the development of at-risk manufacture and procurement of up to 300 million doses of its candidate, should it prove successful in clinical trials.
- Novavax has received R&D funding from both CEPI (\$388m) and BARDA (\$82m) for the clinical development of its NVX-CoV2373 candidate, along with \$1.6 billion in manufacturing funding from BARDA – BARDA's second-largest manufacturing contract to date.

Vaccines keep making strides, but still way off

- Six months have passed since WHO first declared COVID-19 a Public Health Emergency of International Concern. The world has witnessed an unprecedented effort to develop a vaccine targeting SARS COV-2. Currently, 27 vaccine candidates are in the clinical phase of development (not counting the two TB vaccines – BCG and an investigational recombinant form of BCG – also being evaluated in clinical trials for the prevention of COVID-19). Of these 27 candidates, five have advanced to pivotal phase III trials; this includes both traditional (inactivated) vaccine constructs, and novel constructs (non-replicating viral vectors and RNA) that have never before been approved for human use.
- Developers of eight vaccines undergoing clinical testing have so far shared results from early-stage trials. The data readouts from these trials have ranged from peer-reviewed articles, to advance (pre-print) manuscripts, to a company press release, and for some trials only partial data was shared. Coupled with the fact that the evidence generated so far has primarily been limited to looking at reactogenicity and immunogenicity, it is challenging to make any meaningful comparison between candidates beyond noting that all six have demonstrated an acceptable safety profile and have managed to trigger an immune response in some shape or form. The other significant facts emerging from these early-stage results are that it is quite likely that an efficacious vaccine might require a two-dose schedule; that pre-existing immunity against the vectors used in some of the vaccines can potentially impact their efficacy; and, based on the results from the only subunit vaccine, adjuvants may play a critical role as far as subunit vaccines are concerned.
- Besides clinical development, most vaccines in human trials are also undergoing animal testing in parallel. Data from non-human primate studies related to four vaccines in clinical development was shared recently. One such pre-clinical result included the first-

ever correlate of protection analysis; the findings suggest that serum antibody titers may prove a useful immune correlate of protection for SARS-CoV vaccines.

Funding for COVID-19 is more focused on vaccines and diagnostics than in previous outbreaks

- Compared to the R&D funding in response to previous outbreaks of Ebola and Zika captured in our G-FINDER R&D survey, a much larger proportion of COVID-19 funding has gone to diagnostics and vaccines, and much less to basic research (see charts).
 - Looking only at the US\$6.4 billion of COVID-19 R&D funding commitments clearly identifying funds for a specific product, 74% went to vaccines and 11% to diagnostics. Less than 3% went to basic research.
 - During the global response to the West African and DRC Ebola outbreaks, and the South American Zika outbreak, 16% of product-specific funding went to basic research, while 63% went to vaccines and only 4% to diagnostics.
 - Even in absolute terms, both Ebola and Zika received more funding devoted to basic research than has been committed for COVID-19 – albeit over a longer period of time.
 - Funding for treatments drugs and biologics has been relatively similar to past pandemic responses, about 19% of total COVID-19 funding, and about 17% across Ebola and Zika.
- The increased focus on diagnostics for COVID-19 follows broader acknowledgement of the critical importance of testing to control this pandemic – possibly driven by the prevalence of COVID-19 in nations committed to a national-scale test and trace approach to controlling the pandemic – reflected in the inclusion of diagnostics as one of the three key pillars in the ACT-Accelerator.
- The comparative lack of basic research funding is influenced by the fact that productspecific funding lends itself to the announcement of large commitments in a way that basic research doesn't, but it is absolutely the case that comparatively more funding should be directed to building an understanding of the fundamental characteristics of SARS-CoV-2 than is currently the case; experience with past epidemics has shown that investment in basic research generally lags the initial product-specific funding.



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Therapeutics, mostly drugs, making progress

- Close to 150 unique interventions for the management of COVID-19 are currently under clinical investigation. As noted previously, repurposed drugs make up a significant portion of COVID-19 therapies under investigation, with novel agents making up less than a quarter.
- Readouts from two trials were shared recently: SNG001, an inhaled formulation of interferon beta, decreased the progression from mild to severe disease by79% when compared with placebo. In a separate trial, use of favipiravir, an approved broad-spectrum antiviral, was associated with 28.6% faster viral clearance. However, these results should be treated with caution, as the findings from the two trials are not yet formally peer-reviewed
- As the timeline for a vaccine is still uncertain, developers are investigating two biologics

 including a mAb cocktail as prophylactic interventions in high-risk groups, with both
 currently in phase III trials.

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Diagnostics options continue to expand

- The COVID-19 diagnostics pipeline continues to grow, with at least 168 different technologies already approved or under review via the emergency authorization pathway of the US FDA
- A comprehensive and resourceful diagnostic strategy has proved to be a decisive factor in mitigating the spread of COVID-19. Even with the availability of multiple technologies, most countries, high- and low-income, have struggled to scale up SARS CoV-2 diagnostic services. To preserve testing resources, many developers are working on a pooled-sample approach, a well-established technique in an outbreak context. The US FDA for the first time approved the use of pooled sampling, with four molecular pooling assays given emergency use authorisation.

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