

## AGILE: Coronavirus Drug Testing Initiative

### About the programme

- AGILE is a clinical trial platform that aims to speed up drug testing in the ongoing COVID-19 pandemic and ultimately allow us to restart society quicker.
- AGILE is the first trial platform that has the capacity to rapidly test various completely new treatments specifically developed for COVID-19.
- AGILE is flexible and can test drugs that are suitable for patients newly diagnosed with COVID-19 at home, as well as patients in hospital.
- The AGILE platform can test several potential treatments in parallel and speeds up testing by pooling control patients.
- As a result, potential treatments can go through the final testing stages much faster, while maintaining a high level of safety at all times.

### What is the process?

- Drugs that are accepted for the trial will begin by dosing a small group of six patients. After one week, another group of six patients will be dosed, and this will be repeated. This will allow the most effective dose to be found.
- Successful drugs will move to a seamless Phase 1/2A trial that will test in larger groups. These will be used as a proof of confidence that the drug is both safe and has a significant biological impact.
- Safe and potentially highly effective treatments will be referred to partners for Phase III clinical trials.

### Future clinical applications

- AGILE could help to refresh the way that the world responds to emergent viral diseases, shaping the way we deal with potential pandemics in the future.
- This protocol could be applied to many different types of illnesses which require fast action and highly effective results.

### How the platform was developed

- The AGILE initiative is a collaboration between the Universities of Liverpool, Southampton (Southampton Clinical Trial Unit), Lancaster University and Liverpool School of Tropical Medicine, as well as other partners. AGILE has been developed by Infectious Diseases clinicians, clinical and pre-clinical pharmacologists, clinical trials specialists and statisticians.
- AGILE borrows from cancer and rare disease trial design for use in health emergency situations.
- The platform has full ethics and regulatory approval in the UK from the MHRA.

### Who are the partners?

- Programme collaborators:
  - University of Liverpool – *Clinical pharmacology and infectious diseases*
  - Liverpool School of Tropical Medicine – *Infectious diseases*
  - Southampton Clinical Trials Unit, University of Southampton – *Trial/data management and statistics*
  - Lancaster University – *Statistical design*
- External funding for trials implemented through the AGILE platform: [Unitaid](#) and [Steve Morgan Foundation](#). Please note that some drug-specific trials will be funded directly and solely through independent private companies (e.g. Ridgeback Biotherapeutics).
- Current participating companies: Ridgeback Biotherapeutics

## How pharmaceutical companies or academic institutions can participate

- AGILE is actively encouraging other pharmaceutical companies and academic institutions to put forward new COVID-19 treatment candidates for consideration. For further information on AGILE, please visit [www.agiletrial.net](http://www.agiletrial.net).
- If you are interested in participating, please contact the University of Liverpool Clinical Trials recruitment team by calling 0151 706 4863 or by e-mailing [ahn-tr.crurecruitment@nhs.net](mailto:ahn-tr.crurecruitment@nhs.net).