G7 Therapeutics and Vaccines Clinical Trials Charter

Clinical trials are the primary way to generate actionable evidence, informing which vaccines and therapeutics are safe and effective. During the COVID-19 pandemic, rapid, robust and randomised trials have played a critical role in informing public health and clinical decisions.

Many therapeutic trials, however, have been inadequate in size, design and conduct, failing to generate the evidence needed for decision making and to drive practice change. More effective international collaboration on trials would have made better use of scarce resources and may have saved lives. An assessment from the US Food and Drug Administration suggests only about a quarter of enrolled patients contributed to adequately powered and well controlled trials[1].

While vaccine development has been faster in this pandemic than ever before, improvements can be made: during the pandemic, the use of different laboratory testing methods and reagents meant it was often not possible to compare immune responses directly; a lack of pre-agreed processes was a barrier to the cross-border movement of materials; and there was no overall coordination of trial testing methodology.

The G7 are well positioned to contribute to the leadership needed to achieve better coordination and cooperation in the future. By working together, as the G7 and with multilateral organisations and relevant authorities, **we will endeavour to implement these principles** in our own countries and with partners around the world.

I. To avoid the proliferation of trials that do not contribute to valid or actionable scientific evidence, **we will** prioritise support for randomised controlled trials that address key public health and clinical needs, are well designed and sufficiently sized to generate reliable evidence, are consistent with good clinical practices and ethical principles and engage our citizens to strengthen confidence in science. **We will take this forward through** our national healthcare and research systems and agree to promote communication and coordination between them, building on existing collaborations with the World Health Organization (WHO) and other relevant bodies such as the Global Research Collaboration for Infectious Diseases Preparedness (GloPID-R).

II. To avoid unnecessary duplication and produce valid and actionable evidence more efficiently, **we will** coordinate emergency and preparedness research agendas across the G7 as appropriate, e.g. by sharing vaccines and therapeutics national research agendas and priorities, sharing information on ongoing and planned trials including stage of planning, and identifying opportunities for collaboration where mutually beneficial. **We will take this forward** through research funding bodies and through coordination alliances, in particular the WHO, and other relevant bodies such as GloPID-R.

III. To enable timely availability of actionable information from multi-country clinical trials and to increase the comparability of data, **we will** work with G7 regulators, ethics institutions and committees to achieve greater harmonisation and to streamline regulatory process to act more proportionately to risk. **We will take this forward**

[1] Bugin, Kevin, and Janet Woodcock. "Trends in COVID-19 Therapeutic Clinical Trials." Nature Reviews Drug Discovery, 25 Feb. 2021, 10.1038/d41573-021-00037-3. Accessed 29 April. 2021. The same assessment showed approximately 5% of global trial arms were randomised and adequately powered during the current pandemic.

though existing fora, such as the International Coalition of Medicines Regulatory Authorities (ICMRA), the WHO, and the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).

IV. To ensure that we act as quickly as possible in response to positive and negative data results from clinical trials, **we will** accelerate the sharing of data and results so that therapeutics proven to be effective and safe can be approved by regulatory bodies, incorporated into clinical practice guidelines and recommended for use in routine practice. **We will take this forward** with the WHO, national and professional associations and guideline setting bodies where appropriate, ensuring data security. We will promote that all clinical trials are registered in the WHO's International clinical trial registry platform (ICTRP) primary or partner registries.

V. To ensure that health and research systems can respond quickly and effectively to existing and emerging threats, **we will** make preparedness and high quality, ethical research and randomised controlled trials part of normal practice within our healthcare and research systems. We will support the development of the global infrastructure needed to allow rapid set-up, coordinated delivery of trials, and sharing of emerging findings recalling the principles set out in the Charter on Equitable Access to COVID-19 tools by 25 countries. **We will take this forward** through our national and international healthcare and research systems as well as supporting the WHO and non-G7 countries, including low- and middle-income countries, to strengthen sustainable research capacity and capability.

VI. To expeditiously advance the development and testing of vaccines, as well as the investigation of correlates of protection and therapeutics, **we will** agree that as soon as novel pathogens or viral variants appear and become accessible to a G7 country, the G7 will rapidly share testing methods, reference standards and testing materials (as they relate to the virus strain) with any other G7 country and beyond, via an open material transfer agreement. **We will take this forward** through the G7's national research bodies, and where appropriate contract research organisations, and will look to expand on the work of the Global Health Security Initiatives (GHSI), the WHO and the Coalition for Epidemic Preparedness Innovations (CEPI).

VII. To make vaccine development faster, **we will** work to develop a framework to coordinate testing methodology and share testing materials, wherever possible, in response to pandemic threats. Where this is not possible, we will seek ways to compare the results of vaccine assessments in clinical trials. **We will take this forward** through the G7's national and international research bodies, and where appropriate contract research organisations, and will look to expand on the work of GHSI, the WHO, and CEPI.