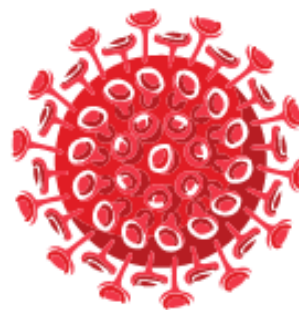


COVID-19 Toolkit for Drug Development



WI COVID-19 Toolkit for Drug Development

September 2020

The COVID-19 pandemic is changing drug development in unprecedented ways.

*We have prepared a **toolkit** to access **up-to-date resources** from regulatory agencies and non-profit groups.*

We would be happy to discuss any challenges you are facing during this time and how we can help.

COVID Toolkit Quick Links

[Regulatory Agencies COVID Tools](#)

[Non-profit Groups COVID Tools](#)

[Articles about COVID Impact](#)

[Contact WI](#)

Regulatory Agencies



US Food and Drug Administration (FDA)

- [COVID-19 guidances](#)
- [COVID-19 emergency use authorizations](#)
- [FDA COVID-19 landing page](#)
- [Drugs COVID-19 page](#)
- [Biologics COVID-19 page](#)



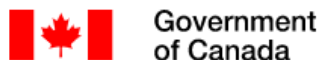
European Medicines Agency (EMA)

- [COVID-19 EMA pandemic task force](#)
- [COVID-19 landing page](#)
- [Guidance for medicine developers](#)
- [Advice for clinical trials affected by COVID-19](#)
- [Fast-track procedures for COVID-19 therapies](#)



Australian Government Department of Health & Therapeutic Goods Administration (TGA)

- [Guidance on clinical trials for institutions, HRECs, researchers and sponsors.](#)



Health Canada

- [Notice to clinical trial sponsors](#) to guide management of clinical trial applications (CTAs).



Medicines & Healthcare products
Regulatory Agency

Medicines and Healthcare products Regulatory Agency (MHRA, United Kingdom)

- [COVID-19 guidances](#) on regulatory flexibilities, clinical trials, inspections and good practice, and medicines during the coronavirus outbreak.



Information from other agencies is available on the **International Coalition of Medicines Regulatory Authorities (ICMRA)** [COVID-19 page](#).

Non-profit Groups

Regulatory Affairs Professionals Society (RAPS)

- [RAPS COVID-19 Resource Center](#) with trackers for vaccines and therapeutics, a COVID-19 Data Portal, and COVID-19 Authority Updates



Transcelerate Biopharma

- [COVID-19 solutions](#), including tools to support centralized trial monitoring, protocol deviation management, issue and risk management, and patient-friendly technology
- [CSR Considerations for Studies Disrupted by the COVID-19 Pandemic](#)



Clinical Trials Transformation Initiative (CTTI)

- [COVID-19 Clinical Trials Issues page](#)
- [Spreadsheet](#) of all COVID-19 related clinical studies listed on Clinicaltrials.gov
- [Best practices document](#) (pdf) for conducting trials during the pandemic
- Free webinars on [engaging minority patient populations](#), [switching to virtual visits](#), and [designing high quality trials](#).



Articles

[Conducting Clinical Research During the COVID-19 Pandemic: Protecting Scientific Integrity.](#) *JAMA*. 2020;324(1):33-34. doi:10.1001/jama.2020.9286

[Clinical Trials During COVID-19: Updates from FDA, MHRA and TGA.](#) *Regulatory Focus*

Please click the link below to learn more about WI and how our level of expertise and individualized service sets us apart.

