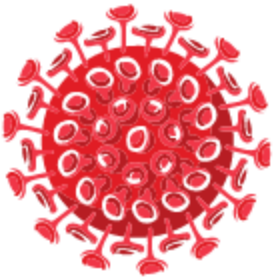
COVID-19 Toolkit for Device Development



WI COVID-19 Toolkit for Medical Device Manufacturers: Design, Development, and Submission

November 2020

The COVID-19 pandemic is changing medical device design and development in unprecedented ways. These hurdles can pose downstream challenges that may impact regulatory submissions and subsequent market approval.

*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 Guidance
- Medical Devices COVID-19 Page
- Medical Devices COVID-19 Guidance
- COVID-19 Emergency Use Authorizations for Medical Devices
- Registration and Listing of Medical Devices during COVID-19 Pandemic

European Commission

- COVID-19 Landing Page
- EU MDR Postponed to 26 May 2021
- COVID-19 Data, Regulations, Guidelines

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

- Guidance on clinical trials for institutions, HRECs, researchers and sponsors.

Health Canada

- Management of clinical trials during the COVID-19 pandemic: Notice to clinical trial sponsors
- COVID-19-related Medical Devices

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

- COVID-19 Guidance on regulatory flexibilities, clinical trials, inspections and good practice, and medicines during the coronavirus outbreak.
- Medical Devices Clinical Investigations during COVID-19 outbreak
- COVID-19-related Medical Device Topics

Information from other agencies is available on the **International Coalition of Medicines Regulatory Authorities (ICMRA)**

- COVID-19 page

Non-profit Groups

MedBoard

- COVID-19 Medical Devices and Diagnostics regulations, guidance, and notices from various authorities

Regulatory Affairs Professionals Society (RAPS)

- RAPS COVID-19 Resource Center

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 for conducting trials during the pandemic
- Free webinars on engaging minority patient populations, switching to virtual visits, and designing high quality trials.

Articles

For general clinical research:

- Conducting Clinical Research During the COVID-19 Pandemic: Protecting Scientific Integrity. *JAMA.* 2020;324(1):33-34.
- Clinical Trials During COVID-19: Updates from FDA, MHRA and TGA. *Regulatory Focus*

For medical regulations in the EU:

- Regulating drugs, medical devices, and diagnostic tests in the European Union: early lessons from the COVID-19 pandemic? *European Heart Journal*. Volume 41, Issue 23, 14 June 2020, Pages 2140–2144.

For COVID-19-specifc medicinal and medical device products:

- COVID-19: Regulatory Landscape of Medicinal and Medical Device Products for Human Use. *Clinical Therapy*. 2020 Aug;42(8):1444-1450.

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

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We Speak Science

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