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.

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:
- Clinical Trials During COVID-19: Updates from FDA, MHRA and TGA. *Regulatory Focus*

For medical regulations in the EU:

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

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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