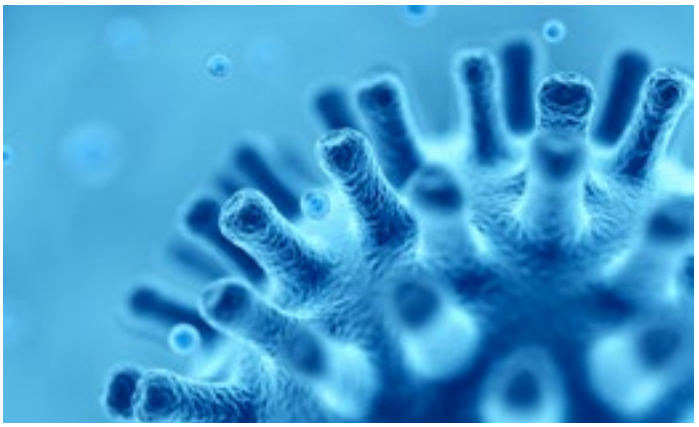
IQVIA Global Regulatory Affairs

Committed to helping you address the impact of COVID-19 today, and provide hope for the future

In the rapidly evolving fight against COVID-19, IQVIA Global Regulatory Affairs is committed to deploying our resources and capabilities to help everyone in healthcare do what needs to be done, and to keep things moving forward.

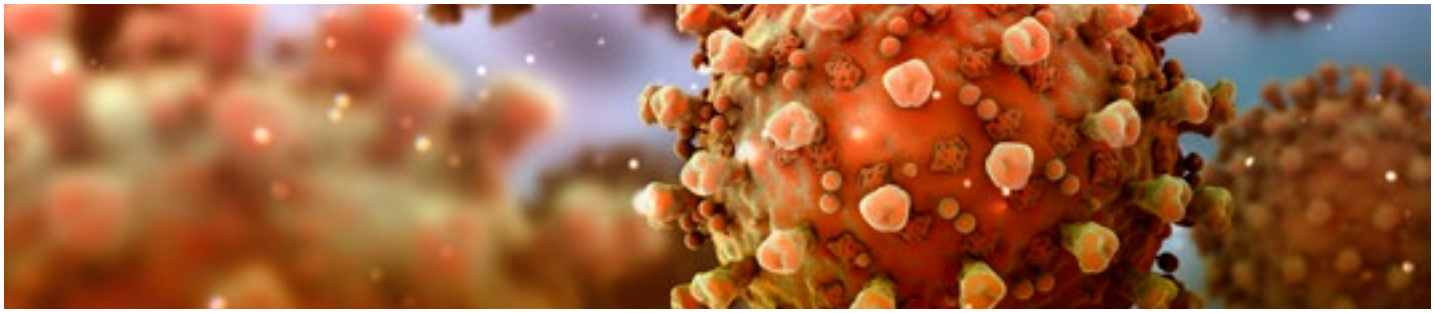
This includes helping drug and medical device developers and manufacturers enable the successful initiation and conduct of clinical trials, as well as streamlining submission strategies and operations based on evolving key regulatory guidance worldwide.



Ways we can help you combat the spread of COVID-19

SUPPORTING INITIATIONS OF NEW CLINICAL TRIALS FOR COVID-19 THERAPIES

- Consult on clinical trial application risk-assessments and expedited reviews enabled by country Regulators and Ethics Committees
- Expert regulatory guidance on multi-disciplinary strategies to address:
  - Consenting procedures
  - Supply strategies for Investigational Product – maintain treatment continuity
  - Consultancy on urgent remedial clinical strategies
  - Remote site selection and monitoring options



REGULATORY SERVICES FOR ACTIVE TRIAL MODIFICATION(S)	• Regulatory guidance on multi-disciplinary strategies to address:
	  • Clinical Trial amendments – interpret evolving RA/EC guidance at regional/country level for appropriate submission (Urgent Safety Measure, Temporary Halt, Amendments/notifications)
	• Consultation on urgent remedial strategies to ensure continuity of clinical trials
	  • Drug supply, e.g. urgent safety measures to allow direct to subject shipment
	  • Labelling of Investigational Product – strategies to maintain subject supply
	  • Remote Clinical Monitoring options; guidance on eSignatures
	  • Handling protocol deviations

REGULATORY STRATEGY AND SCIENTIFIC ADVICE WITH REGULATORY AGENCIES	• Facilitation of scientific advice procedures and meetings, together with our ex-Regulatory Agency staff • Development of the strategic approach for each market, preparation of briefing documentation, and considerations around questions and responses to regulatory agencies • Support with Agency meetings, acting as the representative, presentation of the facts and arguments, and finalization of the advice from each agency
SUPPORTING R&D TEAM'S UNDERSTANDING OF REGULATORY STRATEGIES AND DEVELOPMENT PATHWAYS IN GLOBAL MARKETS	• Define the expedited pathways and development of the regulatory strategy available to pandemic vaccines and treatments, with an objective of getting to market as quickly as possible • Advise on minimum requirements to act as market authorization holder, distribution/legal entity; other procedures that should be considered and impact on the approval and product's commercialization, as a new entity or line extension

FINAL PREPARATION ASSISTANCE AS YOU MOVE TOWARDS REGISTRATION IN THIS UNPRECEDENTED TIME	• Full support for the marketing authorisation applications:
	  • Complete authoring and publishing of BLAs, NDAs or MAAs in any global market
	  • Global labelling (including authoring from CCDS);
	  • CMC support for dossier creation or adaptation
	  • Regulatory dossier project management and gap analyses for geographical expansion projects

IQVIA's Global Regulatory Affairs team is here to support your journey from early development through submissions and beyond. Talk with an expert today to discuss your needs and how we can help you navigate the rapidly changing regulatory landscape.

CONTACT US
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