ICON has developed an integrated solution that deploys functional services driven by overarching COVID-19 regulatory guidance. No two studies are the same so our operational teams are ready to work with you to review study-specific plans and adopt the services needed to reduce disruption to trial timelines and stay compliant.

### Global Regulatory Audit and Guidance

<table>
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<tr>
<th>Challenges</th>
<th>Trial Design</th>
<th>Solutions</th>
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<td>– Increased protocol amendments due to current healthcare environment</td>
<td>– Advice on protocol amendment implications and tracking</td>
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<td>– Cancelled Investigator meetings</td>
<td>– Data Monitoring Committee set-up and management</td>
<td>– Pre-recorded Investigator meetings</td>
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<tr>
<td>– Designing COVID-19 trials for accelerated start-up to respond to urgency of situation</td>
<td>– Advice and technology solutions to optimise the use of real world data</td>
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<tr>
<td>– Difficulty in accessing certain patient populations</td>
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#### Challenges

- On-site monitoring delayed or postponed
- Tracking processes for visit schedules
- Protect patient safety through compliant safety reporting
- Suspended or cancelled trials
- HTA bodies have re-prioritised programs or delayed timelines
- Change in modality of data collection, or how COA is administered
- Trials cancelled or suspended

#### Process

- Remote and central monitoring and remote SDV
- Automated regulatory intelligence and safety reporting solution
- Strategies for trial re-start
- Maximise HTA/HEOR readiness and evidence generation planning
- COA selection, design and validation

#### Data Integrity

- Interpreting regulations to provide clear guidance on changes required for data collection and analysis to address current conditions
- Clear guidance available for data management and statistical plan changes required
- Clinical Risk Management

#### Logistics

- Deployment of In-home clinical service and direct to patient support services
- Technology and logistical support to manage IMP direct to patient
- Range of laboratory specialist services
- eDocument distribution & management

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