EU Clinical Trial Regulation 536/2014
PPD enables a seamless lifecycle development of your product globally

The EU Clinical Trial Regulation (CTR) 536/2014 will replace Directive 2001/20/EC and aims to simplify and harmonise procedures for the authorisation, assessment and supervision of clinical trials in the EU.

There are going to be big changes
The cross functional PPD EU CTR readiness team is ideally positioned to help you navigate these requirements.

The EU Clinical Trial Regulation ((EU) No_536/2014)) will be implemented on 31 January 2022 and aims to simplify and harmonise procedures for the authorisation, assessment and supervision of clinical trials between the EU Member States. The new CTR will allow sponsors to make one clinical trial application (CTA) for all EU Member States intended to participate in a given trial, via a centralised portal, the Clinical Trial Information System (CTIS).

Within the first year of the implementation of the EU CTR, sponsors will have the option of submitting new clinical trials under the current EU Clinical Trial Directive or the new EU CTR. This includes the addition of Member States for ongoing trials. After the first year of the implementation (after 31 January 2023), the trial will be required to transition to the EU CTR prior to adding the new Member States. Ongoing trials will need to transition to the EU CTR within a three-year transition period and by no later than 31 January 2025. Trials ending before the transition period will not be mandated to transition.

PPD has multiple cross functional teams dedicated to this regulation enabling us to deliver up to date intelligence on the impact of the changing regulation. With our patients in mind, all steps will be taken to assure that the EU CTR implementation will have no impact on patient safety and access to medicines.
An overview of the impact of the new regulation on global lifecycle management is outlined below.

<table>
<thead>
<tr>
<th>Protocol Optimisation</th>
<th>Submission Strategy and Planning</th>
<th>Authorisation</th>
<th>Lifecycle Management</th>
<th>Post Trial Activities</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Ensuring that a harmonised or consolidated protocol is in place prior to transition</td>
<td>• Directive or Regulation?</td>
<td>• Clinical Trial Information System (CTIS) registration and user management</td>
<td>• Authoring, Publication and Submission of:</td>
<td></td>
</tr>
<tr>
<td>• Protocol synopsis in Lay Persons language</td>
<td>• Transition strategy</td>
<td>• Selection of Reporting Member State (RMS)</td>
<td>— Lay Persons Summary</td>
<td></td>
</tr>
<tr>
<td>• Categorisation of your clinical trial: New Low Interventional Trial category</td>
<td>• New definition: Non-authorised Auxiliary Medicinal Products</td>
<td>• Single CTA submission to the Competent Authorities and Ethics Committees for multi-national trials</td>
<td>— Summary of Results</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Transparency Requirements</td>
<td>• Parallel or sequential Part I and Part II submissions</td>
<td>• Authoring and Submission of Annual Safety Reports</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Redaction of:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>— Commerically Confidential Information</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>— Personal data</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>— Confidential communication between Member States</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Revised labelling requirements</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Regulatory Challenges

- Navigating around the Regulation in line with your Global Development Plan
- Limited country specific guidelines
- Adhering to the Transparency requirements
- Responding to agency requests in a maximum of 12 calendar days

### PPD’s Solution

- Understand and manage the requirements of leading and executing trials under the Regulation
- Customised level of outsourcing to meet your specific needs
- Preparedness and Implementation
  - IT Systems
  - SOPs
  - Training
- Transition strategy across book of work
- Apply and adapt EU strategy globally using our Subject Matter Experts (SMEs) and strategic expertise
- Build efficiencies in compiling core documents
- Provide a flexible and skilled-cross-functional resource pool

PPD will be carefully factoring in the transition of clinical trials from the Directive 2001/20/EC to the EU CTR as part of your clinical trial development plan to allow for a seamless lifecycle development of your product, while ensuring compliance with the required regulations.

PPD is focused on providing the support to progress and conduct the required regulatory strategies, assessment and submission activities so that companies are prepared and ready for these changes.

Learn more at Regulatory Affairs | PPD Inc

Contact your Business Product Lead or our Regulatory Policy and Advocacy Team RISSM@PPD.COM

For more information, please contact us at +1 877 643 8773, +1 919 456 5600 | ppdi.com

© 2021 PPD, Inc. All Rights Reserved. 12.2021