Regulation of Clinical Research in European Union (EU)

- **Current Process:**
  - Clinical Trial Directive (2001/20/EC) describes a single harmonized process across all EU Member States

- **New Process:**
  - Clinical Trial Regulation (EC) 536/2014 (published 27 May 2014)
  - Regulation applies 6 months after the publication of the confirmation note in the OJ and not earlier than 2 years after the publication of the Regulation (not earlier than 28 May 2016)
New EU clinical trial legislation will result in a submission to all countries using a central portal and increased transparency

<table>
<thead>
<tr>
<th>From</th>
<th>To</th>
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<tr>
<td>• Separate national clinical trial and ethics committee (EC) submissions</td>
<td>• Single, joint submission for all EU Member States via a single portal</td>
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<td>• Sequential approvals: FPFV approach to trial initiation</td>
<td>• Approval in all countries at same time allowing synchronised start</td>
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<td>• Transparency requirements not defined</td>
<td>• All information submitted to the portal will be in principle publically accessible; sponsors must submit summaries of results</td>
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<td>• Within 60 day approval timeline (excludes EC approval times)</td>
<td>• Within 60-106 day timeline (includes EC approval)</td>
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<td>• Penalties for not meeting timelines for responses limited to submission / country</td>
<td>• Failure to respond in timelines results in automatic withdrawal for entire application</td>
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<td>• ~ 35 day timeline for approval of substantial amendments (excludes EC approval times)</td>
<td>• 49-95 day timeline for approval of substantial amendments (includes EC approval)</td>
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<td>• Local language submissions will be allowed</td>
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Companies must be submission-ready by the time of portal launch

- 1 year timeline from portal going live and sponsor being mandated to follow new process for new trials (3 years for ongoing studies to transition)
- May 2016 is the earliest this could come into practice

- May 2014
- Dec 2014
- Transition period of 3 years starts
- Earliest May 2016
- Earliest May 2019
- Final regulation published
- Functional requirement for audit agreed by EMA MB
- System ready and available for audit
- EMA MB agrees system is functional
- EC publishes confirmation
- Application of regulation
- 6 months