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Incoming EU clinical trial laws could mean more strategic CRO partnerships – executives

New CTA legislation likely to come into play mid-2016

Sponsors have 12 days to answer member state questions, speedy CRO responses a must

Lessons learned from VHP shows need for closer CRO collaboration

CRO strategic relationships and preferred vendor status could become more common in order to gain sponsor trust to meet incoming EU clinical trial regulations, industry executives said on the sidelines at the DIA EuroMeeting in Vienna.

Under the new legislation - anticipated to come into play in mid-2016 -- sponsors will file clinical trial applications with all its desired EU member states simultaneously through an EMA-managed database, rather than separately to each country.

The decision process is split into two parts -- a 10-25 day validation period for member states to decide whether they will take part in the trial and assign a lead member state for the project, and the second for member states involved to set definitions and ask questions, Nick Sykes, senior director worldwide safety and regulatory, Pfizer (NYSE:PFE), said during a DIA presentation.

The total authorization period is 60 days plus potential stop clock, with one decision issued per trial per member state, Andrzej Rys, Director of Health Systems and Products, European Commission (EC) added. Additional time which could be added to the 60-day authorization period include substantial amendments to the clinical trial application (CTA) which adds 49- 95 days for member states to respond, while the addition of extra member states allows 52- 83 days to respond, Sykes added.

If the member states concerned ask questions during the second validation period, sponsors have 12 days to respond, Skyes noted, adding late or no response could mean the application is forfeited. It is therefore vital to set strong communication levels with affiliates - such as CROs - in order to respond quickly, Elena Bolanos, director, European clinical operations, Eli Lilly (NYSE:LLY) noted.

A certain level of trust in the CRO partner to provide necessary information to meet the 12-day deadline is crucial, a pharma executive said. Although specific requirements will be written into the contract, sponsors would likely prefer to work with a small number of preferred CROs, and strategic partners with a track record and history of past success, he said.

Another reason drug developers will work more closely with CROs is setting up cross-functional teams between regulatory, clinical operations, medical affairs, manufacturing and quality with the internal and external teams, Bolanos noted.

Lessons learned from current EU Heads of Medicines Agency (HMA) guidance for the Voluntary Harmonisation Procedure (VHP) -- CTFG/VHP/2013--submission route also shows a need for closer relationships with partners such as CROs to improve understanding, Surendra Gokhale, head of clinical trial regulatory management, F. Hoffmannn La Roche noted.

VHP has been running through the HMA clinical trials facilitation group (CTFG) since 2004 and is the forerunner for the new EU clinical trial legislation, giving sponsors the option of registering for CTA in all member states simultaneously, Gokhale said. More than 380 VHPs have been submitted in the last four to five years, over 300 of which had substantial amendments and 95% of which had complete agreement between member states, he said. Only the German, Spanish and Portuguese authorities are currently working with the guidance, he said.

There was lack of understanding within CROs about VHP activity, so training and awareness is crucial for the new CTA process, he noted.

Unlike the VHP process, companies will need to have all information for both part one and two of the authorisation process when they file, Bolanos added. Significant changes to the submission or addition of member states will add considerable time to the approval process, so a full and complete plan with all players involved in the clinical trial is key, she said.

EU CTA Implementation

A European Parliament plenary session will take place on 3 April 2014, where parliament is expected to agree upon the EU clinical trial document and its wording, Sykes said. Publication in the EU journal is expected around May or June, after which the legislation will be implemented, Andrzej Rys, Director of Health Systems and Products, European Commission (EC), noted in the DIA Regulatory Town Hall meeting.

Sponsors and regulators will then have a two-year period before the legislation is enforced, he said.

It is not yet known exactly when the legislation will be implemented due to unknown timing on publication in the journal, though the pharma executive noted an "educated guess" would be 1 July 2014.

A second source familiar with the situation noted publication in the journal in June would be a more reasonable expectation than May as it takes a couple of months to translate the text.

by Natalie Morrison in Vienna

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