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CLINICAL TRIALS IMPLEMENTATION MONITOR Q2/2015

This continuous survey (The Clinical Trials Implementation Monitor (or "CTiMonitor") aims to build knowledge on how the implementation of the Clinical Trials Regulation (CTR), (EU) No. 536/2014 is progressing in different European countries. This information is of interest to various stakeholders including Pharmaceutical Industry Regulators, the Commission and national Ministries.
Surveys are sent to the EFPIA National Trade Associations (NTAs) Regulatory Network. This, the third survey, covers the Q2/2015 period. Results have already been collected for Q4/2014 and Q1/2015. The survey will be repeated quarterly until mid-2016.

Responses

The results consist of responses from 20 countries: Austria, Belgium, Croatia, Denmark, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Lithuania, Norway, Poland, Portugal, Slovenia, Spain, Sweden, The Netherlands and the United Kingdom.

The Q2/2015 survey contains a response from one new country: Greece

The survey has not been scientifically validated and aims only to give some indication of emerging trends within the issues of interest. As all countries have not yet responded, it is important to keep in mind that the situation in these countries could be different. The aim will be to reach out to these countries in future surveys for a more complete analysis.

Key messages based on responses so far:

- **While all national trade associations are currently implementing activities with national stakeholders there is only a small increase in planned activities. Most of the countries are building on already existing strategies.**
- **75% of national assessment timelines will be in accordance with the CTR. Only 15% of respondents are still unsure of timelines. 10% predict they will be shorter.**
- **Many respondents are unsure about future workload & fees. Comments suggest that discussions are ongoing around national implementation and working procedures.**
- **For the majority of respondents, national assessment responsibilities for NCAs and ECs have either been established or discussions are ongoing.**

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Member State Activity and Progress

95% of the respondents state that their Member State has initiated activities to prepare for the implementation of the Clinical Trials Regulation (Figure 1)

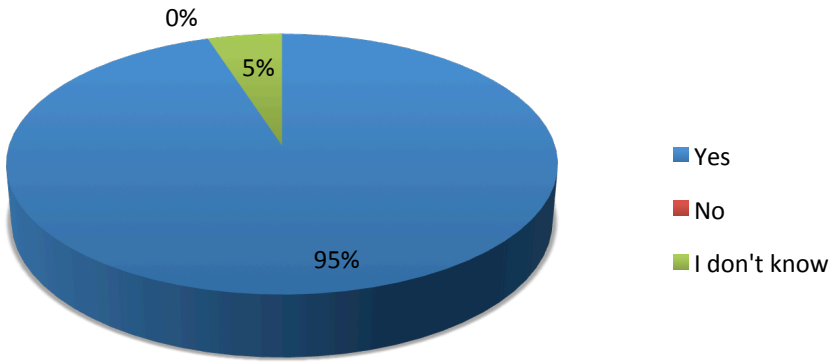

Figure 1. Has your member state (e.g. competent authority, Ethics Committee, Ministry) initiated any activities for the implementation of the clinical Trials Regulation? (n=)

There are a lot of new and continuing developments involved in preparation for the implementation of the Clinical Trials Regulation. Most countries are continuing their previously established efforts.

However, below is also a list of countries that have indicated new activities:

Belgium	*Dialogue has been initiated and is actively ongoing between the Ministry of Health, the competent authorities (Federal Agency of Medicines) and the ethics committees but also with other stakeholders such as the pharmaceutical industry (pharma.be) in order to implement the new regulation on CT (incl. adaptation of the current legislation).*
Denmark	*In addition to the latest answer provided The Ministry of Health is hosting a second public meeting to inform about the process and status of national implementation of CTR (21st September 2015). A draft proposal for adapting national legislation following CTR is expected to be open for public consultation Q3 (start Q4) 2015.*
Greece	*As mentioned before a working group has been initiated by HA, National Drug Organization.*
Norway	*Both the competent authority and the ethics committee are working on how to smoothly implement the regulation.*
Spain	*Different meetings with 20 EC and industry. The new royal decree on CT will be published in the coming months.*

Timelines

The following countries have provided information in regards to planned assessment timelines (n=20):

- **Assessment timelines according to the Clinical Trials Regulation:** Austria, Croatia, Denmark, Finland, Germany, Greece, Hungary, Ireland, Italy, Lithuania, Norway, Portugal, Slovenia, Spain, The Netherlands
- **Assessment timelines shorter than according to the Clinical Trials Regulation:** Belgium, UK
- **Assessment timelines longer than according to the Clinical Trials Regulation:** No respondent countries
- **Unsure at this point in time:** France, Poland, Sweden

Fees and Administrative Burden

43% of respondents **cannot yet estimate a change in workload** following implementation of the Clinical Trials Regulation. Another **43%** of respondents estimate an **increase in workload**. **(n=14)**

64% of respondents **cannot yet estimate a change in clinical trial application fees** following implementation of the Clinical Trials Regulation. **14%** expect an **increase**, **14%** expect **no change**, and the remaining **7%** expect a **decrease**. **(n=14)**

Additional comments have suggested that the **fees and future working procedures** are **currently under discussion** in a **number of countries**. **(n=14)**

Assessment and Ethics Committees

Number of Ethics Committees in respondent countries ranged from **1 to 140** per country. **(n=20)**

85% of respondents reported that the **Competent Authority** and **Ethics Committees** in their country are **collaborating** in order to **plan their national assessment procedures**. This is a **similar result** to that obtained in the **Q1/2015 survey**. **(n=20)**

30% of respondents stated that the **assessment responsibilities** for the **Competent Authority** and **Ethics Committees have not** yet been defined. **55%** reported that they **have** been defined. This is a **similar result** to that obtained in the **Q1/2015 survey**. Of those that stated that responsibilities had **not** been defined, **a good number stated that they were currently under discussion**. **(n=20)**

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EU Portal / EU Database

25% of respondents state that there are **no discussions taking place** in their country regarding how any **national databases will fit the EU Portal/Database**. **50%** state that discussions **are** taking place. These are **similar percentages** to the **Q1/2015 survey**. **(n=20)**

Some examples from countries are shown below:

Belgium: *Discussions are ongoing around the development of an adequate IT support system for the process, and its link to the EU portal and database. Potential integration of existing IT systems is foreseen.*
Croatia: *A national portal is being developed. It will be ready for integration.*
Denmark: *Lif DK has engaged with national stakeholders hosting national databases to discuss how to coordinate with the EU CTR.*
France: *Discussions in France are more around portal access – more information on access rights (EC vs. NCA) would be useful.*
Hungary: *Discussions have been initiated.*
Portugal: *The new national law on clinical research states the creation of a portal (RNEC) for the submission of all requests for clinical studies. Not yet operational.*
UK: *Initial discussions between MHRA and HRA have taken place. Once the EMA specifications have been finalised, more detailed discussions will begin.*

Safety Reporting

20% of the countries who responded to the detailed safety monitoring questions **(n=20)** state that their requirements differ from the EU requirements. Those countries included DE, FI, NL, NO. Since information from five additional countries was received for this survey round Q2-2015, we could see decrease in the percentage of countries who indicate any differentiating requirements to the EU standards. There are differences between the countries on the reporting requirements on SUSARs and line listings and whether blinded/unblinded/both are accepted when sent either to National Competent Authorities, Ethics Committees or Investigators. Further information on detailed safety reporting requirements would be needed to form a full picture, as now n=14 responses have been received.

FOR MORE INFORMATION:

This summary is based on the details gathered through the EFPIA Clinical Trials Implementation Monitor Survey.

For more information and feedback, please contact Sini Eskola at sini.eskola@efpia.eu