http://efpia.eu/mediaroom/167/43/EFPIA-launches-clinical-trial-data-portal-gateway

EFPIA launches clinical trial data portal gateway

(Brussels – 20 May 2014): EFPIA has launched a new gateway to clinical trials data. The new facility includes a published list of member companies' online portals aimed at advancing responsible clinical trial data sharing.

The publication coincides with International Clinical Trials Day, which celebrates the day of the first-ever clinical trial, by James Lind on the 20th of May 1747.

A promise to develop these portals was established as part of joint EFPIA-PhRMA commitments on clinical trials data transparency, which came into full force on 1st January 2014.

EFPIA and PhRMA member companies have made great strides towards meeting these commitments, establishing diverse partnerships and various portals designed to enhance clinical trials data sharing in a responsible manner. A full list of these initiatives is available on the EFPIA website.

Richard Bergström, Director General EFPIA, stated: "I am pleased to see the progress our member companies are making implementing the EFPIA-PhRMA Principles. These commitments to data sharing serve as a common baseline across the industry that our companies can agree to, and will provide new avenues for the scientific community and patients to benefit from clinical research, while maintaining patient privacy, the integrity of national regulators, and investments in biomedical research."

The EFPIA-PhRMA Principles include:

• Patient-level clinical trial data, study-level clinical trial data, full clinical study reports, and protocols from clinical trials in patients for medicines approved in the United States and EU beginning this year will be shared with qualified scientific and medical researchers upon request and subject to terms necessary to protect patient privacy and confidential commercial information. Researchers who obtain such clinical trial data will be expected to publish their findings.

• Companies will work with regulators toward a mechanism to provide factual summaries of clinical trial results to patients who participate in clinical trials.

• The synopses of clinical study reports for clinical trials in patients submitted to the Food and Drug Administration, European Medicines Agency, or national authorities of EU member states will be made publicly available upon the approval of a new medicine or new indication.

• Biopharmaceutical companies also reaffirm their commitment to publish clinical trial results regardless of the outcome of the trials. At a minimum, results from all phase 3 clinical trials and clinical trial results of significant medical importance should be submitted for publication.

EFPIA Member Companies & Clinical Trials Data:

Abbvie
Amgen
Bayer
Biogen Idec
Boehringer
BMS
GSK
Johnson & Johnson
Lilly
Merck & Co (MSD)
Merck
Novartis
Novo Nordisk

Pfizer
Sanofi
Shire
Roche
UCB
Celgene

http://transparency.efpia.eu/clinical-trials/clinical-trials-2

Clinical Trials

A clinical trial is a research study conducted in human participants to evaluate the safety and efficacy of a medicine expected to improve patients health.

Clinical trials can only be started after a compound has survived rigorous pre-clinical development work, which involves laboratory testing (chemical/biological/pharmacological/toxicological). It is only when these tests show favourable and promising results that a company can proceed to assess the medicine in humans. Clinical trials are the link between the results of pre-clinical testing and actual medical practice. They allow researchers to demonstrate the efficacy and safety of a new medicine or treatment, which is a prerequisite for marketing authorization. Without clinical trials a medicine could not be made available for treating patients. It is only through clinical trials that progress will be made on new medicines and improved treatment for diseases.

Clinical Trials represent on average 58.6% of a product total development costs. The current Clinical Trials Directive 2001/20/EC introduced a first level of harmonisation among Member States' procedures for Clinical Trials Approval. It carried provisions notably on protection of health and safety of clinical trials' participants, which represent value for the Community. However, a substantial lack of homogeneity subsists in terms of administrative requirements, which leads to delaying the conduct of clinical trials and increased costs. Clinical trials are an essential part of the medical research as they aim at providing the community with the latest innovative treatments and state-of-the-art clinical practice while fuelling innovative thinking in the clinical scientists' teams for the benefit of European Patients.

EFPIA welcomes the Commission's proposal for revised clinical trial legislation in the interest of maintaining the EU's competitiveness in clinical research. EFPIA acknowledges that the Commission has tried to address concerns and proposals from all stakeholders.

The EFPIA and PhRMA Joint Commitment to Responsible Clinical Trial Data Sharing is available here.

Here are our position papers -- updated information will be available in the future:

Clinical trial standards in developing and emerging countries in the context of the proposed EU Regulation on clinical trials on medicinal products for human use - 30 October 2012

Transparency on Clinical Trial results:

The pharmaceutical industry recognizes that there are important benefits associated with making clinical trial results widely available to healthcare practitioners, patients, and citizens, and actively supports their publication. The posting of clinical trials on public registers serves an important function for patients and their health care providers to learn about and gain access to relevant clinical trials of experimental treatments or preventative agents and authorized medicines.

Joint Position on the Publication of Clinical Trial Results in the Scientific Literature - 10 June 2010

Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases (1) - Updated 10 November 2009

For more information on what clinical trial data is and what is publicly available today please see this presentation:

Clinical Trial Transparency – What is available? - 29 January 2013

For more information on where to find clinical trial results, please see: http://clinicaltrials.ifpma.org/clinicaltrials/no_cache/en/myportal/index.htm & http://www.clinicaltrials.gov

EU institutional calendar on the issue of Clinical Trials - Please find here an overview:

Commission proposal: COM(2012)369

Title: Proposal for a Regulation of the European Parliament and of the Council on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC

Procedure: Ordinary legislative procedure (ex-codecision)

Links to EFPIA Members Associations website pages on Clinical Trials

Austria -Fachverband der Chemischen Industrie Österreichs (FCIO):

Belgium - Association Générale de l'Industrie du Médicament (AGIM-pharma.be) : http://www.theinitiative.be/

Denmark - Laegemiddelindustriforeningen The Danish Association of the Pharmaceutical Industry (LIF)/ http://www.lifdk.dk/sw16983.asp

Finland - Lääketeollisuus ry / Pharma Industry Finland (PIF) http://www.pif.fi/frontpage/pharmaceutical_industry/pharmaceutical_research

France - Les Entreprises du Médicament (LEEM): http://www.leem.org/les-essais-cliniques-0

Germany - Verband Forschender Arzneimittelhersteller (VfA): http://www.vfa.de/en/search?search=clinical+trials&searchbutton=search

Greece - Hellenic Association of Pharmaceutical Companies (SfEE): http://www.sfee.gr/en/clinical-trials

Ireland - Irish Pharmaceutical Healthcare Association (IPHA): http://www.ipha.ie/alist/clinical-trials-in-ireland.aspx

Italy - Associazione delle imprese del farmaco (Farmindustria):

Netherlands - Vereniging Innovatieve Geneesmiddelen Nederland (Nefarma): http://www.nefarma.nl/english/search-results

Norway - Legemiddelindustriforeningen / Norwegian Association of Pharmaceutical Manufacturers (LMI): http://www.lmi.no/soek?query=clinical+trials

Poland - Employers Union of Innovative Pharmaceutical Companies (Infarma): http://infarma.pl/fileadmin/badania_kliniczne_raport/Clinical%20trials%20in%20Poland%202010.pdf and http://www.infarma.pl/uploads/media/Rules_for_conducting_clinical_trials.pdf

Portugal - Associação Portuguesa da Indústria Farmacêutica (Apifarma): http://www.apifarma.pt/Pesquisa/Paginas/resultados.aspx?k=clinical%20trials

Russia - Association of International Pharmaceutical Manufacturers (AIPM):

Spain - Asociación Nacional Empresarial de la Industria Farmacéutica (Farmaindustria): http://www.farmaindustria.es/Farma_Public_ING/Buscar/index.htm?cadenaBuscar=clinical+trials&x=0&y=0

Sweden - Läkemedelsindustriföreningen / The Swedish Association of the Pharmaceutical Industry (LIF/Sweden): http://www.lif.se/default.aspx?Criteria=clinical%20trials&id=42985#
Switzerland: scienceindustries:
Turkey - Turkey Arastirmaci Ilac Firmalari Dernegi (AIFD): http://www.aifd.org.tr/en/arama-sonuclari.aspx?prm=Clinical%20trials

United Kingdom - The Association of the British Pharmaceutical Industry (ABPI): http://www.abpi.org.uk/our-work/mandi/Pages/clinical-research.aspx

Dear Clinical Trial Disclosure Community,

The European Ombudsman has posted on their website EMA's Redaction Principles - Draft. The document is dated 5 May 2014.

In response to an enquiry, EMA stated that a Sponsor can use and upload a summary attachment of results from ClinicalTrials.gov into EudraCT as long as the modality/timing of posting are appropriate as listed in Modalities and Timing of Posting. This capability will facilitate cross-registry congruence.

Citeline published a white paper on Reporting Bias in Clinical Trials: What's the current status? Doro Shin, a Citeline analyst, presented the findings of her analysis 10 September at the Pharma CI USA Conference in Parsippany, NJ. The analysis focused on approximately 7,500 Phase II/III industry-sponsored trials with primary completion dates between 2008 and 2012 to determine how many of these trials provided results in peer-reviewed sources or at ClinicalTrials.gov. Shin's presentation also focused on the disclosure rates among the top 20 pharma companies, which ranged from 55-98% when all sources were considered.

TransCelerate BioPharma Inc. Releases Recommended Approach for Protecting Personal Data in Clinical Study Reports

Publish Date: Sep 3, 2014

EmailPrintShare on facebook Share on twitter Share on linkedin

SaveLicense

TransCelerate BioPharma Inc. ("TransCelerate") today announced that it has developed a recommended approach for protecting personal data in Clinical Study Reports (CSRs) that are shared with researchers, patients and others. The document describes an approach to apply when redacting or removing personal information from CSRs and other related clinical trial documents, and is available here.

The goal of the TransCelerate CSR Redaction approach is to provide organizations that share CSRs with a consistent way of protecting personal data that is contained in these documents. Information in CSRs will be removed or redacted in order to protect the privacy of patients and those associated with a clinical trial.

"Through the implementation of this approach and additional forthcoming work from this team, TransCelerate will aid in simplifying and operationalizing enhanced transparency, while safeguarding the privacy of individuals involved in clinical trials," said Dalvir Gill, PhD, Chief Executive Officer of TransCelerate. "By developing and providing a consistent approach, TransCelerate continues to drive efficiencies that will help ensure industry resources are focused on improving the health of people around the world."

The approach provides practical details to help implement the July 2013 commitment by the Pharmaceutical Research and Manufacturers of America (PhRMA) and the European Federation of Pharmaceutical Industries and Associations (EFPIA) member companies titled, "Principles for Responsible Clinical Trial Data Sharing."

"Increasing transparency of clinical trial information by making clinical study reports more widely available is a goal we all share. This must be done in ways that protect the privacy of those involved, and the adoption of a consistent approach is an important step forward," said Andrew Freeman, Director and Head of Medical Policy at GlaxoSmithKline, and TransCelerate Clinical Data Transparency initiative co-lead.

TransCelerate announced 2 September that it has developed a recommended approach for protecting personal data in Clinical Study Reports (CSRs) that are shared with researchers, patients and others. The document describes an approach to apply when redacting or removing personal information from CSRs and other related clinical trial documents.

The approach provides practical details to help implement the July 2013 commitment by PhRMA/EFPIA Principles for Responsible Clinical Trial Data Sharing.

The UK's NHS Health Research Authority (HRA) announced that they have developed draft guidance on how and what information should be supplied to participants (including children and their parents/carers) at the end of a study: Information for participants at the end of a study: Guidance for Researchers**.** It is aimed at those undertaking clinical trials and other interventional or diagnostic studies. "We welcome comments on these proposals from individual patients, researchers and research staff as well as from partners and stakeholders. Please email Amanda.hunn@nhs.net for further information or to submit your comments."

INTRODUCTION

For any submissions filed as of January 1, 20142, following approval in the US and EU, biopharmaceutical companies will make publicly available, at a minimum the synopses of clinical study reports (CSRs) for clinical trials submitted to regulatory authorities in the US, EU, and to national competent authorities of EU Member States.

- Companies will evaluate requests for full CSRs by researchers / investigators as they do for requests for access to patient-level data, study-level data and protocols for legitimate uses.

These data sharing principles also have applicability in major markets other than the US and EU at the discretion of individual companies.

While companies' approaches to providing CSRs align with these principles, individual companies may differ in: the scope of CSRs provided; when reports are provided; and other

aspects. For example some companies will publicly disclose full CSRs while others will publicly disclose CSR synopses and provide full CSRs to other researchers according to specific criteria. Companies will make this information available, but will comply with the need to protect privacy of individuals, groups and staff associated with a clinical study.

PhRMA, EFPIA Principles for responsible clinical trial data sharing. July 18, 2013 http://www.phrma.org/sites/default/files/pdf/PhRMAPrinciplesForResponsibleClinicalTrialDataSharing.pdf

EFPIA Press Release.: http://efpia.eu/mediaroom/132/43/Joint-EFPIA-PhRMA-Principles-for-Responsible-Clinical-Trial-Data- Sharing-Become-Effective

© 2014 TransCelerate BioPharma Inc. All rights reserved.

RECOMMENDED APPROACH: CSR REDACTION OF PRIVACY INFORMATION

The protection of Commercial Confidential Information (CCI) is a matter for individual companies, and further discussions and considerations are needed on this topic. In contrast, privacy considerations are not company specific and, because the global privacy landscape is diverse, they can be region or country specific. TransCelerate establishes a general approach that can be applied across most CSRs globally, however, adjustments need to be made for local national privacy laws and regulations.

Privacy Considerations and Scope

The TransCelerate members have agreed that privacy concerns are paramount in the context of public disclosure of CSRs. Due consideration has been given to protect the privacy of individuals and groups associated with a clinical study: patients / subjects (also referred to as research participants); investigators, site staff, research institutions and staff; vendor/co-development partner companies and their staff; and sponsor company staff.

Accordingly, the following privacy considerations are being applied to the sharing of CSRs:

- The standard approach seeks to protect privacy regardless of the audience.
- The extent to which the content of a CSR is disclosed is at the discretion of an individual company and may differ for current and legacy CSRs. If content is disclosed, then the agreed standards apply to all sections disclosed. This is an evolving approach.
- Case-by-case assessments may be required by individual companies to determine the appropriateness of disclosing a particular CSR in special circumstances (e.g., rare diseases, small populations), where any disclosure may jeopardize privacy. Additionally, for individual patient cases where normal redaction approaches would have a higher risk of re-identification, these would also require case-by-case assessment (e.g. survival data in a small subset of patients, a single subject with complete response).
- Aggregated data or descriptions of aggregated data and study level information (e.g. public register IDs, tabular, graphic, or cross-patient data) will rarely raise privacy concerns and can be retained. An exception might be aggregate categories with a single subject and a reasonable likelihood of being re-identified .

Anonymized datasets and CCI are out of scope for the standard approach described in this consensus document.

© 2014 TransCelerate BioPharma Inc. All rights reserved.

General Approach

In keeping with the principles of protecting privacy, all personally identifiable information (PII) within a CSR is de-identified by removal (i.e., certain sections of the CSR are removed) or redaction (i.e., specific content is masked irreversibly from view, for example with a black bar) prior to CSR disclosure. An attempt should be made to explain why information has been removed. Appropriate explanatory text should be provided in a manner and location selected by the sponsor (see Appendix 1 for examples).

The assessment of what information to remove or redact has been based upon the determination of the potential risk of jeopardizing personal privacy by disclosing the information. Consideration was also given to direct and indirect personal identifiers suggested by the Health Insurance Portability and Accountability Act (HIPAA3) and EU data protection regulations No. 45/20014 and Data Protection Directive 95/46/EC5, which define personal data broadly to encompass any information relating to an identified or identifiable natural person. Also considered were the minimum standard for de-identifying data as described in Hrynaszkiewicz6. Sections of CSRs that contain many identifiers, such as investigator curriculum vitae (CVs) / biographies, present a high risk to personal identification and these sections are removed in their entirety. For information within sections of a CSR that present a lower risk to privacy, such as a signature, these are redacted as individual pieces of information.

What is Removed and Redacted

Details of the approach for individual CSR sections and associated information are described below :

- Appendix 2: **Summary of What is Removed and Redacted** - By category: patient / subject; investigator, research institution and their staff; vendor / co-development partner company and staff; sponsor company staff; and study level
- Appendix 3: **Summary of Approach - By clinical study report section** an illustrative implementation aid, which will need to be refined according to individual company CSR practices

ClinicalTrials.gov released a new version of the Protocol Registration and Results System (PRS) Test site (https://prstest.nlm.nih.gov) on August 28, 2014. These updates are planned to be implemented in the PRS on September 17, 2014. The first thing you may notice is the new name, which better reflects the dual functions it serves. The updates are user interface improvements primarily focused on the process for entering and submitting data for a single record. We've also made new Help resources available. The updates do not involve changes to data elements, but data elements were re-ordered to match the new PRS workflow and new versions of the data element definitions documents will be made available. Use the What's New link on the Main Menu for a complete description of all the changes.

ClinicalTrials.gov encourages you to test the updates and to submit feedback on any issues encountered to register@clinicaltrials.gov. You can also use this email if you need assistance gaining access to the PRS Test System.

2) Kinapse has kindly provided a guidance document with screenshots for "Registration of European Economic Area (EEA) or Third Country Trials on EudraCT". This is the process that needs to be followed in case the study results needs to be posted per EU requirements but the trial has not been registered and does not have the EudraCT number. This guidance document has been posted in the EudraCT folder in the File Library.

UCB has become the latest in a line of pharma firms to sign up to a website which allows researchers to access some of the data from manufacturers' clinical trials. Bayer, Boehringer

Ingelheim, GSK, Lilly, Novartis, Roche, Sanofi, Takeda and ViiV Healthcare have already signed up to Clinicalstudydatarequest.com but UCB says it is the "first midcap biopharma company" to do so, according to an August 1st press release. The site allows researchers to request access to anonymised patient level data and supporting documents from clinical studies - but their proposals are reviewed by an independent panel which decides whether permission should be granted. UCB will accept requests relating to all clinical studies that were considered 'pivotal studies' for purposes of regulatory approval of the core UCB medicines. Requests for access to additional clinical study data will be considered on a case-by-case basis, the company concludes in a statement.

The European Medicines Agency announced 1 August the launch of the EudraCT result training environment. "The application is aimed at representatives of sponsors and sponsor-investigators who want to familiarise themselves and get a better understanding in the preparation and posting of trials results in EudraCT. Please log in **here**".

IFPMA made an announcement 1 July that the IFPMA Clinical Trials Portal discontinued, visitors will be re-directed to the WHO International Clinical Trials Registry Platform:

….IFPMA has taken the decision to discontinue the IFPMA Clinical Trials Portal. To ensure that the IFPMA Clinical Trials Portal visitors and registered users continue to have access to quality, comprehensive, and publicly-accessible clinical trials information, IFPMA will direct queries to the World Health Organization (WHO) International Clinical Trials Registry Platform (ICTRP)…….The IFPMA Clinical Trials Portal was set up as a web crawler and designed to aggregate data from three existing registries, i.e. clinicaltrials.gov, Japan Pharmaceutical Information Center, Current Controlled Trials, and IFPMA member companies' corporate websites. All of this information is captured by the WHO ICTRP sources. Thus, by closing the IFPMA Clinical Trials Portal, no clinical data will be lost and current users will benefit from access to more comprehensive clinical trials information….

Noémi Manent (European Medicines Agency) provided further clarification concerning their May 7th announcement on EudraCT v10 and 'Day 0' when results reporting in EudraCT v9 will become mandatory:

*There will be another **release** in relation to the provision of results by the sponsor as per the requirements of the guidance on results. This is expected for **mid-2014**. Shortly, we [EMA] will inform the community on the anticipated Day 0 for the final date of programming of the EudraCT database which will make the posting of results for clinical trial mandatory.*

*For the **mapping** EudraCT/EMA result information, we are still working with the NIH [ClinicalTrials.gov] to finalise the document. We cannot yet anticipate the date of publication of this document but hope that it will be in June/July.*

EMA made the following announcement on 7 May*:

*The Agency is pleased to inform you that **EudraCT version 10.0 went live yesterday** [6 May]. Also, there was an **update to EU-CTR version 2.1**. In the scope of this release are:*

- Automatic assignment of results users based on CTA information

- View results in EudraCT Secure

- Search for Art 45 trials in EU-CTR

- Upload of Art 46 trials to EudraCT Public

- Substance information is collected through the SMS service

Thank you for your comments. Below is the link to the Commission Q&A they issued on 2 April:

Q&A: New rules for clinical trials conducted in the EU. Normal 0 false false false EN-US X-NONE X-NONE

I also attached it in a Word document in case the link doesn't come through.

"The Council today [14 April] approved a draft regulation aimed at facilitating and speeding up the authorisation procedure of clinical trials, following the first-reading agreement reached with the European Parliament in December (PE-CONS 2/14 + 8245/14 ADD 1).

This means that the regulation is now adopted. It will enter into force 20 days following its publication in the Official Journal of the European Union and apply six months after a EU portal for the submission of data on clinical trials and a EU database identifying each clinical trial have become fully functional (but not earlier than two years after the regulation's publication)."

ABPI has recently updated their Code of Practice. "Clinical Trials and Non-Interventional Studies of Marketed Medicines" is found on page 19 where it is stated "13.1 Companies must disclose details of clinical trials in accordance with the Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases and the Joint Position on the Publication of Clinical Trial Results in the Scientific Literature."