VIRTUAL EVENT

Clinical Data Disclosure, Transparency And Plain Language Summaries

May 10 - 12, 2021
VIRTUAL EVENT,
Delivered in EDT and BST Time Zone

THE GLOBAL CLINICAL DATA TRANSPARENCY LANDSCAPE IS EVOLVING. DON'T GET LEFT BEHIND.

Meet the Regulatory Deadlines. Master Data Sharing. Maintain Patient Privacy

FOR SPEAKING OPPORTUNITIES CONTACT
Louisa Maitland
Email: louisa.maitland@informa.com

FOR SPONSORSHIP AND EXHIBITION OPPORTUNITIES CONTACT
John Egan
Email: johne@informaconnectls.com

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Times- Eastern Time/BST

GLOBAL CLINICAL TRANSPARENCY REGULATIONS

08:00/13:00 **Getting closer to the EU CT Regulation implementation, some things to consider for the implementation**

- What is the functionality of CTIS for Sponsors and Regulators?
- Understanding the biggest issue that all of the data submitted will be made public – what issues will this bring? Will they need to disclose everything? What implications will this have?
- How will people, manage the changes? Hear from other organisations and how are they managing this?
- Are small and Mid- sized Pharma ready for the changes? Of not how to ready yourself?
- Hear from sponsor companies what they are doing and what organisational changes they have made to become ready?
- The implications of the major regulation asking for plain language to be submitted
- What are the operational changes? What will the new system look like?
- What will be the Implication of the implementation of the CTIS
- Process change? What doing to proactively make better?
- Who will be responsible to put this data on the CTIS and who will control the updates?
- Leading discussion internally what is going to be publicly available? What will be published? And what does it mean for the company? How to write these documents?
- Some Personal data will be included - Some commercial information – when and how to redact it?

Merete Joergensen, Senior Director, Clinical Transparency, **Novo Nordisk,** *Denmark*

08:20/13:20 **How and why clinical disclosure teams need to interact with their company's patent attorneys**

Lars Taavola, Vice President, Chief Intellectual Property Counsel, **Mallinckrodt Pharmaceuticals,** *USA*

08:40/13:40 **Challenges of Writing Disclosure-Friendly Documents Up-front for Submission in the CTIS**

- The document challenge: Prepare initial document package ready for submission
  - All regulatory documents must be included at the time of application
  - All documents appropriate for public disclosure (e.g., redacted as necessary) must be included at the same time the regulatory documents are uploaded
  - We need to know upfront, the details for everything that will be required, and what information we should not include in specific documents, to avoid risk of inadvertently disclosing sensitive information
- The process challenge: Establish the mind-set conversion to "start at the beginning with the outcome in mind"
  - Take the time for strategic planning and preparation of complete, submission-ready document packages
  - Use adaptive trial designs to reduce protocol amendments
  - Revise data collection techniques to incorporate Privacy by Design
  - Prepare summary aggregate tables and clinical study reports to ensure Privacy by Default

Joyce Hauze, Associate Director, Clinical Trial Disclosure and Transparency, **Mallinckrodt Pharmaceuticals**, *USA*

09:00/14:00 **Transparency and Disclosure in Medical Devices: Current Knowledge**

The medical device industry has been underserved in the field of transparency and disclosure. This presentation will provide the current knowledge in public disclosure and data transparency requirements for medical devices in the EU. The EU Medical Device Regulation (MDR) 2017/745 released in 2017 was a game changer for the industry This was further reinforced by the updated ISO 14155:2020 Clinical investigation of medical devices for human subjects — Good clinical practice. Most of the requirements on transparency and public access to information are linked to the European database on medical devices (Eudamed) which is planned to become fully functional by May 2022. The Eudamed has 6 different modules: Actors, UDI, Certificates, Clinical Investigations, Vigilance, and Postmarket Surveillance. For each module, two interfaces are being developed - one accessible for the actors (member states, operators and notified bodies), and one for the public. An overview of each module will be discussed, including the expectations regarding publicly available information. Focus will be given to the Clinical Investigations Module, the module covering clinical trials in medical devices.

Raquel Billiones, Associate Director, Medical Writing, **Alexion Pharmaceuticals,** *Zurich Switzerland*

09:20/14:20 **How to Build a Data-Sharing Strategy for Pharma Innovation**

- While individual patient-level data sharing is largely done on a voluntary basis, the expectation that pharma companies will engage in sharing should be managed as carefully as a regulatory imperative.
- Now more than ever, the eyes of the world are on clinical trial sponsors to co-operate and collaborate (in some cases with competitors), sharing their clinical data to combat human health emergencies.
- There are a number of different considerations:
  - Where should the data be hosted?
  - Who will be able to access it?
  - What will it be used for?
- Anonymization is a requirement for voluntary data sharing, but how should the data be anonymized? How can a clinical trial sponsor get this right from the start?
  - Qualitative versus quantitative approaches
  - How to balance patient privacy and data utility
  - Should you build an in-house capability, buy software or engage a vendor?
- In this presentation we will investigate the different decisions that can be taken by a pharma company in their data-sharing journey and look at the impacts that these decisions can have on brand reputation and public trust.

Niamh McGuinness, Senior CTT Analyst, **Privacy Analytics,** *USA*

09:40/14:40 **LIVE Virtual Hub Networking**

10:20/15:20 **PANEL: Preparedness for CTIS – Are you ready?**

- Big Pharma- go on old or new regulation- how have they approached this?
- How have companies approached the voluntary stage 1?
- What process changes have had to have within a company?
- Have they had to change PLS (Plain Language Summaries) process?
- Experiences of working towards the implementation
- What are the considerations and what needs to be taken into account?
- Challenges of setting this up and learn from
- Practical implications of transparency - deferral rules and preparing for the redaction/anonymisation of the 'for publication' documents.

MODERATOR: Dr Matthias Zerm, Lead Scientific Expert, Clinical Trial Disclosure and R&D Processes, **Merz Therapeutics,** *Germany*

Merete Joergensen, Senior Director, Clinical Transparency, **Novo Nordisk,** *Denmark*

Joyce Hauze, Associate Director, Clinical Trial Disclosure and Transparency, **Mallinckrodt Pharmaceuticals**, *USA*

Lars Taavola, Vice President, Chief Intellectual Property Counsel, **Mallinckrodt Pharmaceuticals,** *USA*

Sameer Sharma, Clinical Trial Transparency, Biopharma | Global Biostatistics, Epidemiology and Medical Writing, **Merck,** *Germany*

11:00/16:00 **Make it Public: transparency and openness in health and social care research and Post- BREXIT- Overview and Clarity of Latest HRA Guidance for Disclosure and Transparency for Clinical Trials**

- What will be the impact of a no-deal Brexit on the rest of the world be?
- Where does the UK HRA stand on transparency considering BREXIT?
- How will it be working? How will drugs be reviewed?
- Will there be any delays? How different it will be?
- How will it affect the efficient of EMA operations – how long will the delays continue?
- UK- not functioning through EMA- how will the existing approaches be adapted in the UK?
- Will any data disclosure aspects change with the UK or will it adapt with what was required in the past? How different will they be?
- The need for clarity - What are the requirements? What types of study will be required? What are the timelines? Will there be a format to follow?
- What does it mean for posting results? Will they have their own registry in the UK?
- Working through the detail- published strategy document in the UK that will make PLS compulsory for all studies- no more details. What format should this be on?
- Plain Language Summaries - will it be required in UK post BREXIT?
- Lack of clarity – will there be a portal where theses summaries will be posted?
- Is the UK going to push PLS to be provided earlier? What is the UK plan on PLS?
- What are the rights of patients?

Andrew George, non-executive Board member, **Health Research Authority,** *UK*

11:20/16:20 **What's Next for T&D in a Post-BREXIT and Post-COVID world?**

- What we know
  - Where does the UK MHRA stand on transparency considering BREXIT?
  - How has transparency of clinical data been impacted by COVID-19 and the necessary global collaboration that has been required by the agencies?
- What we don't know, but can speculate:
  - What are the implications of the UK following other international agency standards and approaches?
- What is more difficult to speculate:
  - How will transparency look post Brexit and what should we plan for?
  - Will we see a new impetus for patient engagement resulting in timely data reporting and sharing, could we see novel ways that the agencies will collaborate on data sharing post Covid-19?

Nirpal Virdee, Global Head, Transparency and Disclosure, **Certara,** *UK*

11:40/16:40 **SPOTLIGHT PRESENTATION:**

Please contact John Egan: johne@informaconnectls.com +13392982205 if you are interested in participating as a speaker, panellist, moderator or hosting a webinar

12:00/17:00 **LIVE Virtual Hub Networking**

TRANSPARENCY AND DATA SHARING

12:40/17:40 **EMA Plan for Policy 70 - When with this be resumed and what will the changes be?**

- New inclusion criteria what is the plan of EMA policy?
- Companies want to know how they should be posting this information.
- Companies need guidance from the EMA?
- Data Sharing is not happening? What impact will this have?
- EMA are still urging Sponsors to publish clinical trial results
- When they reinstate the policy, what will that mean? How far will companies need to go back?
- What will the EMA do with all the submission at are in the queue - will the go back retrospectively? Huge task to go back and what will the criteria be?
- Can the Health Canada submission be used by EMA?
- What criteria be for ones in the queue?
- When will they pick up, will proceed with all the new submission? In chronological order? What's the priority?
- File for Marketing Authorisation- need to be redacted and anonymised

Alexander Roussanov, International Partner, **Arnold & Porter,** *Belgium*

13:00/16:00 **ClinicalTrials.gov Essentials; What to know and How to do**

- Updated HHS Regulations and NIH Policies for clinical trial transparency
- Benefits of posting and penalties for noncompliance
- Essential elements of Academic-based compliance Programs
- Introduction to the Clinical Trials Registration and Results Reporting Taskforce
- Tips for registering, updating and reporting results on the ClinicalTrials.gov Registry

Anthony Keyes, Director, Johns Hopkins ClinicalTrials.gov Program and co-chair of the **Clinical Trials Registration and Results Reporting Taskforce,** *USA*

13:20/16:20 **PANEL: Balancing Sharing Results and Data Whilst Protecting Participants Data Privacy**

- Challenges to be open but can't put all the information there as be able to identify the individuals
- How create trust when there is a limit to how much information to share
- Current debate with the European commission – what is the requirements?
- Further clarification on GDPR and other data privacy requirements and implication for data sharing initiatives.
- Hear from European commission with GDPR issues – European Health Data Project

MODERATOR: **Julie Holtzople,** Head of Clinical Transparency and Data Sharing, **AstraZeneca,** *USA*

Rebecca Li, Executive Director, **Vivli,** *USA*

Anthony Keyes, Director, **Johns Hopkins ClinicalTrials.gov Program and co-chair of the Clinical Trials Registration and Results Reporting Taskforce,** *USA*

Raquel Billiones, Associate Director, Medical Writing, **Alexion Pharmaceuticals,** *Zurich Switzerland*

Lora Killian, Transparency and Disclosure Lead, **Pfizer,** *USA*

Liz Roberts, Data Policy and Privacy Lead, Data Office, **UCB,** *USA*

14:00/17:00 End of Day One

Times- Eastern Time/BST

HARMONIZATION

08:00/13:00 **Global Harmonization for Clinical Trial Transparency: Progress, opportunities and challenges**

BACKGROUND: Clinical Data and documents are shared by sponsors via multiple channels to meet various global needs and regulations.

- Hear about the ongoing harmonization efforts to date
- Increased demand in transparency since the COVID-19 pandemic and what this has meant for disclosure and data sharing across the industry
  - What success stories have we seen? I.e. Same data packages published by HC and EMA
  - What challenges have we seen? I.e. Early disclosure has a risk around trial integrity and means a more conservative open publication approach may be required
- The need to ensure that information is being disclosed timely and appropriately, while abiding by current regulations
- The sponsor ecosystem that has been built to support clinical data sharing for research
- Impact on multiple stakeholders of lack of harmonization
- Hope for regulatory harmonisation and preferably one global site for document sharing, having many versions of the same documents with different anonymisation-redaction applied to them, does not built transparency and trust.
- How does a company ensure oversight to meet various global requirements

Julie Holtzople, Head of Clinical Transparency and Data Sharing, **AstraZeneca,** *USA*

DATA SHARING REQUIREMENTS

08:20/13:20 **Bioethical Standards – Update on the Good Pharma Score Card other initiatives**

- Discuss the new 2021 GPS transparency rankings which newly include small companies
- Identify challenges and best practices in transparency and data sharing
- Explore the new GPS rankings under development to address equity and inclusion in research and access to medicines

Jennifer Miller, Founder, Bioethics International and the Good Pharma Scorecard, Assistant Professor, **Yale University School of Medicine,** *USA*

08:40/13:40 **Considerations for sponsors when using a Data Sharing Platform - Vivli as a case study**

- As data sharing becomes the norm, what should a sponsor consider when deciding on how to securely share clinical data
- The benefits of a multi-sponsor platform for sponsors and for researchers
- How to ensure your data sharing policy is transparent and your process is efficient and safe

Julie Wood, Director of Strategy and Operations, **Vivli,** *USA*

09:00/14:00 **Harmonisation or Re-use of Content from other Clinical Documents of Library of Terms**

- PLS, differently written CSR how to make it as simple as possible
- Need for streamlining
- Creation of the lay summary should be easy

Laura Sheppard, Director of Medical Writing, R&D Operations, **Endo,** *USA*

09:20/14:20 **Hydrating a Data Lake to Power Innovation - Enabling Pharmaceutical Companies to Automate Data De-Identification for Secondary Use**

Over the last decade the field of clinical trial transparency has grown exponentially, with a tremendous focus on external data sharing and secondary research. But what about sharing data internally? As a sponsor's greatest asset, effort must be made to maximize clinical trial data. The industry must master the art of internal data sharing. Recent challenges encountered during the rapid development of COVID-19 vaccines have highlighted this issue.

In this session we'll cover:

- The importance of exploratory analysis on previously collected data to support future studies or potentially reveal new breakthroughs
- Obstacles you may face with compliance standards and data de-identification automation at large scale
- How you might overcome these challenges by implementing data standardization methods and template-based anonymization
- A case study review of how we were able to address these challenges and solutions in partnership with a sponsor

Kristin McDougall, Director of Transparency, **d-wise,** *USA*
Cathal Gallagher, Senior Life Sciences Consultant, **d-wise,** *USA*

09:40/14:40 **LIVE Virtual Hub Networking**

10:20/15:20 **PANEL: Harmonization- Requirements of what we Have to do? What does the Future look like Post-Brexit?**

- Main issue is the policy is not the same only about 95% the same
- What are other countries going to do? Can't do over 100 versions for redact documents- lots of money to vendor to anonymise and redacted
- Harmonisation and the future- Health Canada –
- Will UK have their own?

MODERATOR: **Amanda Hunn,** Principal, **A J Hunn Associates,** *UK*
Alexander Roussanov, International Partner, **Arnold & Porter,** *Belgium*

LEARNINGS FROM THE FUTURE OF COVID-19

11:00/16:00 **Downstream Benefits of Transparency**

The scope of trial data disclosure regulations continues to grow, with ever-increasing demands for more public clinical data availability. Organizations with generous transparency policies are finding downstream benefits beyond merely compliant disclosure. Investments in trial disclosure are paying dividends with:

- Improved global compliance
- Increased efficiencies leading to reduced costs
- Opportunities for patient engagement
- Accelerated recruitment
- Reduced friction with mergers, acquisitions, and licensing
- Enhanced visibility with industry analysts

Thomas Wicks, CSO, **Pharma Intelligence,** *USA*

11:20/16:20 **COVID-19, Public Interest in Clinical Trials, and PLS**

The COVID-19 pandemic has increased public interest in clinical trials.
A considerable amount of medical information and misinformation is found across social networks.
Plain Language Summaries, which include easy-to-grasp language and infographics, are an ideal medium to share on social media.

Lee Holland, Manager, Medical Writing, **Xogene,** *USA*

Dr Malia Jones, Social Epidemiologist, University of Wisconsin and Co-Founder and Editor-in-Chief, **Dear Pandemic,** *USA*

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12:00/17:00 **LIVE Virtual Hub Networking**

12:40/17:40 **Plain Language Summaries of Publications: A New Approach to Providing Easy to Understand Information about COVID-19 Vaccine Trials**

- What is a Plain Language Summary of a Publication?
- Who is our target audience?
- How do we ensure it is easy to understand?
- How do PLSP increase transparency and build trust with the public specifically for COVID-19 vaccine trials?
- As an industry, how can we leverage PLSP in all therapeutic areas to increase trust and transparency?

Dr Kimbra Edwards, Senior Manager, Health Communication Services,
Center for Information and Study on Clinical Research Participation (CISCRP), *USA*

Sarah Griffiths, Communications Team Leader, Patient Engagement, **Oxford PharmaGenesis Ltd,** *UK*

13:00/18:00 **CASE STUDY: Lessons learned from COVID-19 Vaccine disclosure requirements**

- Managing disclosure requirements from unanticipated requirements
- Managing multiple agencies simultaneously for large disclosure submissions (HC, EMA, PMDA)
- Accommodating non-standard accelerated timelines
- Preparing public disclosure documents for an on-going blinded trial
- Unique privacy considerations for a COVID related product

Lora Killian, Transparency and Disclosure Lead, **Pfizer,** *USA*

13:20/18:20 **PANEL: The Changing Transparency Environment in the Covid age**

- The value of disclosing COVID trial results in plain language
- Transparency and trial integrity and how two things are being balanced in the Covid era
- Pressure for rapid disclosure?
- Encouraging diversity in trial participation and the importance of patient engagement to inspire confidence
- Using transparency to inspire confidence in the public to take the covid-19 vaccine encouraging ethnic minorities and BAME groups to take the vaccine
- Ministers have noted the speed – what can you do turn out round like this al that time?
- Setting up work group – how to significantly increase the speed- Look at whole internal pathway
- Reflect on the learnings - Where does that put transparency in 5 years?
- Teams have worked on quick timelines- not missed any key process step
- Transparency aspects around Covid-19 studies
- Increased transparency has been implemented for COVID-19 Documentation; Will this be the new norm for also Non-COVID-19 related products?
- Reflect on the learnings - Where does that put transparency in 5 years?

MODERATOR: **Thomas Wicks,** CSO, **Pharma Intelligence,** *USA*

Nicholas DeVito, DPhil Candidate and Researcher at **University of Oxford,** *UK*

Scott Patton, Clinical Trials Manager, Office of Clinical Research Quality, **Stanford Medicine Research Office,** *USA*

Behtash Bahador, Associate Director, Relationship Management and Development, **Center for Information & Study on Clinical Research Participation (CISCRP),** *USA*

Sini Eskola, Director, Team Leader, Regulatory, Drug Development and Manufacturing, **EFPIA,** *Belgium*

14:00/17:00 End of Day Two

Times- Eastern Time/BST

PLAIN LANGUAGE SUMMARIES OF CLINICAL TRIAL RESULTS

08:00/13:00 **EU Clinical Trial Regulation: New Commission Recommendations on Good Lay Summary Practice (GLSP)**

Background: PLS upload onto CTIS in NEW and will be just European requirement and will start in Dec 2021 when CTIS go live

- Why a new recommendations document was needed?
- The process of developing the GLSP
- Content of the GLSP
- Status of GLSP release by EU Commission
- Preparation of GLSP roll-out by Roadmap Initiative and stakeholder training

Dr Ingrid Klingmann, Chairman, **European Forum for Good Clinical Practice (EFGCP),** *Belgium*

08:20/13:20 **Expanding the Foundations of the Good Lay Summary Practice (GLSP) Guidance: Hot Topics**

- How to present secondary endpoints in lay summaries – if at all?
- The importance of lay summaries for interim results – is there a corresponding functionality with CTIS?
- Beyond CTIS: What are potential dissemination pathways for lay summaries and their translations?

Dr Thomas Schindler, Innovation Medical Writing, **Boehringer Ingelheim Pharma GmbH & Co. KG,** *Germany*

08:40/13:40 **Considerations for Presentation of Secondary Endpoints in Plain Language Clinical Trial Result Summaries: Multi-stakeholder Perspectives for Emerging Practice**

- What are the various responses from sponsors with regards to presenting patient-relevant secondary endpoints in the Plain Language Summaries (PLS)?
- How can patient-relevant secondary endpoints be defined or determined?
- What are the considerations for selecting and including patient relevant secondary endpoints in the PLS?
- Should additional endpoints (e.g., tertiary, exploratory) be included in the PLS?
- When and how should patient input be obtained?
- What are the considerations for summarizing patient-relevant secondary endpoints in the PLS?

Caragh Murray, Plain Language Summary Program Manager, **Janssen Pharmaceutical Companies of Johnson & Johnson,** *USA*

09:00/14:00 **Plain Language Clinical Research Glossary (Either)**

- Industry recognised endorsed the definitions but also participant friendly
- Update on the pilot – 53 terms and procedures-
- Definition with common clinical terms – adverse event, protocol, etc….,
- Importance of the glossary and why common consistency is key
- Talks about ensuring some consistency that does promote transparency – overcome the definitions

Sylvia Baedorf Kassis, Program Manager, **Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard,** *USA*

09:20-14:20 **Plain Language Summaries for Pediatrics**

- Brief overview of pending EMA regulations for PLS
- Differences between adult and pediatric PLS
- What do children and young people need and want?
- Design a PLS template with children in mind
- Consider readability; how is that different from adult PLS?
- Ask children what they want: consider user testing and qualitative data

Theresa M. Shalaby, Senior Regulatory Services Manager, **Synchrogenix, a Certara company,** *USA*

09:40/14:40 **LIVE Virtual Hub Networking**

10:20/15:20 **PANEL: Considerations for Presentation of Secondary Endpoints in Plain Language Clinical Trial Result Summaries**

- Are patient-relevant secondary endpoints an important part of the PLS?
- What are patients interested in seeing with respect to patient-relevant secondary endpoints?
- For sponsors who have already selected to present patient-relevant secondary endpoints, what challenges / resolutions have they met?
- Not all sponsor (commercial and non-commercial) can obtain patient input, what are other practical alternatives?
- What references or resources could be used to help develop a robust approach?

MODERATOR: **Debra Guerreiro,** Plain Language Summary Program Lead, Data Transparency, Integrated Data Analytics and Reporting (IDAR), Global Development, **Janssen R&D,** *USA*

Maureen Mooney Kashuba, Plain Language Summary Project Lead, **Merck & Co., Inc,** *USA*

Caragh Murray, Plain Language Summary Program Manager, **The Janssen Pharmaceutical Companies of Johnson & Johnson**, *USA*

Jessica Valencia, Operational Excellence Expert, **Novartis,** *USA*

Dr Thomas Schindler, Innovation Medical Writing, **Boehringer Ingelheim Pharma GmbH & Co. KG,** *Germany*

Deborah Collyar, President, **Patient Advocates In Research (PAIR),** *USA*

11:00/15:40 **CASE STUDY: Plain Language Summaries for early phase trials at Novartis (CT)**

- Possible joint presentation with a vendor
- First peds PLS - lessons learned
- Consolidating the information provided in a PLS.

Jessica Valencia, Operational Excellence Expert, **Novartis,** *USA*

11:20/16:20 **Lessons learnt from PLS implementation (CT)**

- Sharing a vendor's experience of working with multiple sponsors
- Identifying different approaches taken by sponsors for PLSs implementation
- Identifying the best practices for success

Vidhi Vashisht, Associate Director, **Kinapse,** *India*

PLAIN LANGUAGE SUMMARIES OF PUBLICATIONS

11:40/16:40 **Disclosure of Clinical Trial Data Through Scientific Publications (Pub)**

- Deep dive into publications as the oldest means of disclosure
- Discuss areas of collaboration between publications and clinical trial transparency teams

Sonia A. Schweers, Publication Compliance Lead, WW Medical Compliance & Governance, Medical Capabilities, **Bristol Myers Squibb,** *USA*

12:00/17:00 **LIVE Virtual Hub Networking**

12:40/17:40 **Update on the PLSP- Plain Language Summaries Publication - What are PFMD doing with the guidance doc?**

- Share the views and work in progress on providing a better involvement of patients in the elaboration of PLS of publications and conference presentations
- Working Document around this – guideline – PFMD (Patient Focussed on Medical Document)
- How can you really translate a scientific article into a lay article? Who is the audience for that? Who is this intended for?
- What is the reach, and can it be improved?

Anne-Marie Hamoir, Senior Consultant, **Patient Focused Medicines Development (PFMD), the Synergist,** *Brussels*
Dr Thomas Schindler, Innovation Medical Writing, **Boehringer Ingelheim Pharma GmbH & Co. KG,** *Germany*

13:00/18:00 **Plain Language Summaries and how they Evolved from Original need to know and how they can Revolutionize Scientific Disclosures**

- Education through scientific disclosures and publications - opportunities to revolutionize approach and formats
- Origins of Plain Language Summaries (PLS) as clinical documents and regulatory requirements
- How Publications and Scientific Communications can adapt PLSs for scientific disclosures and peer-review articles
- How PLSs are paving the way for Patient Voice and patient-centric manuscripts in scientific disclosures
- Can PLSs drive a change on how we develop peer-reviewed publications?
- Compliance considerations and the need to update Publications Practices in a new era of education

Iwona Bucior, Senior Director, Medical Affairs, **Bristol Myers Squibb,** *USA*

13:20/18:20 **Update on the PLSP- Plain Language Summaries Publication - What are PFMD doing with the guidance doc?**

- Share the views and work in progress on providing a better involvement of patients in the elaboration of PLS of publications and conference presentations
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- What is the reach, and can it be improved?

Dr Thomas Schindler, Innovation Medical Writing, **Boehringer Ingelheim Pharma GmbH & Co. KG,** *Germany*

Anne-Marie Hamoir, Senior Consultant, Patient Focused Medicines Development (PFMD), **the Synergist,** *Brussels*

Dr Oladayo Oyelola, Senior Director, Clinical Trial Information Disclosure, Regulatory Management Operations, **Daiichi Sankyo, Inc.,** *USA*

14:00/17:00 End of the Conference

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