Thank you for joining ISMPP U today!

The program will begin promptly at 11:00 EDT
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TOPICS FOR TODAY’S ISMPP U

• The guideline environment and publication planning principles
• Author’s expectations and understanding of authorship
• Scientific messages across the globe
• Working with local affiliates
• Working with co-development and co-marketing companies
THE GUIDELINE ENVIRONMENT AND
PUBLICATION PLANNING PRINCIPLES
WHAT IS THE SITUATION?

• ‘Good publication practice (GPP)’ is independent of region

• Publication planning principles are independent of region (although additional considerations are required)
### Guidelines Around the Globe

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<th>Guidelines</th>
<th>Date of Issue</th>
<th>What Topics Are Covered</th>
<th>What Countries Are Covered</th>
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<td>ICMJE and other editor policies</td>
<td>Annually (2010)</td>
<td>Authorship, contributorship, publishing of negative studies, duplicate publication, clinical trial registration, etc</td>
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<tr>
<td>GPP and GPP2</td>
<td>2003 and 2009</td>
<td>Authorship, contributorship, publishing of negative studies, duplicate publication, clinical trial registration, etc</td>
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<td>Joint position statement</td>
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<td>Pharma policies</td>
<td>Various</td>
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<tr>
<td>US Public Law 110-85 (FDAAA), Title VIII, Section 801</td>
<td>2007</td>
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US PUBLIC LAW 110-85 (FDAAA), TITLE VIII, SECTION 801

• Protocol requirements
  • What?
    – Broadening of applicable trials
    – Greater level of detail regarding protocol
    – Within 21 days of FPFV

• Results requirements
  • What?
    – Trial results information supplied within 12 months of completion (LPLV) of study for US-marketed products, or within 30 days of US marketing approval (or non-approval)

Applies to any controlled clinical investigation, other than a Phase I clinical investigation, of a drug (or device) that is FDA-approved
EUDRACT: DATABASE OF ALL CLINICAL TRIALS IN EU

- Database on content, commencement and termination of all clinical trials in EU from 1 May, 2004
- Managed by the EMA and previously not accessible to the public
- Article 41 of the Paediatric Regulation (Regulation [EC] No. 1901/2006) and Article 57 of the Regulation [EC] No. 726/2004 requires trial registration and results posting to become public
WHAT INFORMATION WILL EUDRACT CONTAIN?

- **Protocol requirements**
  - **What?**
    - Protocol-related information supplied before the start of paediatric trial for all trials dating back to 2004
  - **When?**
    - Once EudraCT programming finalised (STILL moving target)
    - Latest update
      - “The release of EudraCT Version 8.0 and consequently the EU Clinical Trials Register has been delayed due to the complexities of the final data migration and testing. Once these activities have been completed successfully, a firm date for the release of EudraCT Version 8.0 and the EU Clinical Trials Register will be announced. We will inform you on the expected timeframe within one or two months from today (3 Sept 2010).”

- **Results requirements**
  - **What?**
    - Paediatric trial results information supplied within six months of completion (LPLV) of study
    - Adult trial results information supplied 12 months of completion (LPLV) of study
    - Will include ‘discussion and interpretation of study results’ by sponsor and by competent authority, if available
  - **When?**
    - Once detailed guidelines for reporting format published and programming finalised

Applies to Phase II, III and IV study (any trial in paediatric population) where ≥1 investigator is in EEA or if it is part of a PIP, irrespective of marketing authorisation
PUBLICATION PLANNING PRINCIPLES
IN GLOBAL PUBLICATION PLANNING

• More relevant conference and journal choices

BUT

• More regions to consider
WHAT CAN GO WRONG?

• Probably more of an issue for conferences rather than journals (because of the reach of the information beyond the ‘subscribed / registered’ audience)

• For example, low awareness of product data in certain regions because congress abstract / presentations have been focused in other regions
WHAT ARE THE SOLUTIONS?

• Simple, a planning process that appropriately considers all regions and relevant audiences within those regions

• Dissemination of plans (or inclusion in decision-making process) of relevant stakeholders from those regions
AUTHOR’S EXPECTATIONS AND UNDERSTANDING OF AUTHORSHIP
WHAT IS THE SITUATION?

• Generally, most authors in North America and Western Europe are aware of their requirements as authors
  
  – “... drafting the article or revising it critically for important intellectual content ...”
  
  – “All persons designated as authors should qualify for authorship, and all those who qualify should be listed”
  
  – “All contributors who do not meet the criteria for authorship should be listed in an acknowledgments section. Examples of those who might be acknowledged include ... writing assistance...”

• Not always the case globally, often because of locally ‘accepted norms’
WHAT CAN GO WRONG?

• **Examples**
  - Author does not understand he cannot have a junior colleague write the manuscript for him without acknowledging him on the article
  - Author does not realise professional writing support will be acknowledged
  - Author does not appreciate the importance of properly reviewing and commenting on the manuscript

• **Consequences**
  - Strained relationships
  - Delayed deliverables
WHAT ARE THE SOLUTIONS?

- Documentation
- Agreements up-front and in writing (when can that occur in your organisation?)
- Calmness and sensitivity
SCIENTIFIC MESSAGES ACROSS THE GLOBE
• Within a specific market, there will be standard indications, dosing schedules, formulations etc

• Across more than one market this is not necessarily the case. For example,
  
  – Dosing is once daily in one market (where most other products are twice daily), but twice daily in another
  
  – Different dose in different markets; each market wants to rationalise why the dose in that market is appropriate
  
  – Certain indications not approved in a particular market
WORKING WITH LOCAL AFFILIATES
As a global publication planner, you will often have a remit over all publications with company involvement, particularly those delivered in English language.

So how do you manage / be knowledgeable of publication activity that is as widespread as the UK, Singapore, Canada and New Zealand?
WHAT CAN GO WRONG?

Global publication team is not aware of a publication from a UK-based study until it is published.

Global publication team has an original manuscript that is rejected because most of the results have been reported in a supplement supported by the French affiliate.

Transparency issue (COI or professional medical writer non-disclosure) from a locally-initiated study is reported globally.
WHAT ARE THE SOLUTIONS?

• Process
  – Ensure processes are in place to inform the appropriate people of the activities they are responsible for

• Education / training
  – Ensure individuals involved in publications have appropriate knowledge, training and support
WORKING WITH CO-DEVELOPMENT AND CO-MARKETING COMPANIES
WHAT IS THE SITUATION?

One pharma

One agency

One plan / agency

One pharma

Another pharma
The involvement of more than one company in a publication plan raises many important questions:

- Who is responsible for the plan?
- Who is going to pay for the deliverables?
- Who is going to manage the relationship with investigators?
- Who chooses if an agency is contracted?
- Whose processes and systems will be used?
- How can the process be efficient?
WHAT CAN GO WRONG?

- The process is slow, costly, duplicitous and puts across a poor image to external individuals (eg, investigators)

- There are gaps in key activities
  - For example, nobody ensured that lead authorship was discussed in a timely manner across the author group
WHAT ARE THE SOLUTIONS?

• Up-front agreement on what needs to be clarified
• Reference to publication obligations at contractual level
• Clear roles and responsibilities and processes specific to the alliance in question
  – Dissemination of that information to those involved outside the companies
Questions & Answers

To ask a question, please type your query into the ‘Q&A’ chat box at the bottom left of your screen. Every attempt will be made to answer all questions.
Next ISMPP U

DATE: November 10

TIME: 11am EDT

TOPIC: Three R’s of CMPP Certification: Review, Results, and Recertification
Thank you for attending!

We hope you enjoyed today’s presentation.

Please take a moment to fill out the survey sent to you after today’s program so you can provide valuable feedback, as it will help us to develop future educational offerings.