

Thank you for joining ISMPP U today!

The program will begin promptly at 11:00 EDT

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PUBLICATION PLANNING ON A GLOBAL SCALE: COMPLICATIONS AND CONSIDERATIONS

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DISCLAIMER

- The opinions expressed in this presentation are those of the speakers and do not necessarily reflect the views or policies of AstraZeneca, Complete Medical Communications or ISMPP

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 background features a stylized, abstract design with overlapping geometric shapes. A large green shape is at the top left, an orange shape is in the middle, and a blue shape is at the bottom right. The shapes have a slightly textured, crystalline appearance with some internal lines and gradients.



















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

Guidelines	Date of issue	What topics are covered?	What countries are covered?
ICMJE and other editor policies	Annually (2010)	Authorship, contributorship, publishing of negative studies, duplicate publication, clinical trial registration, etc	  
GPP and GPP2	2003 and 2009	Authorship, contributorship, publishing of negative studies, duplicate publication, clinical trial registration, etc	  
Joint position statement	2005, 2006, 2008, 2010	Clinical trials registration, clinical results posting, publication of trial results in scientific literature	  
Pharma policies	Various	Various	  
US Public Law 110-85 (FDAAA), Title VIII, Section 801	2007	Clinical trials registration, clinical results posting	  
EU (Article 41 of EC No. 901/2006 and Article 57 of EC No. 726/2004)	2008 and 2009	Paediatric clinical trials registration and results posting ((Article 41 of EC No. 901/2006) Clinical trials registration and result posting (Article 57 of EC No. 726/2004)	  

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?

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

- 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

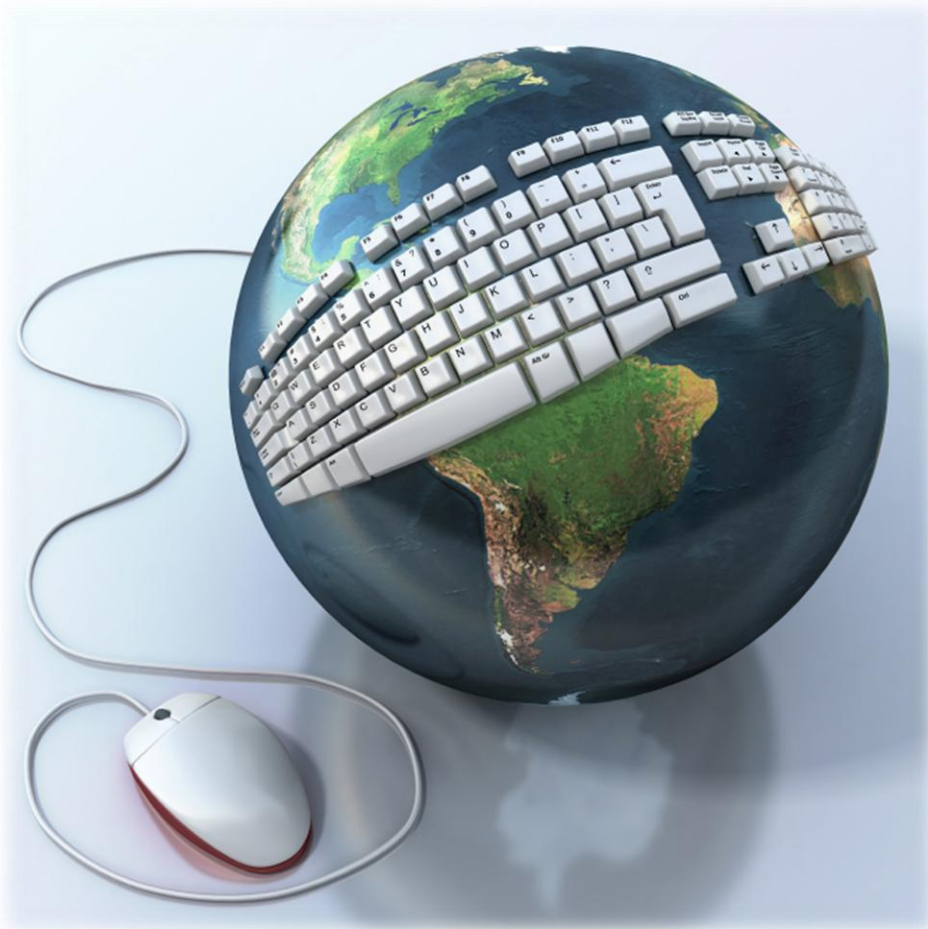
- What?

- 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

PUBLICATION PLANNING PRINCIPLES IN GLOBAL PUBLICATION PLANNING



- More relevant conference and journal choices

BUT

- More regions to consider

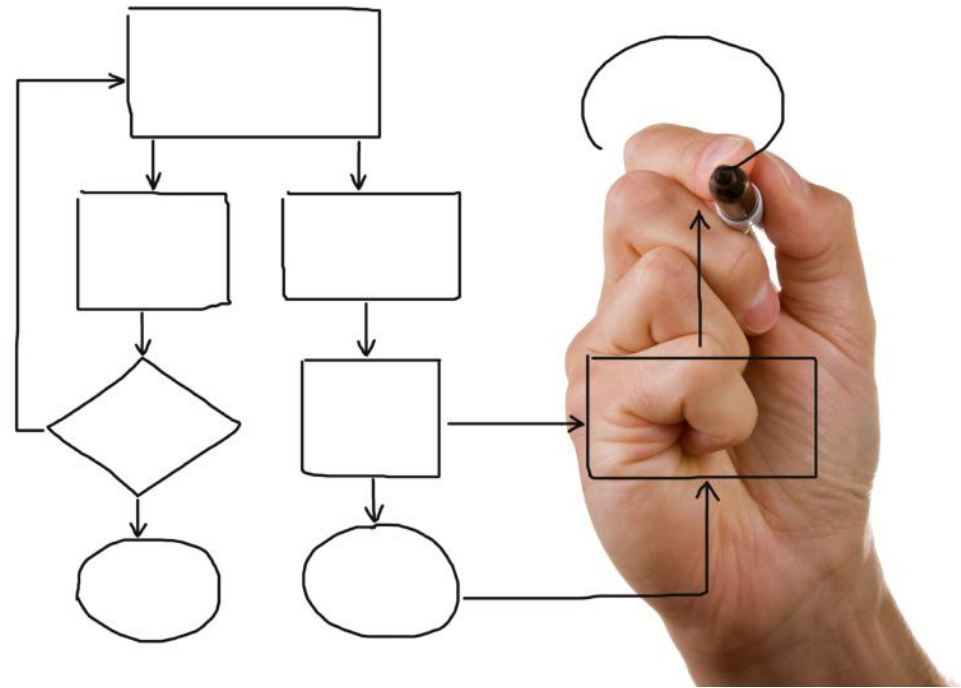
WHAT CAN GO WRONG?

- 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

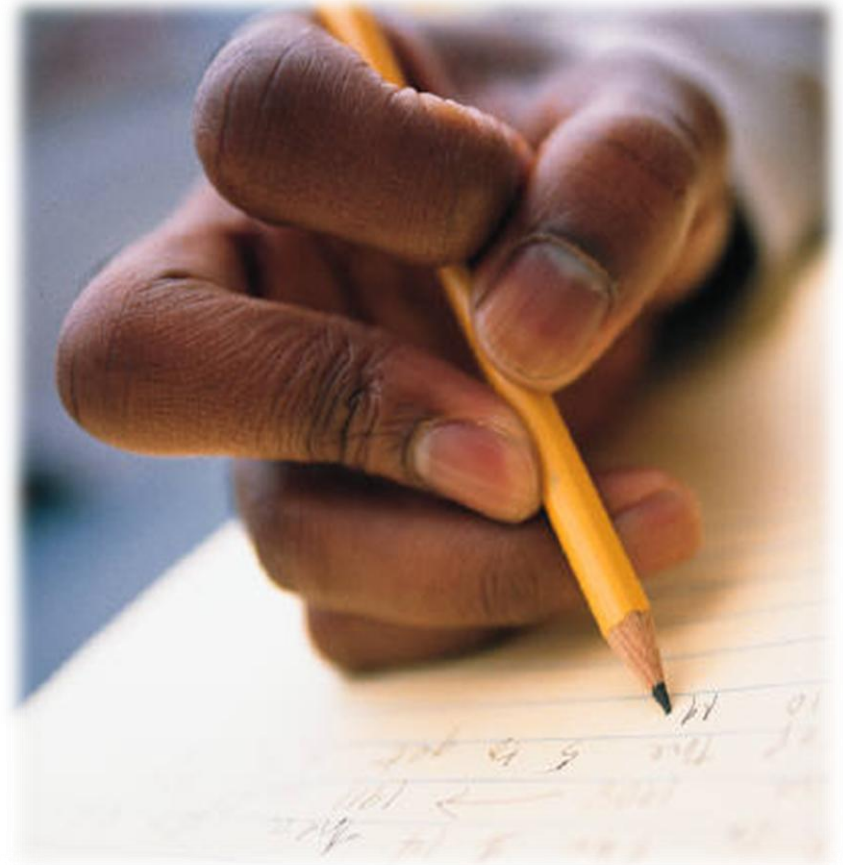


The background features a stylized profile of a human head in shades of green and blue. The interior of the head is filled with a pattern of overlapping hexagons in various shades of blue. Below the head, there is a large, curved shape in shades of orange and blue, also featuring a hexagonal pattern. The overall composition is abstract and modern.

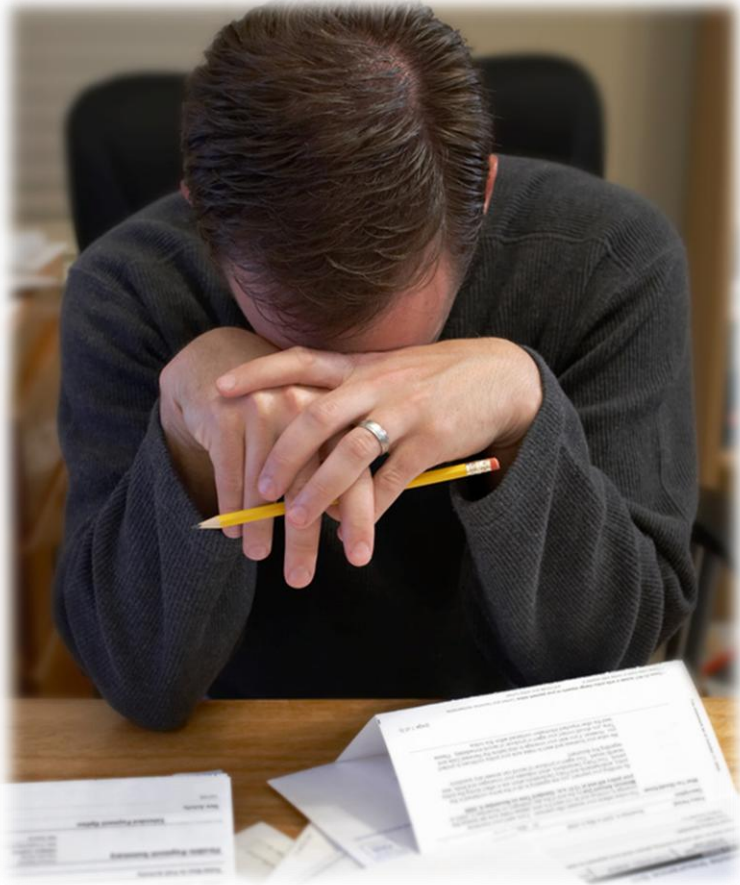
AUTHOR'S EXPECTATIONS AND UNDERSTANDING OF AUTHORSHIP

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

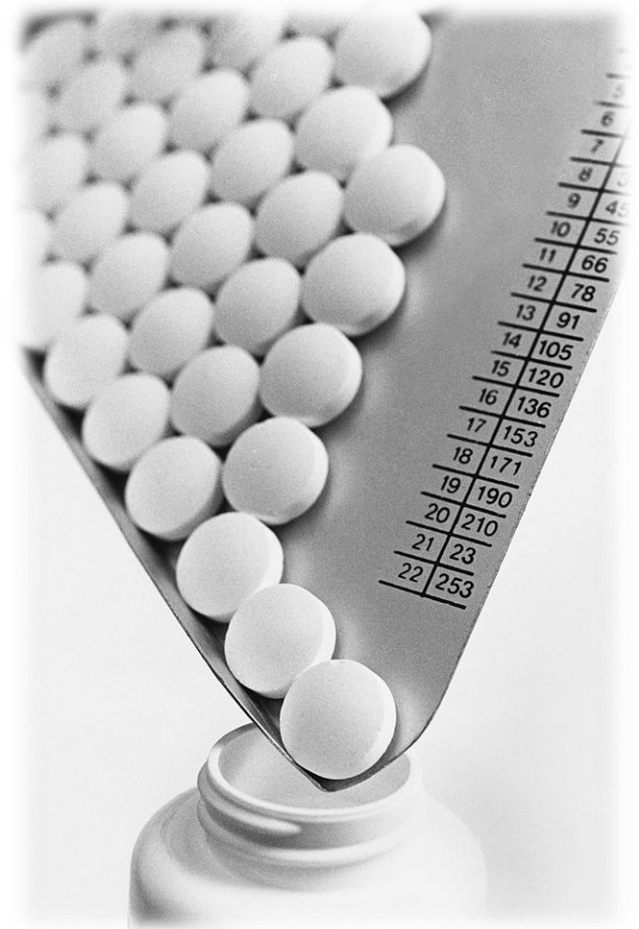


A stylized, abstract representation of a globe. The globe is composed of several large, curved segments in green, orange, and blue. The blue segments, located in the upper right and lower left, feature a hexagonal pattern, resembling a molecular structure or a crystalline lattice. The overall design is modern and scientific.

SCIENTIFIC MESSAGES ACROSS THE GLOBE

WHAT IS THE SITUATION?

- 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

WHAT IS THE SITUATION?



Global Publication
Planner

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

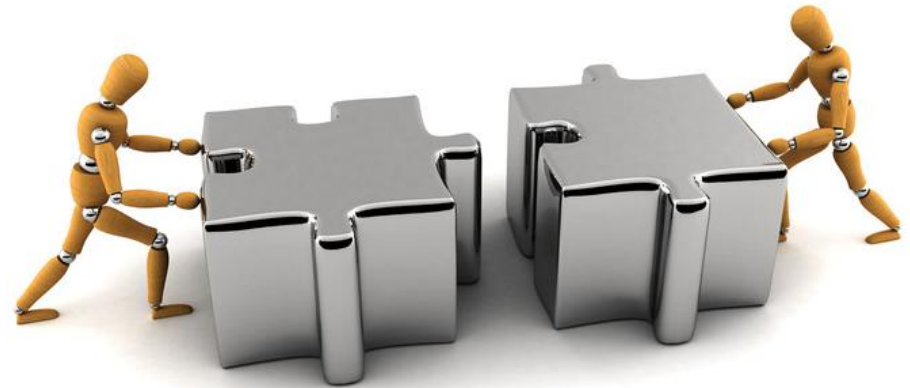
WHAT ARE THE SOLUTIONS?

- Process

- Ensure processes are in place to inform the appropriate people of the activities they are responsible for

- Education / training

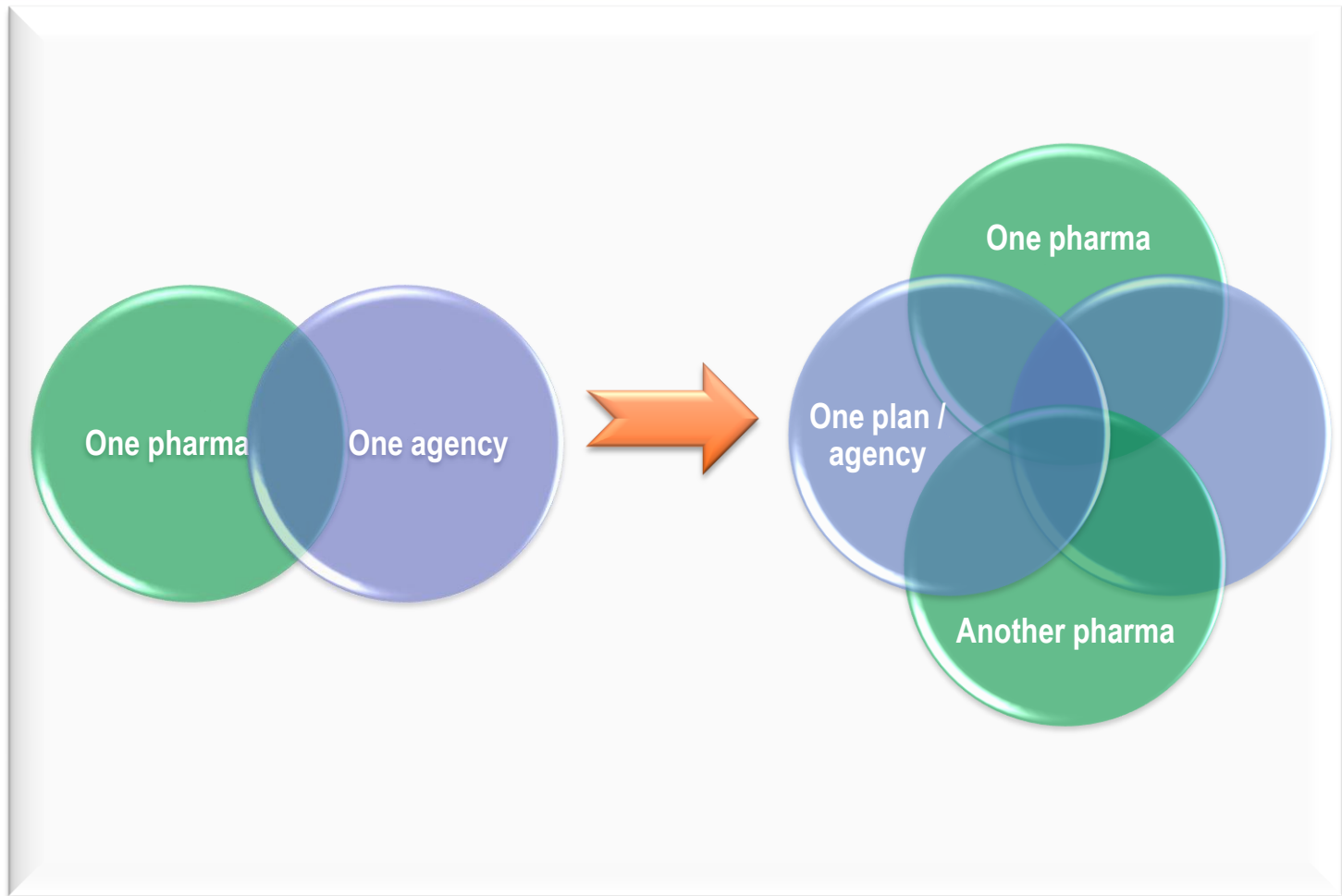
- Ensure individuals involved in publications have appropriate knowledge, training and support



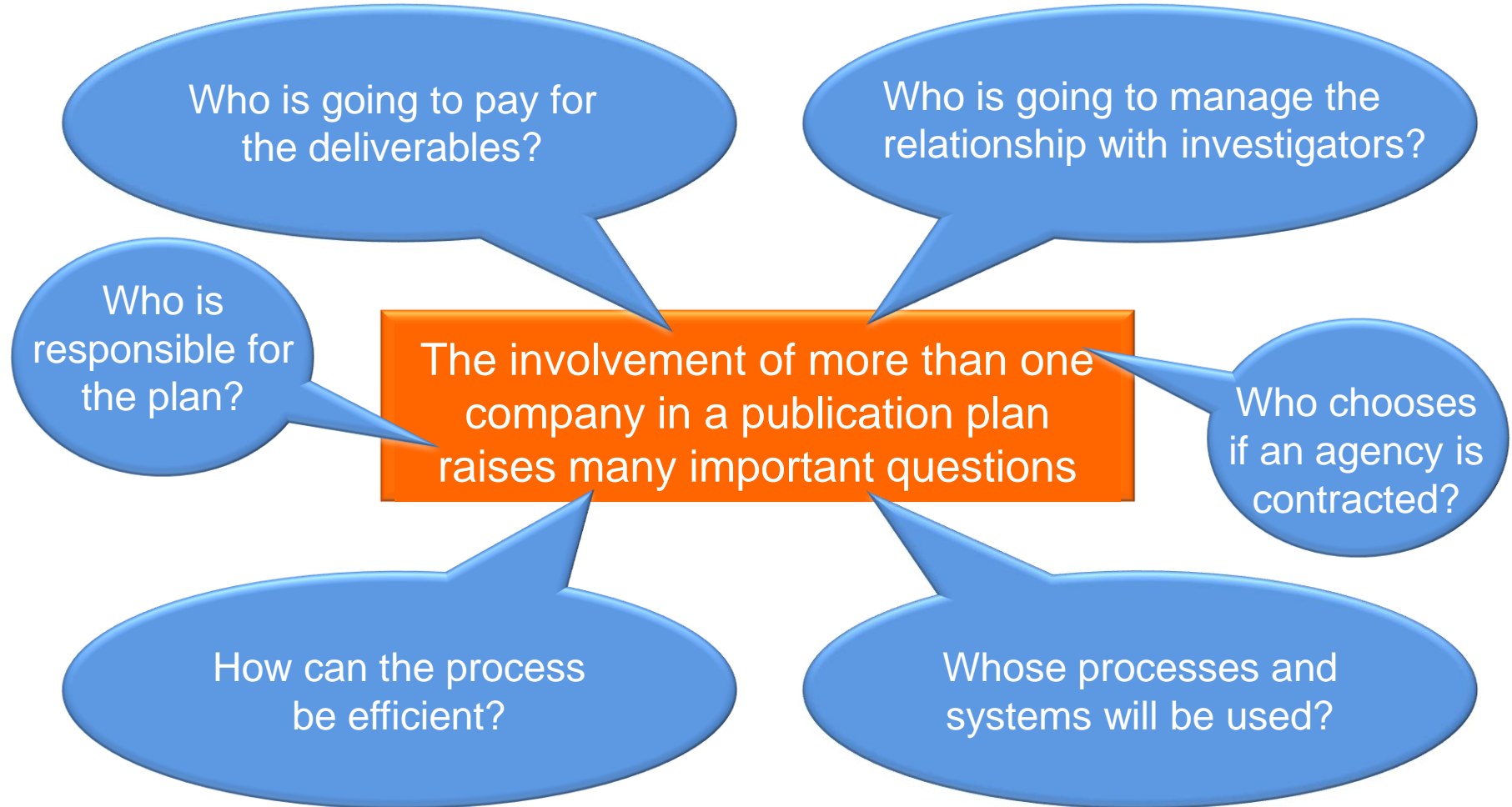
The background features a stylized, abstract design. It consists of several overlapping, semi-transparent shapes in shades of green, blue, and orange. A prominent feature is a large, light blue hexagonal pattern that resembles a honeycomb or molecular structure, which is partially obscured by the other shapes. The overall aesthetic is modern and geometric.

WORKING WITH CO-DEVELOPMENT AND CO-MARKETING COMPANIES

WHAT IS THE SITUATION?



WHY DOES THAT MATTER?



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.