THANK YOU FOR JOINING ISMPP U TODAY!

The program will begin promptly at 11:00 am eastern

May 22, 2013

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ISMPP ANNOUNCEMENTS

- **2013–2014 ISMPP Certification Board Elections** are now open. The Certification Board Nominating Committee is seeking qualified candidates for the following:
  - 2-year term voting Director (3 open positions)
  - Those interested need to submit a Candidate Nomination Form to cmpp@ismpp.org **no later than Friday, May 31st.**
- ISMPP Research, Grants and Publications Committee has an open call for proposals through July 31, 2013. Contact research-grants@ismpp.org for more information
- This program qualifies for 1 credit towards recertification

GLOBAL PUBLICATION PLANNING: GLOBAL TO LOCAL – MANAGING ENCORE ABSTRACTS

May 22, 2013

INTRODUCTIONS

- **Faculty:** Diane Moniz Reed is Director, Global Medical Publications, Oncology and Immunoscience at Bristol-Myers Squibb where she leads a team accountable for publication operations. Prior to her current role, Diane led the US Immunoscience medical communication strategy team through two critical launches and held various roles of increasing responsibility within the Field Medical Liaison organization.

  Diane joined Bristol-Myers Squibb in 1996 from Xavier University College of Pharmacy, in New Orleans where she was on faculty in the College of Pharmacy and served as Coordinator of Clinical Pharmacy Services for the Medical Center of Louisiana. She earned her Doctor of Pharmacy degree from Howard University in Washington DC and completed a clinical pharmacy residency at Thomas Jefferson University Hospital in Philadelphia.

INTRODUCTIONS

- **Faculty:** Gary Burd is Director of Scientific Services at Caudex Medical with 12 years of medical communications and scientific publishing experience. Gary has led communication planning and publication planning activities in several therapy areas, including diabetes, solid tumour oncology, haematological malignancies, transplantation, multiple sclerosis, rheumatoid arthritis, and respiratory and lung disease.

  Prior to his medical communications work he gained valuable editorial experience in journal publishing with Portland Press. Gary obtained his PhD from the Kennedy Institute of Rheumatology, London working on a monoclonal antibody therapy for systemic lupus erythematosus.

INTRODUCTIONS

- **Moderator:** Tom Drake is Vice President, Business Development with The JB Ashtin Group, Inc. Tom has been involved in global pharmaceutical marketing, supported strategic medical communications and publication planning for over 20 years.

  Tom is an ISMPP Certified Medical Publication Professional(tm) (CMPP), a member of the ISMPP-U committee and the ISMPP Annual Meeting committee.

DISCLAIMER

The information and opinions presented here reflect those of the presenter and do not represent the position of Bristol-Myers Squibb, Caudex Medical or the International Society of Medical Publication Professionals. Presentation at this forum should be not construed as an endorsement by any of these entities.

TODAY'S OBJECTIVES

- At the end of this session, attendees should be able to:
  - Define an encore abstract
  - Recognize key considerations when including encore abstracts as part of a publication plan
  - Understand how to best manage global and local teams in the development of encore abstracts

DEVELOPING AN ENCORE ABSTRACT PROCESS THAT COMPLIES WITH GPP

Diane Moniz Reed, PharmD, CMPP™
Director, Global Medical Publications
Bristol-Myers Squibb Company

OVERVIEW

- Discuss rationale for incorporating encore strategy within publication plans
- Differentiate between the features of encores and adaptations
- Review key considerations when including encores as part of the publication plan
- Highlight strategies for maintaining integrity in the process

AUDIENCE RESPONSE: ENCORE PLANNING SCENARIO

The first disclosure of the results of a pivotal phase III registrational trial is planned at ASCO congress in June. The product is expected to receive US market approval late 3rd quarter. The publication plan also calls for these same data to be encored at 5 secondary congresses, including two domestic congresses over the twelve months following first disclosure. Additionally, 3 adaptations are planned for Asia-Pacific and Latin American markets during this same time period. Is this justified?

a. It is a launch year so more exposure the better

b. It depends on overlap of congress attendees

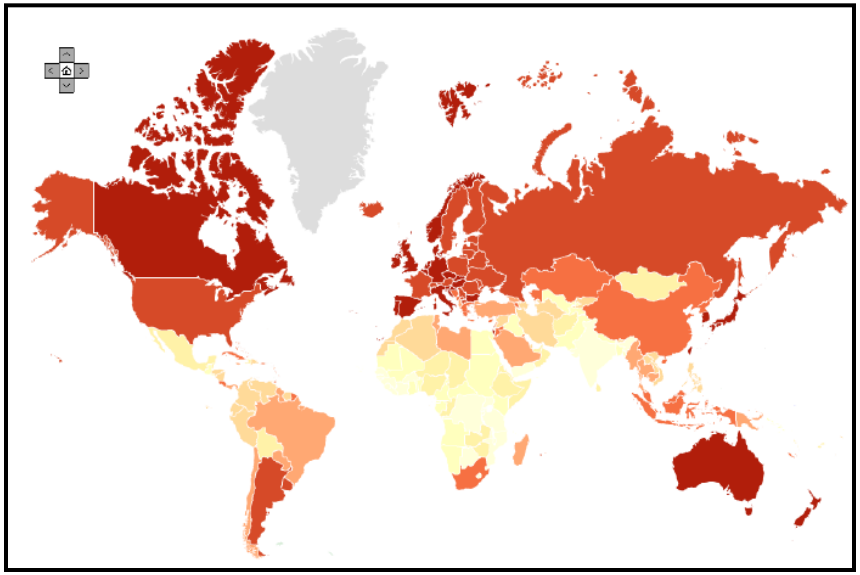
c. Encores should be limited to no more than 3 to avoid data fatigue

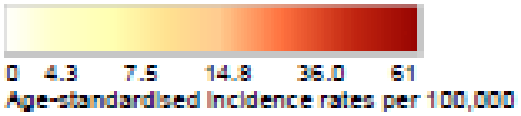
d. Encores appear excessive but the adaptations may be okay

e. b and d are correct

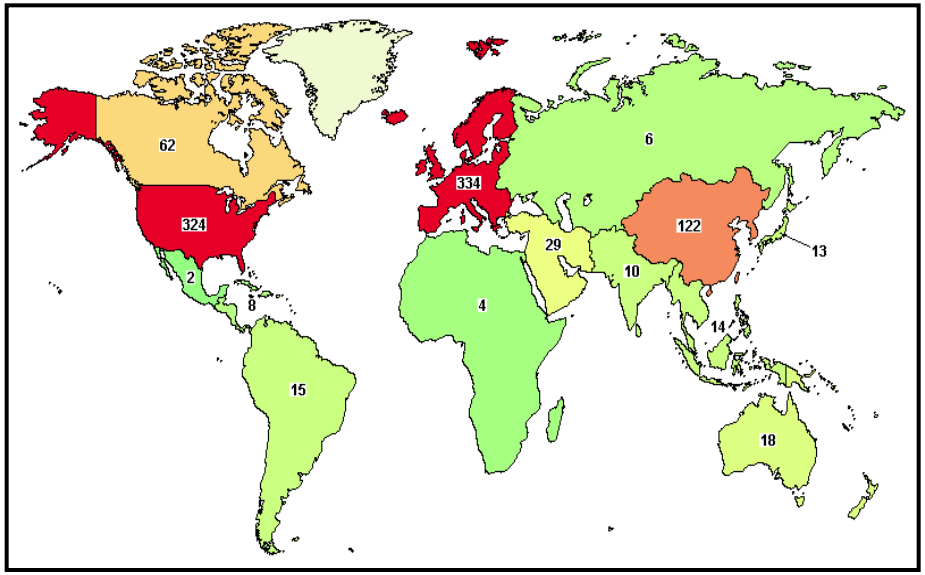
HIGH INCIDENCE OF COLORECTAL CANCER IN AUSTRALIA/NEW ZEALAND & WESTERN EUROPE YET DISTRIBUTION OF COLORECTAL CLINICAL TRIALS MODEST

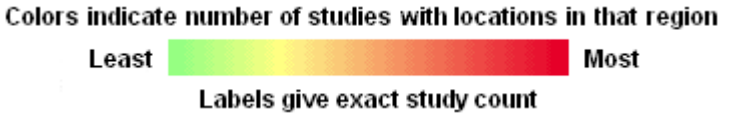
Incidence of Colorectal Cancer in Men*





Distribution of Colorectal Cancer Clinical Trials

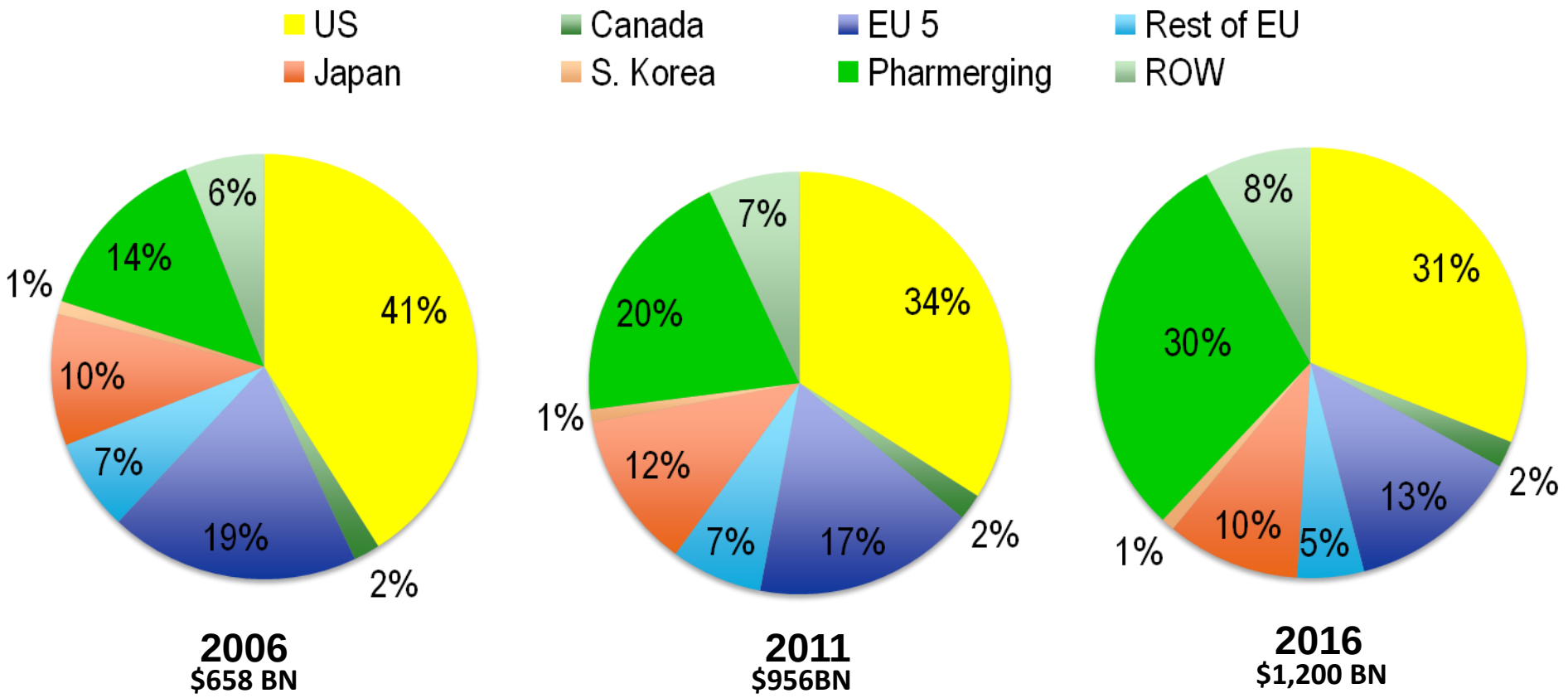




*estimated, 2008 http://globocan.iarc.fr/factsheet.asp accessed 5-5-13

http://www.clinicaltrials.gov/ct2/Colorectal accessed 5-1-13

NON-WESTERN GEOGRAPHIES CONTRIBUTION TO OVERALL GLOBAL SPEND ON MEDICINE IS INCREASING WHILE THAT OF WESTERN GEOGRAPHIES IS DECREASING



Adapted from IMS Institute for Healthcare Informatics. The Global Use of Medicines Outlook through 2016; May 2012

WHY INCLUDE AN ENCORE STRATEGY WITHIN PUBLICATION PLANS?

- Globalization of clinical trial execution with increasing generation of data outside of US and western Europe
- Non-western geographies accounting for increasingly greater proportion of global spend on medicines
- Changing dynamic of spend type across geographies
- Impact of healthcare policy changes on access and reimbursement
- Need for timely access to (relevant) data to inform decision-making

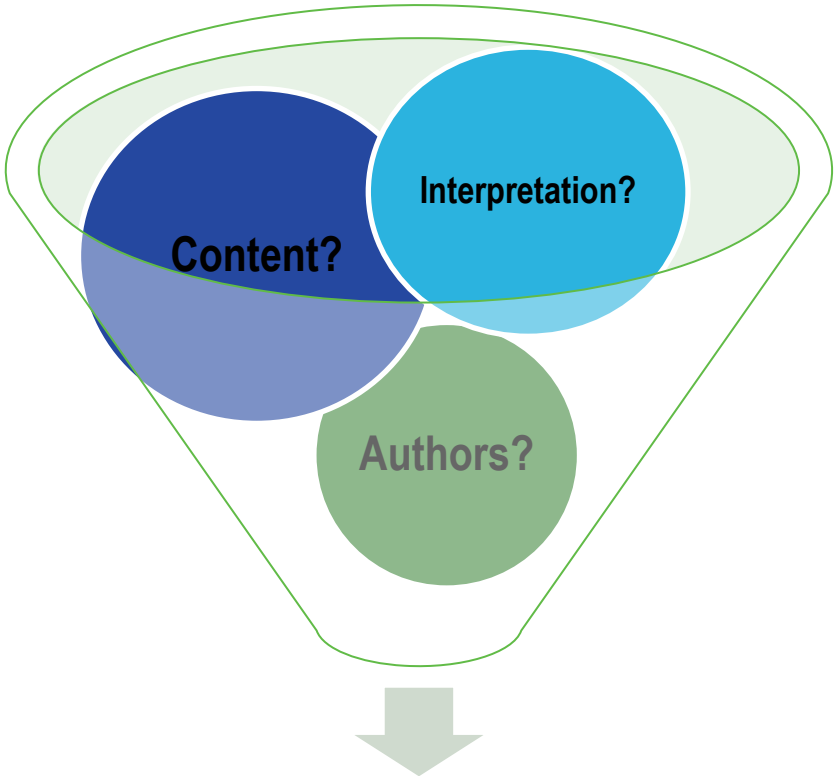
THE CHEESE IS MOVING

AUDIENCE RESPONSE: WHAT IS PERMISSIBLE WITH RESPECT TO ENCORES AND AUTHORSHIP?

Within your organization what is permissible with respect to encore abstracts and authorship?

a. No changes to authorship (or order) are allowed
b. Authors cannot change but the order of authors can
c. A new presenting author can be added to accommodate local language of congress
d. Changes to both the authors (additions/deletions) and the order are allowed
e. I follow the client's policy and guidance on authorship
f. I am not sure/I do not know

DIFFERENTIATING BETWEEN AN "ENCORE" AND "ADAPTATION"

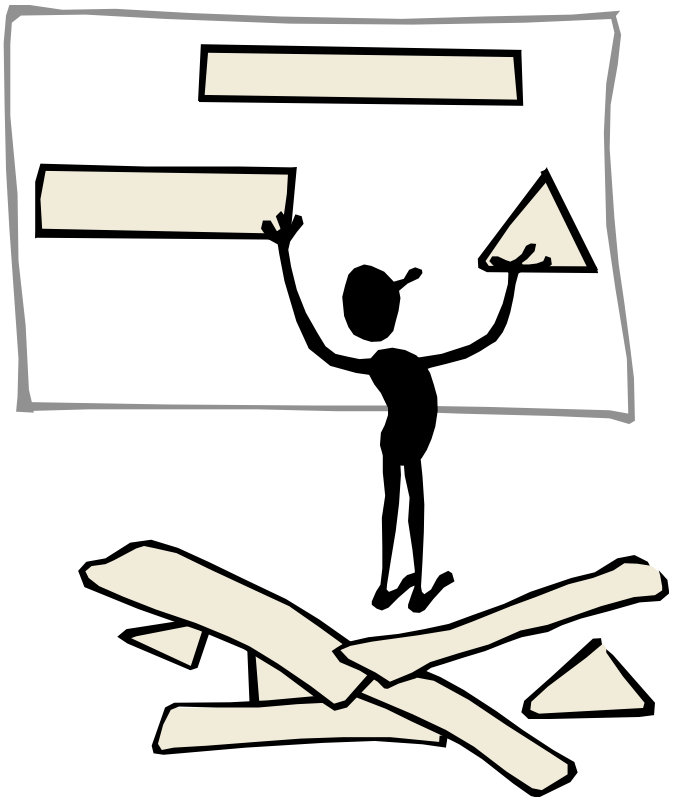


Encore or Adaptation?

FEATURES OF AN ENCORE AND KEY CONSIDERATIONS

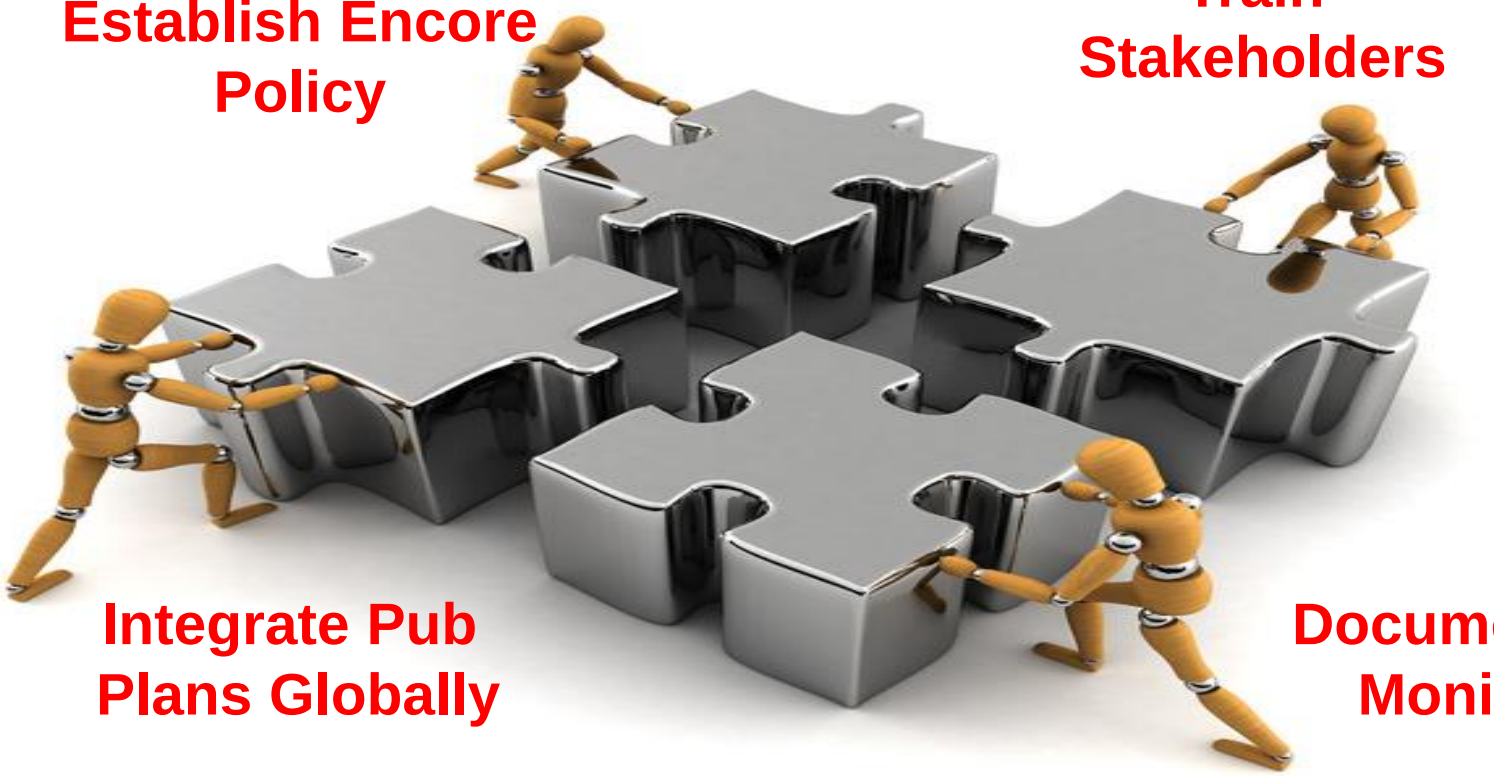
- Reproduction of the original abstract
- Editorial changes only to accommodate congress requirements
- Authors remain the same
- Obtain agreement of initial abstract authors
- Respect embargoes, cannot jeopardize first disclosure
- Understand copyright and adhere to copyright rules
- Permissions needed prior to submission
- Author review and approval of encore abstract

FEATURES OF AN ADAPTATON AND KEY CONSIDERATIONS



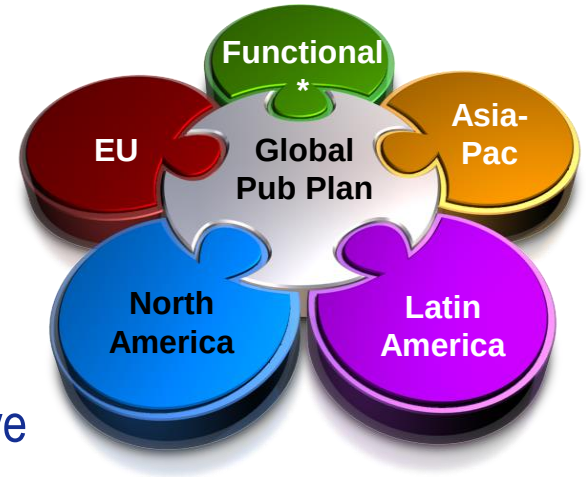
- Content overlaps original but contains new data, analyses, and/or interpretations
- Must not jeopardize first disclosure presentation
- Seek agreement of authors on the original abstract
- Authorship can change
- Authors added to an adaptation must meet all ICMJE criteria
- Requires input of new author(s) and input must be evident
- Consider copyright and permissions

STRATEGIES FOR ENSURING THE INTEGRITY IN THE PROCESS



DEVELOP GLOBALLY INTEGRATED PUBLICATION PLANS

- Ensure the right input - who has a seat at the planning table and when?
- Document unmet medical and/or educational needs in plan
  - Be clear in the goal/purpose of encore strategy
  - Global, regional and local market environments
- Understand data availability relative to target audiences
- Consider timing of launch in various markets
- Shift the encore strategy paradigm from reactive to proactive
- Align encore strategy as a function of the product lifecycle
- Extend the lens on publication tactical planning



* Functional areas such as health economics, biostatistics, clinical pharmacology, clinical research

ENCORING - WHEN IS TOO MUCH, TOO MUCH? AVOIDING DATA AND AUTHOR FATIGUE

- **Seek External Advisement Early**
  - Publication steering committees
  - Medical advisory boards
  - Authors

CONSIDERATIONS WHEN DEVELOPING INTERNAL GUIDANCE FOR ENCORES

- Unmet Need/Rationale
- Consider addressing restrictions
  - maximum number of encores per data set?
  - expiration i.e. how “old” is too old to encore?
  - audience overlap?
- Delineate how authorship is managed
- Highlight copyright and permissions requirements
- Establish review and approval process
- Address documentation needed
- Delineate who is **R**esponsible, **A**ccountable, **C**onsulted, **I**nformed (**RACI**)

EDUCATE AND SELF-REGULATE

Train & Re-train

- Utilize multiple strategies
- Incorporate into new-hire training globally
- Annual re-certification on GPP & publication policies
- Establish “ambassadors” of GPP
- Use push “gentle reminder” communications
- “Agenda it”

Document & Monitor

- Institute publication plan review process
- Utilize publication management systems
- Establish audit schedule
- Conduct random checks
- Implement corrective actions

MANAGING THE ENCORE ABSTRACT PROCESS

Gary Burd, PhD, CMPP™
Director of Scientific Services
Caudex Medical

OVERVIEW

- What is available for encore?
- Understanding congress opportunities
- Key differences to look out for when encoring
- Author roles and responsibilities
- Issues and challenges
- Case study

HELPING COUNTRIES DETERMINE WHAT IS AVAILABLE FOR ENCORE

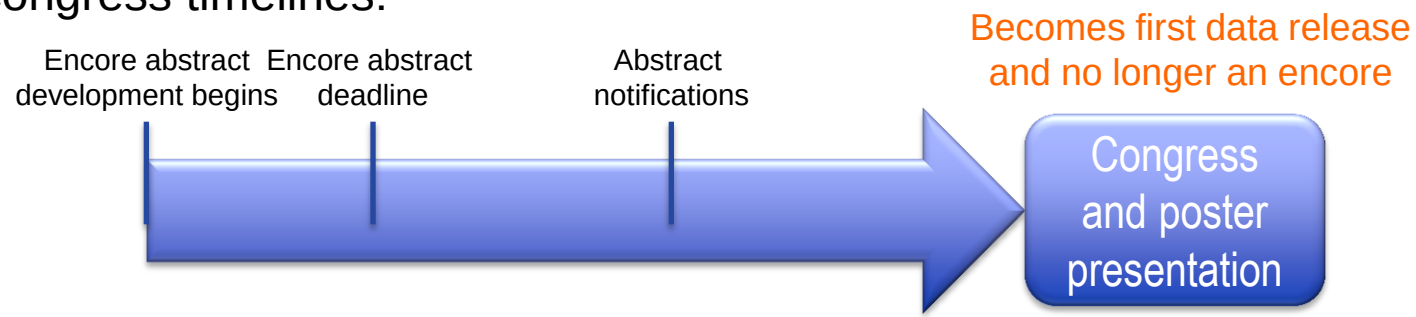
- Share global publication plans in advance to allow countries to plan their local congresses
  - Of course we know that things can change!
  - Ask countries to share their encore plans so there is 'line of sight' at global level
- Share submission plans in the run up to the abstract deadline
- Share submissions following abstract deadline
  - Note embargo policies!
- Share acceptance information as soon as possible
  - Reminder of embargo policy

ENSURING INITIAL PRESENTATIONS ARE NOT JEOPARDISED

- It's all in the timing...

Large, international congress timelines:

Small, local congress timelines:



UNDERSTANDING CONGRESSES

- Are encores allowed?
  - *"The International Gynecologic Cancer Society does not allow encores"*
  - *"Abstracts containing data that has been presented or will be presented at a different scientific meeting during a 12 months period prior to EULAR 2013 can be submitted. This fact must be indicated on the submission form."*
- Do you need the original congress's permission to reproduce?
  - Exclusive vs non-exclusive licence to publish
  - *"No abstracts may be reproduced in any form or by any means, without the prior permission of the publisher."*

KEY DIFFERENCES TO LOOK OUT FOR WHEN ENCORING: WORD CHANGES

- Word / line count / character count differences

FROM:

- EULAR: The acceptable length of the abstract is not more than 3 600 characters and 50 lines, author's details and headers included

TO:

- ACR: The abstract limit is 2 750 characters, which excludes the title, names of authors/co-authors, authors' affiliations, spacing and disclosures.

KEY DIFFERENCES TO LOOK OUT FOR WHEN ENCORING: FIGURE CHANGES

- Are tables / figures allowed?
- What space do they take up in the abstract?
- EULAR: One graph/image can be included with the following criteria:
  Image width: min. 50 pixels - max. 750 pixels
  Image height: min. 50 pixels - max. 750 pixels
- ACR: Table or figure counts towards character count by 250 characters (it is actually ~250 characters!)
- CRA: Figures and tables are not allowed

KEY DIFFERENCES TO LOOK OUT FOR WHEN ENCORING: LANGUAGE

- EULAR: English
- ACR: English
- CRA: English
- SFR: French
- SIR: Italian
- DGRh: German
- BSR: English
- SSR: Spanish

- Submission sites can be in local language and you may need a translation of the guidelines
- Utilise country affiliate support / local agency support to help
- European languages tend to take up ~15% extra text over English

KEY DIFFERENCES TO LOOK OUT FOR WHEN ENCORING: POSTER DIMENSIONS

- EULAR: The usable poster board surface is 94 cm high and 180 cm wide (landscape format)
- ACR: The backboard panel for each poster presentation board measures 44 inches (111.76 cm) high and 90 inches (228.6 cm) wide (landscape format)
- DGRh: 60 inches high and 36 inches wide (portrait format)

TOP TIPS

- Include key data values on figures, so if the figure has to be removed at least you can use the data values in the text
- Draft structured abstracts, even if they don't ask for a structure – it helps encore where a structure is needed
- Skilled editors can reduce word counts without changing the sense of what is written
- Look to abbreviate words that may not have been abbreviated originally (eg, 'patients' to 'pts')

AUTHOR ROLES AND RESPONSIBILITIES

- Who is the presenting author? A local author needs to be an author on the original submission
- Are there restrictions meaning that authors must be members of the local society?
- All authors need to accept an invitation to author the encore
- All authors need to review the encore (amended to meet new requirements)
- All authors need to approve the encore (following any changes)

TRANSLATIONS AND REVIEWS

- At what stage should the translated version be reviewed by authors?
- Tend to send English version and translation at all author review
  - Remember to check length of translated version!
- Make a note that English version and translation are equivalent.
  - Expectation is for presenting author to confirm translation is acceptable
  - Client may also have a role in approving translations

ISSUES AND CHALLENGES

- Managing author expectations
  - Why am I being asked to review so many abstracts?
- Managing local affiliates
  - Why are we starting the process months before my submission deadline?
  - Can I encore the abstracts that weren't accepted?

CASE STUDY

- 8 abstracts have been submitted to EULAR
- German affiliate would like to encore 3 of the abstracts at their local congress, but we don't have notifications of acceptance yet
- What if the abstracts are not accepted, or are accepted for book only – there will be no poster to develop an encore from?

OPTIONS

OPTION 1: Encore not possible

- Develop abstracts on the understanding that if they are not accepted / are accepted for book only at EULAR, then they will not be submitted to German congress

OPTION 2: A new poster (not an encore)

- If abstracts are accepted for book only, German congress could be a first data disclosure opportunity – provided resources are in place locally to support development of presentation from first principles

OPTION 3: An encore presentation

- If abstract is accepted as a poster, German congress can accommodate both abstract and poster as encore presentations

QUESTIONS?

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.

THANK YOU

UPCOMING ISMPP U TOPICS

- Stay tuned for the upcoming ISMPP U topics – dates to be announced shortly
  - CMPP Certification
  - Data transparency
  - SPIRIT Guidelines

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