Thank you for joining ISMPP U today!

The program will begin promptly at 11:00 EDT

Publication Steering Committees

Ensuring timely and balanced publications from your clinical development program

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Today's presenters

- **Mina Patel, PhD**
  - Senior Director, Medical Communications, Cephalon Inc.

- **Dan Bridges, PhD**
  - Group Program Director, Global Medical Communications, Excerpta Medica

The views in this presentation are those of the individuals and not of their companies or ISMPP

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Introduction

- Good publication practice (GPP2) recommends the formation of publication steering committees (PSC)[1]
  - A subgroup of contributors to the trial program who are responsible for all publications resulting from the trial
- However, there is no standard practice in this field, and formation of such PSCs may depend on many factors
  - Size of company, therapy area, product lifecycle, size of trial or trial program
- Many companies have adapted their trial publication policies to reflect FDAAA requirements for timeliness of publication
- A PSC will support these policies as well as:
  - Ensuring disclosure of clinical trial results to physicians at the earliest opportunity (best practice)
  - Avoiding negative public perception

1. Graf C, et al. BMJ. 2009;339:b4330.

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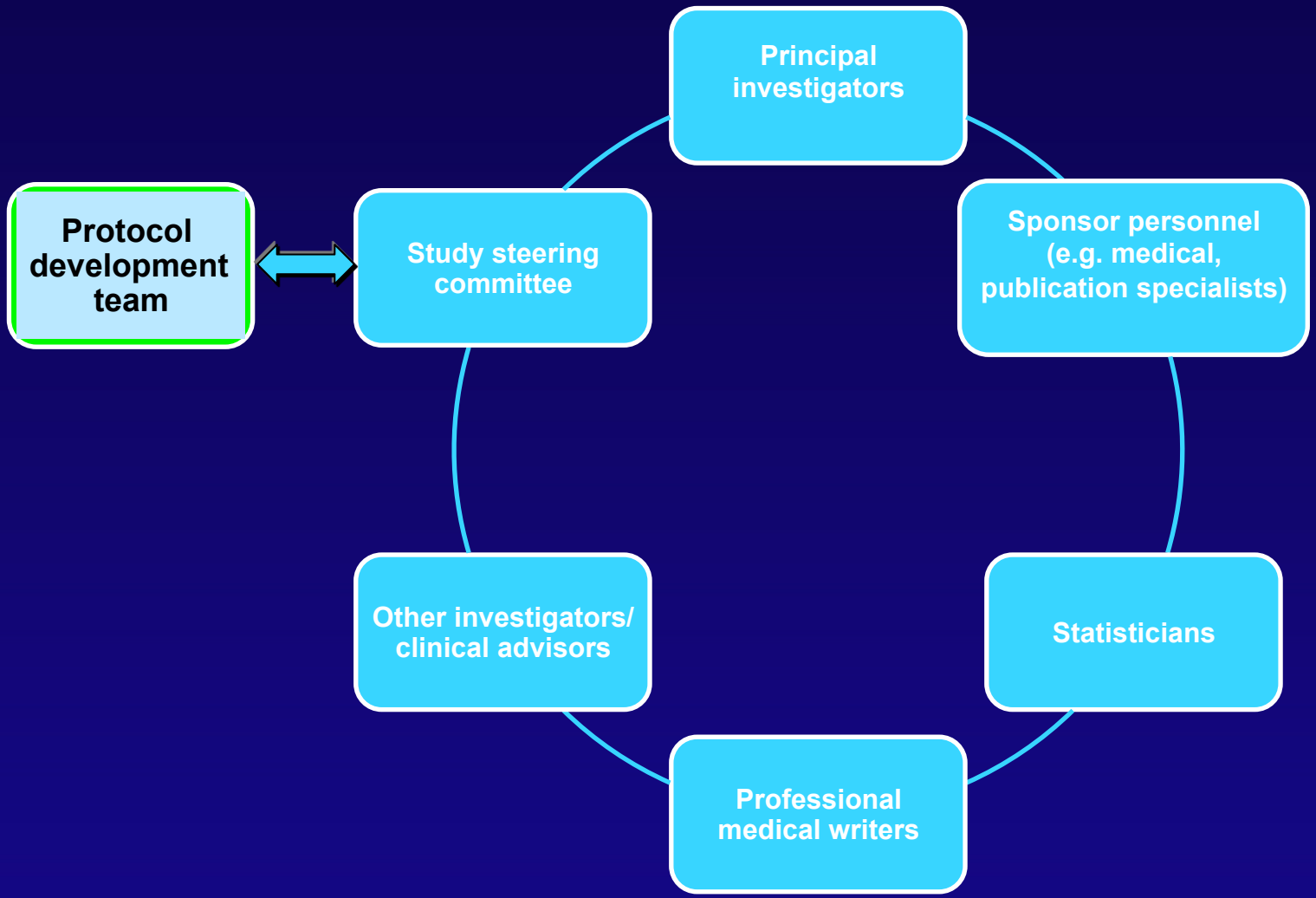
Who can comprise the PSC?



Adapted from Graf C, et al. BMJ. 2009;339:b4330.

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Goals of the PSC

- The PSC should:
  - Commit to publishing the key primary and secondary results of the trial in an objective and timely manner
  - Provide input into discussions of unmet needs in the therapeutic space
  - Identify, based on robust medical hypotheses, and publish sub-analyses or exploratory endpoints that would be of interest to the scientific/medical community
  - Avoid inappropriate publications
  - Provide input into authorship, contributors, journal choices

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When to form a PSC

- There is no current standard for the “best time” to form the PSC
- Considerations:
  - When should you start thinking about publications in a trial program?
  - Should this be part of the original contracting procedure?
  - How many people should be in your PSC?
    - What is the ratio of internal sponsor to external?
  - Who should be in your PSC?
  - Whose role in (or outside of) the company is it to initiate and lead this process?
  - Are there standard operating procedures/guidance regarding this in your company?

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Roles and responsibilities within the PSC

- All members should:
  - Clearly understand and accept their roles and responsibilities at formation of the PSC
  - Commit to objective and timely publication of trial results (following applicable reporting/authorship standards)
  - Commit to a written publication policy (based on those from the sponsoring company, academic institute, etc)
- Study sponsors should:
  - Help to form and run the PSC (including logistics)
  - Assign chairs to the PSC (likely trial investigators)
  - May include written agreements on the roles and responsibilities
- Chairs will:
  - Promote the aims of the PSC
  - Mediate and assign authorship on publications/presentations

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Authorship

- Authorship should follow the International Committee of Medical Journal Editors (ICMJE) guidelines, with each author meeting all of the following criteria:
  - Substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data
  - Drafting the manuscript or critically revising it for important intellectual content
  - Give final approval of the version to be published
- Each publication should endeavor to have a member of the PSC as an author
- Guest and ghost-authorship is unacceptable

Does the type of study impact PSC roles/responsibilities?

- Is there any variation in the role of a PSC between different study types?
  - Phase of trial (phase II, phase III, phase IV)
  - Type of study (clinical trial, observational, registry)
- A PSC can be as crucial in a registry as in a clinical trial
  - As the research questions are less prospectively defined in a registry, it is imperative to have guidance on what interesting research and, therefore, publications will be invested in
  - The relatively lower “importance” of a registry often leads to reduced output over time. The PSC chairs are a key driver in productivity via peer-to-peer pressure

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Potential issues – payment for writing?

- GPP2 states that no payment should be given specifically for writing a publication
- Out of pocket expenses for presentations may be reimbursed (in line with company/academic guidelines)
  - How do you avoid the misconception that you have paid an author for a publication in a clinical trial?
  - Do you have separate agreements for the trial conduction and the manuscript?
  - Do you ever combine trial agreements and publication agreements into one document?
    - What are the pros and cons of doing so?

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Potential issues – management of PSC

- How often should a PSC meet?
  - Does this depend on the scope of the trial program and the number of publications?
  - Proportion of live meetings to virtual meetings?
- Who is responsible for organizing the PSC meetings?
  - What should be the sponsors role at these meetings?
  - How do you keep marketing in check?
- What tools can you use to keep the PSC engaged between meetings (especially if you create the committee at protocol finalization for a long trial)?

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Conclusions

- GPP2 recommends the formation of PSCs
- Key members can include:
  - Study PSC members (including protocol development team)
  - Investigators
  - Sponsor employees (medical, statisticians, etc)
  - Professional medical writers
- The benefits of a PSC are:
  - Timely publications and presentations
  - Decision-making group for publication/authorship issues
- Important considerations of PSCs are:
  - When to form a PSC
  - Defining specific roles and responsibilities for all members
  - Focus on the main desired output of a PSC – publications and presentations

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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: September 8

TIME: 11am EDT

TOPIC: To be determined…Mark your calendar and stay tuned!

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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.