



Regulatory Submissions
and Advisory Committee Meetings

Preparing Content



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Topics



- **Introductions**
- **Preparing Submission Content**
- **Preparing Advisory Committee Content**
- **Parallels in the Process**
- **Q&A**





- **Octagon Research Solutions, Inc. is a development partnering organization that offers regulatory, clinical, process and IT solutions to the life sciences industry**
- **The Octagon Advantage:**
 - Deep Domain Knowledge
 - Cross-functional eSub Expertise
 - A Holistic Process Approach
 - Creative Use of Technology



- **Presentation Strategies Inc. is a premier interactive production company serving the pharmaceutical industry**
- **Single Source for mission critical media solutions:**
 - Strategic Audiovisual Services
 - Multimedia development and deployment
 - Video production
 - Digital printing
 - Regulatory presentation management

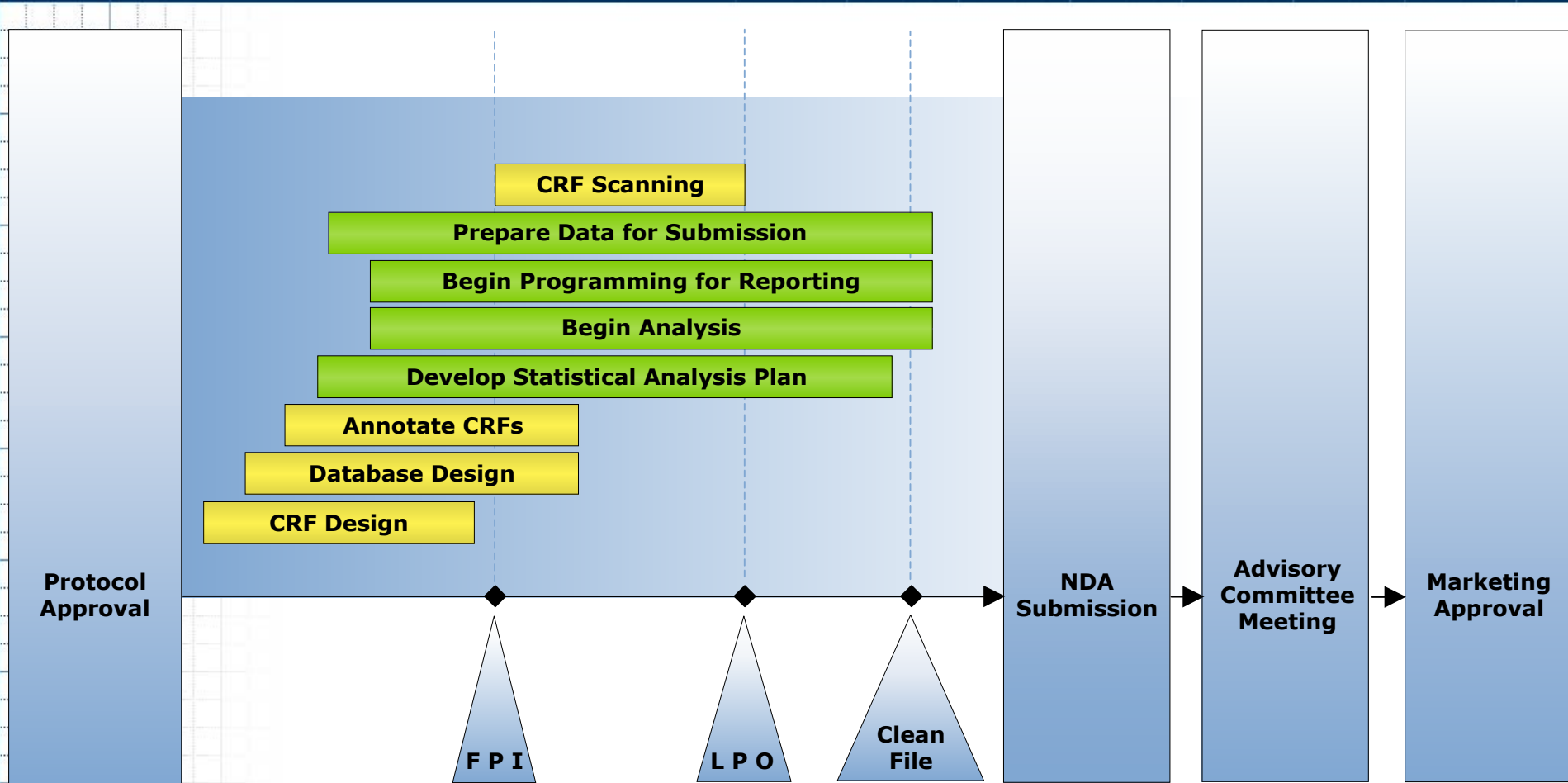
Polling Question



How many attendees have produced an electronic submission?



The Big Picture



Similarities



- **Submissions and Advisory Committee Meetings:**
 - Both require significant resources
 - Both demand cross-functional teams
 - Both require very specific domain expertise
 - Both are considered mission critical activities
 - Both have huge risk associated with failure



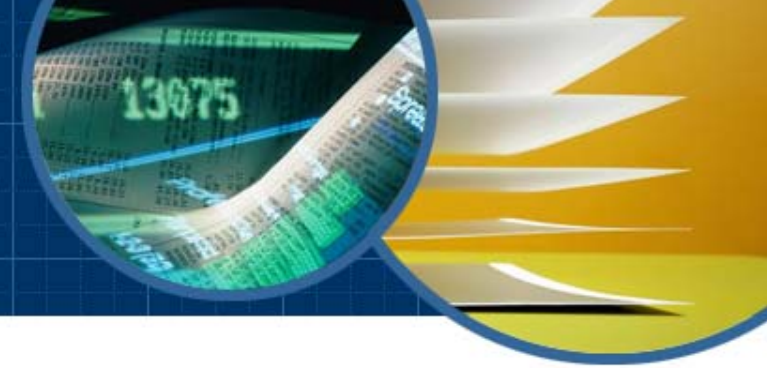
Preparing Submission Content



- **Identify deliverables early**
 - Format: electronic vs. paper
 - Organization: CTD, eCTD, Hybrid, etc.
 - Region: US, EU, Canada, Japan, etc.
 - Both demand cross-functional teams
- **Identify common components**
- **Identify regional requirements**
 - Reference relevant guidance

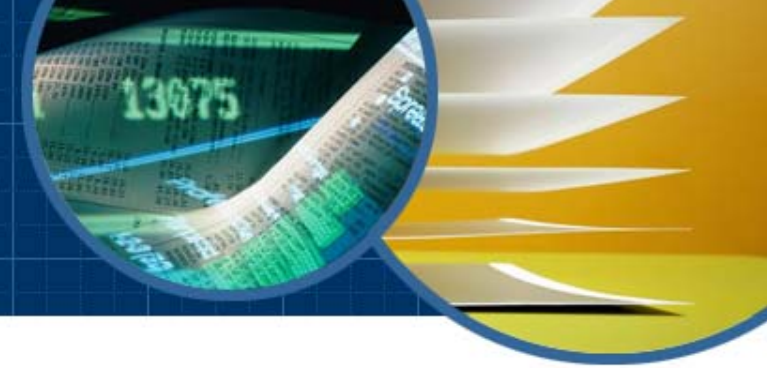


Organizing Submission Content



- **Identify document/data dependencies and map expected completion dates**
- **Identify owner of content (including any required metadata)**
- **Track content creation status for each deliverable component**
- **Incorporate QA of new aspects of submission (metadata)**
- **Lock down submission documents and data as complete**
- **Use process or technology to secure final approved versions**

Submission Content Creation Processes



- **Train authors on new deliverables**
- **Implement standards such as authoring templates, style guides, table shells, etc.**
- **Develop and document processes that minimize rework between functional areas**
- **Address legacy documents and data**
- **Evaluate all components of submission from process perspective**
 - Documents
 - Data
 - Metadata
- **Incorporate/update QA throughout process**

Content Challenges for Submissions



- **Changing deliverables**
 - Lack of eSub expertise
 - Lack of organizational understanding of eSubs
 - New metadata requirements
- **Specific format requirements**
 - Require organizational standards for format and content
 - Require guidance interpretation
- **New technologies being incorporated require training**
 - Tools
 - Submission deliverables (xml)
 - Processes

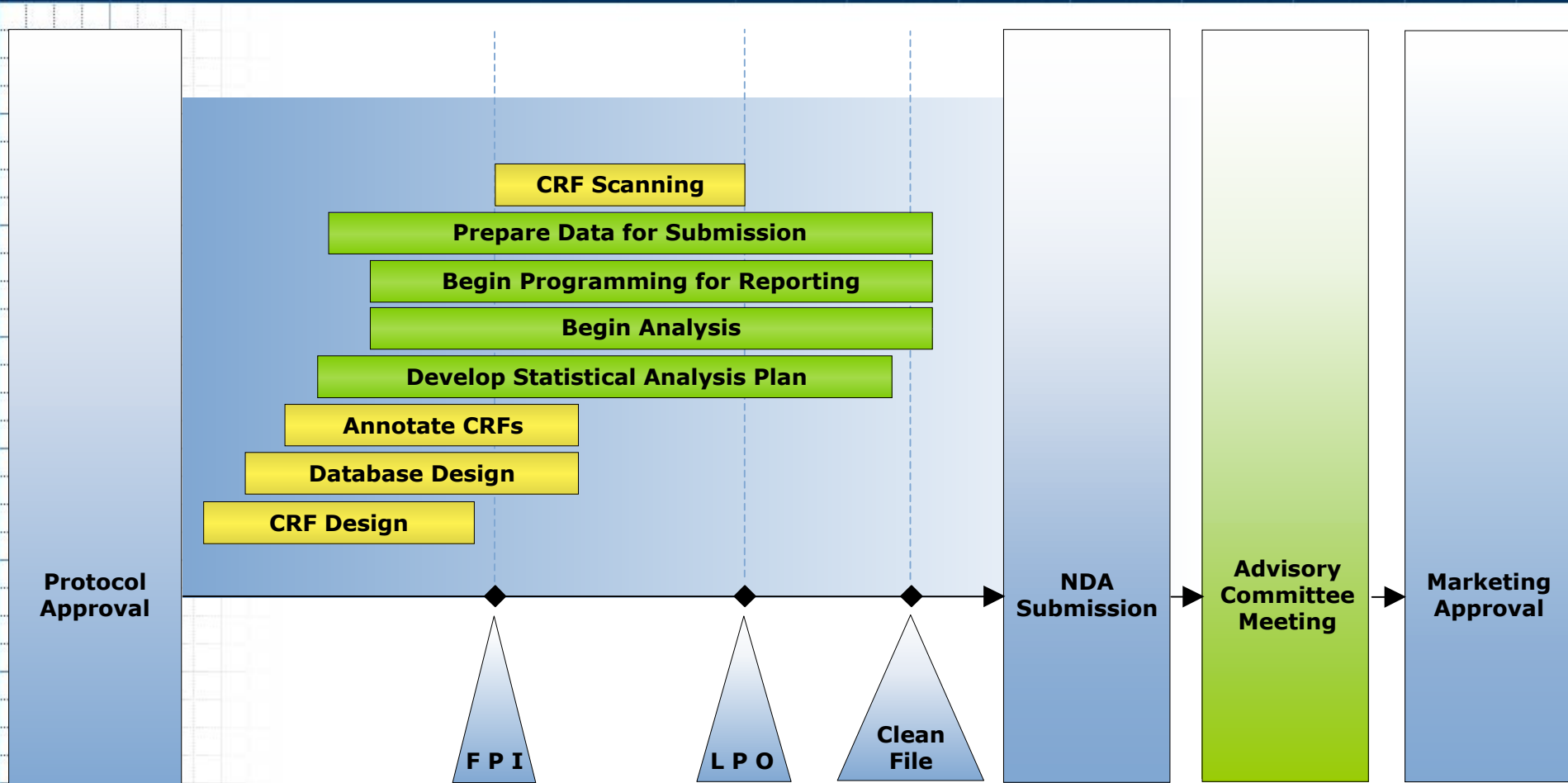
Polling Question



How many attendees have been involved in preparation for an Advisory Committee presentation?



The Big Picture



Developing Content for Advisory Committee Presentations



- **Preparation**
- **Organization**
- **Creation**
- **Challenges**



Preparing Advisory Committee Content



- **Sponsor objective at an AdComm**
 - Give the data its best chance for success
- **What are AdComm deliverables?**
 - Highly effective presentation team
 - A compelling 45 minute “story”
 - Direct, complete and credible responses to questions
- **What do AdComm panel members want?**
 - The Sponsor knows the submission inside and out
 - The Sponsor has done everything possible to address safety concerns

Organizing Advisory Committee Content



- **Early Preparation is Key**
 - Build digital assets throughout clinical development
 - Enlist the help of a communication strategist
 - Develop presentation and Q&A skills simultaneously with content development
- **Less is more**
 - The number of backup visuals doesn't matter...
 - Complete, credible responses to questions does matter
 - Prepare to address all likely questions and concerns
- **Commit to rigorous scientific integrity in the presentation of data**

Advisory Committee Content Creation Processes



- **Record / transcribe informal presentations**
- **Pre-load backup visual database**
- **Train team on systems and technology**
 - Format for supplied data
 - Version control
 - File transfer
 - Security
 - Visual retrieval process
 - Display technologies
- **Process of rehearsing and refining both content & delivery**
 - Formal mock panel rehearsals
 - Informal in-person rehearsals
 - Working sessions (web conferencing and live streaming)

Content Challenges for Advisory Committee Meetings



- **Lack of organizational experience**
 - Team has never been through the process
- **Lack of defined process for visual development**
 - QA, version control, locating and retrieving visuals
- **Lack of clear communication strategy**
 - No compelling story to tell
- **Poor presentation skills**
 - EASL speakers, inexperienced presenters, high stress environment
- **Technically challenging presentation environment**

Parallels in the Process



- **Identify and track content requirements early**
 - Content AND format are essential topics
- **Submissions and Advisory Committee presentations**
 - Have multiple moving parts
 - Require strong content (science) presented in a specific format
 - Require cross-functional collections of information
 - Have traditionally been addressed as end-stage activities
 - Often resulting in rework and redundancies
 - Are mission critical events
- **Put your effort toward doing it right the first time**



Question and Answer Session

Presenter Contact Information



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Regulatory Submissions and Advisory Committee Meetings: Preparing Your Organization for Success

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March 22, 2005

11:00 a.m. EST

Part 3: Bringing it all Together

April 19, 2005

11:00 a.m. EST

www.octagonresearch.com

