How was the Common CSR Template Developed and What Does it Look Like?
How was the Common CSR Template Developed? Structure and Content

<table>
<thead>
<tr>
<th>Structure</th>
<th>Section Content</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Adherence with ICH E3 &amp; CORE guidance</td>
<td>• Streamlined structure to report data (no benefit/risk interpretation)</td>
</tr>
<tr>
<td>• Consistent with CPT headings</td>
<td>• Streamlined common wording consistent with CPT</td>
</tr>
<tr>
<td>• Template only contains CSR body; appendices and TFLs are left to company standards</td>
<td>• Adherence with ICH E3 and CORE guidance</td>
</tr>
<tr>
<td></td>
<td>• Avoidance of redundancy by referring to appended documents</td>
</tr>
</tbody>
</table>
Approach to the common Clinical Study Report

Collaboration

• The expertise of sponsor companies has been tapped to develop the template
• Stakeholders have the opportunity to suggest revisions; the template will be maintained and updated over time
• Broad adoption will help drive greater efficiency for regulators and better feedback for sponsors

Based on well-known standards

• The template was initiated in adherence with ICH E3 and CORE

Improved efficiency

• The template is lean
  • Reduced redundancy due to reference to Protocol and SAP in the appendices
  • Less chance of error
  • Avoids duplication and possible contradiction with submission summaries
How was the Common CSR Template Developed?

Participating Member Companies

- Allergan
- AMGEN
- astellas
- AstraZeneca
- Bristol-Myers Squibb
- EMD Serono
- gsk GlaxoSmithKline
- Johnson & Johnson
- MERCK & CO., INC.
  Komilworth, N.J., U.S.A.
- novo nordisk
- Novartis
- Pfizer
- Roche
- SANOFI
- SHIONOGI

Guidance

- E3: Structure and Content of Clinical Study Reports
- Clarity and Openness in Reporting: E3-based
Focus on a streamlined template to be used to report data, retaining any interpretation of benefit/risk profile of the product for clinical summary documents.

1. CSR Structure and Content will provide value to regulators
   - The same information is located in the same place and means the same thing across Sponsors

2. CSR Structure and Content are adherent with ICH E3 and CORE (Clarity and Openness in Reporting: E3-based)
   - Information requested in guidance is present in CSR content; order has been rearranged in some places

3. Refer to primary sources of information (e.g. Protocol, SAP) in appendices instead of duplicating information in the protocol
   - CSR content is significantly shorter and allows writer and reviewers to focus on the results of the study
What Does the Common CSR Template Look Like? The Model

**Common CSR Backbone**

- Common Level 1 Headings
- Common streamlined text
- Used across all phases
- Focus on reporting data

**Appendices & TFLs**

- Clarity and Openness in Reporting: E3-based
- Apply Sponsor specific standards

**Guidance & Governance Model**

- TransCelerate Implementation toolkit materials
- Governance model in development at TransCelerate

**E3: Structure and Content of Clinical Study Reports**

**ICH**
What Does the Common CSR Template Look Like?
Common CSR Template Editions

**Basic Word Edition**
- A document based template for use across phases and study types
- Use as-is or modify current format template to reflect Common CSR content
- Initial Public Release: November 2018

**Technology Enabled Edition**
- An MSWord-based template with add-ins
- Automation to reuse content from the protocol
- Anticipated Public Release: Fall 2019

For Microsoft Windows-based usage, not compatible with Apple iOS.
Common CSR Template is Intended to Prepare for the Future State

- A common CSR template structure with harmonized language
- Streamlined content and consistent structure enables identification of critical information for end users

- Facilitate automated reuse of content from protocol to CSR to ensure consistency and improve efficiency
- Reconnect processes (protocol to SAP and CSR)
- Enable efficient content reuse downstream of the CSR (e.g. disclosures)
Thank you