

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

# How was the Common CSR Template Developed?

## Structure and Content

### Structure

- Adherence with ICH E3 & CORE guidance
- Consistent with CPT headings
- Template only contains CSR body; appendices and TFLs are left to company standards



### Section Content

- Streamlined structure to report data (no benefit/risk interpretation)
- Streamlined common wording consistent with CPT
- Adherence with ICH E3 and CORE guidance
- Avoidance of redundancy by referring to appended documents

# 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



## Guidance



E3: Structure and Content of Clinical Study Reports



Clarity and Openness in Reporting:  
E3-based

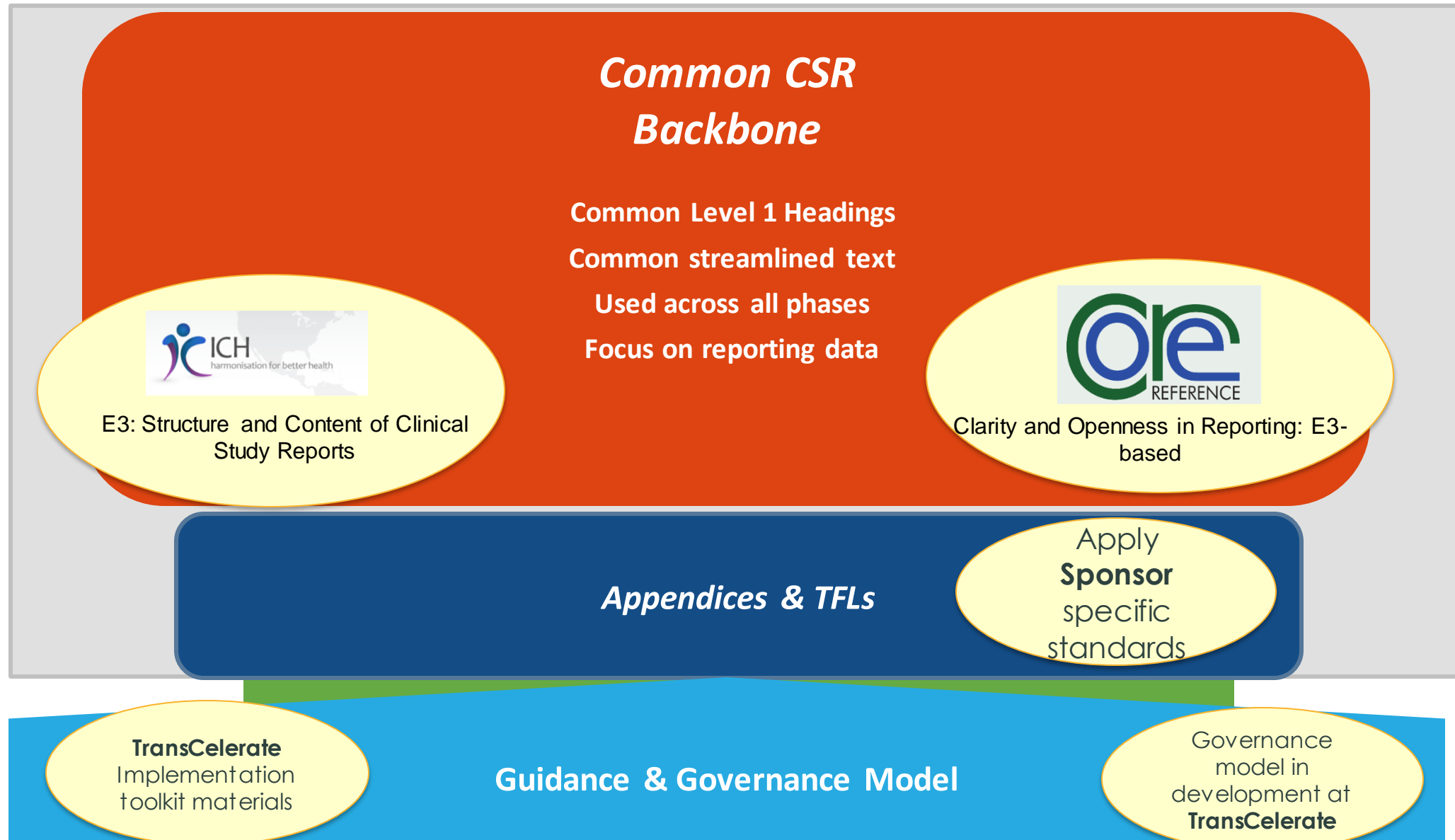
# How was the Common CSR Template Developed?

***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



# What Does the Common CSR Template Look Like?

## Common CSR Template Editions

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### Basic Word Edition

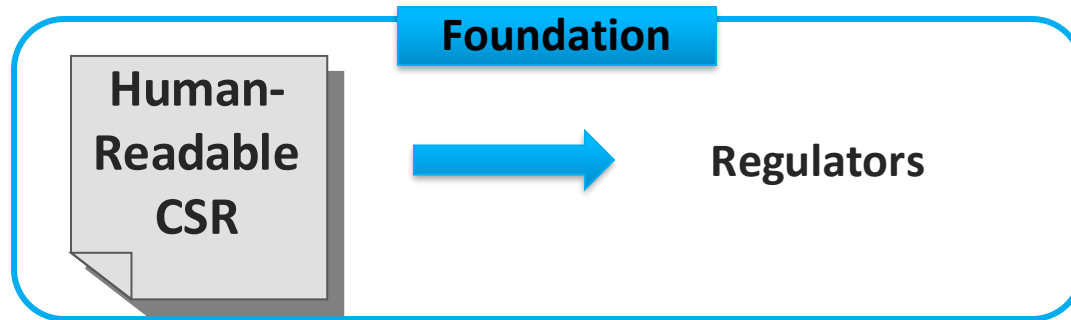
- A document based template for use across phases and study types
- Use as-is or modify current format template to reflect Common CSR content
- Initial Public Release: November 2018

### Technology Enabled Edition

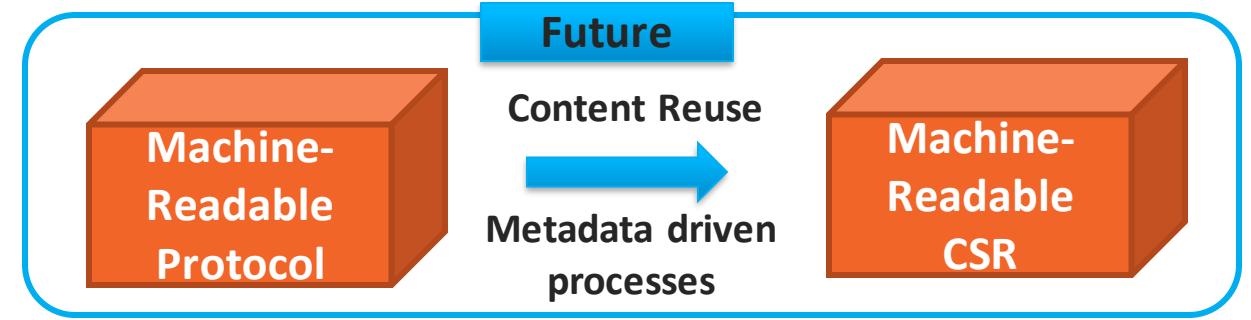
- An MSWord-based template with add-ins
- Automation to reuse content from the protocol
- Anticipated Public Release: Fall 2019

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*