



SA04: Diversity, Equity, and Inclusion of Your Submission Package

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PHUSE EU CONNECT 2021

Submissions & Agencies Stream

16-NOV-2021

Agenda slide

- 1 Introduction to Diversity, Equity and Inclusion (DEI)

- 2 DEI in teams

- 3 DEI in clinical trials

- 4 DEI in regulatory submissions

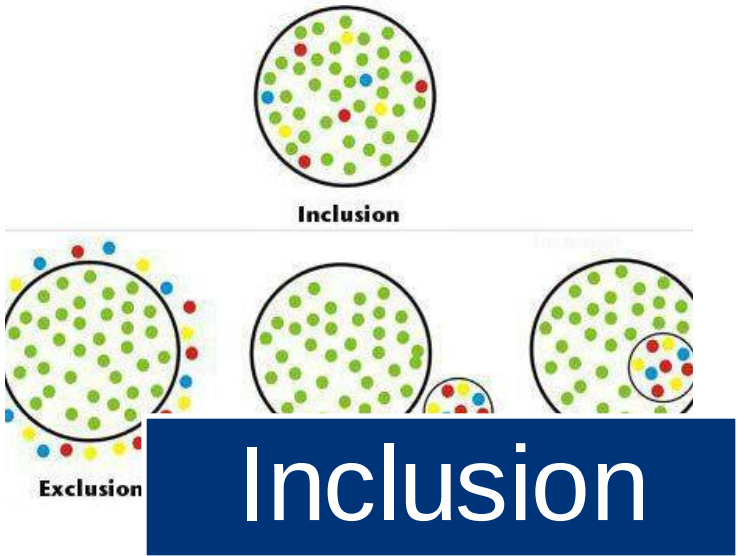
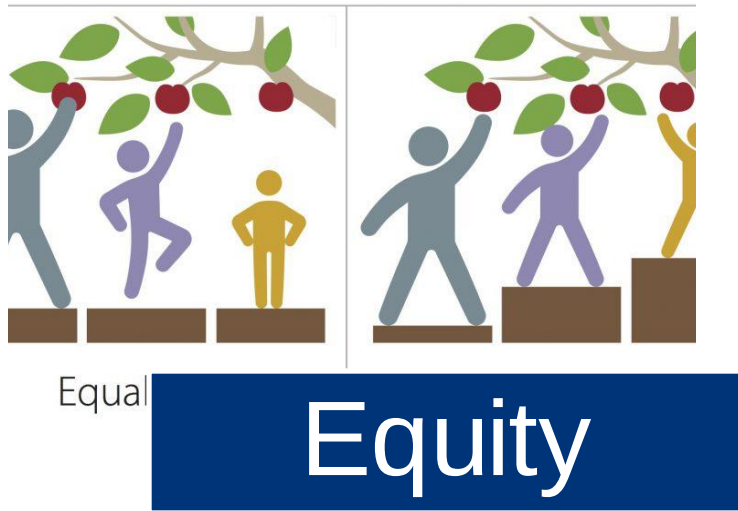
- 5 Section 508

- 6 FDA feedback & Conclusion

An abstract graphic consisting of a network of light blue dots connected by thin lines, forming a complex, web-like structure that spans the width of the slide. The dots are of varying sizes and are distributed across the background, with a higher density of connections in the center and more sparse connections towards the edges. The overall effect is a sense of interconnectedness and complexity.

Intro to DEI

Introduction to DEI



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https://uploads-ssl.webflow.com/5be759f8b95161f3c1ce8125/5d43d7f3500bcb5968d1cb7f_Variations-Diversity.png
<https://oer18.oerconf.org/wp-content/uploads/sites/28/2018/02/What-does-equity-mean--1024x560.jpg>
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DEI in teams

DEI in teams



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DEI in clinical trials

DEI in clinical trials

- FDA published guidance in 2020 on increasing diversity of clinical trial populations:
<https://www.fda.gov/media/127712/download>

Enhancing the Diversity of Clinical Trial Populations — Eligibility Criteria, Enrollment Practices, and Trial Designs Guidance for Industry

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

November 2020
Clinical/Medical



DEI in Clinical Trials

1. Broadening Eligibility Criteria

- Inclusive Trial Practices
- Trial Design
- Trial Enrichment Strategies ([specific FDA guidance](#))

2. Study Design & Conduct to Improve Enrollment

- Trial Participation Burden
- Enrollment and Retention Practices
- Expanded Access

3. Rare Diseases

- Engaging Patient Groups
- Re-enrollment
- Open Label Extensions

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DEI in regulatory submissions

Digital Accessibility

Accessible Design

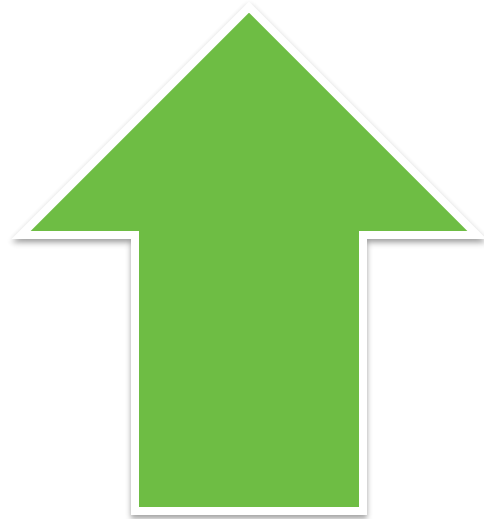
- Design that takes into consideration how people are able to understand the information presented
- Helps people living with:
 - Color blindness
 - Visual impairments
 - Neurodiversity
 - Autism
 - Dyslexia

Assistive Technology

- Assistive technology is any item (including software) that is used to increase, maintain, or improve the functional capabilities of persons with disabilities

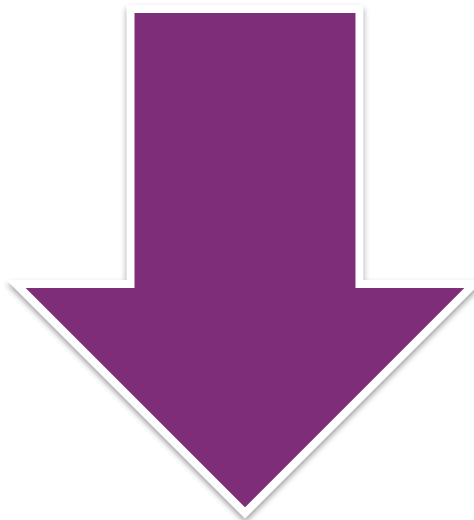
Digital Accessibility – Dyslexia Example

Accessible Design



DOs

- Use images and diagrams to support text
- Align text left and keep a consistent layout
- Produce materials in other formats (e.g. Videos)
- Keep content short, clear, simple
- Allow users to change contrast settings



DON'Ts

- Use large blocks of heavy text
- Underline word, use italics, write in capitals
- Rely on users to remember information from a previous page
- Rely on accurate spelling
- Put too much information in one place

Assistive Technology

- Speech recognition software
- Text-to-speech software
- Mind-mapping software
- Scanning software and hand reading pens
- Spell- & Grammar-checker
- Apple iOS Accessibility
 - Voice Over
 - Guided Access
 - Assistive Touch

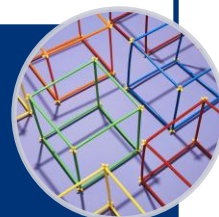
Section 508

- Section 508 is an Amendment to the U.S. Rehabilitation Act of 1973.
- It stipulates that U.S. federal agencies are responsible for ensuring their information and services are accessible to persons with disabilities.
- Section 508 standards are applicable to:
 - IT tools and systems
 - Electronic content:
 - Documents (Word, PDF, Excel),
 - Web pages,
 - Presentations (PowerPoint),
 - Social media content,
 - Blogs,
 - Certain emails
- The U.S. Department of Health & Human Services (HHS) has developed checklists that provide the evaluation criteria that must be met to ensure content is accessible to all users: <https://www.hhs.gov/web/section-508/accessibility-checklists/index.html>
- These checklist have been adopted by the FDA and are also available on their website: <https://www.fda.gov/about-fda/internet-accessibility/requirements-checklists-section-508>

Section 508 – Common requirements

- **No flashing or flickering** elements.
- **Track changes** need to be accepted or rejected and then **turned off** as well as comments and formatting marks.
- All the **URL's must be active** and linked to the correct destination.
- There must be an alternate method if color was used to **emphasize importance** of text.

Document Layout



- Include **alternative text** (alt-tag) descriptions to be read by assistive technology (for images and non-text elements).
- No watermarks or background images
- The **image text wrapping style "In Line with Text"** must be used for all images.
- **Group associated images** as one object.

Document Images



- All tables **must have a Row and/or Column header** and be read from **left to right, top to bottom**.
- Tables must **not use merged cells**.
- All charts should have a **Title, Legend and Axis labels** associated with them.

Document Tables & Graphs



- **Footnotes, page numbers** etc. should be added to a document using the **tools available within the application** (e.g., When working in Word, add footnotes using the Word Footnote tool).
- Document file names should be **concise and free of special characters**.
- Run the **Inspect Document** function as well as the **Microsoft Accessibility Checker**.

Other



Section 508 – Specific Requirements



Word Checklist

- Format using **style elements** in a **hierarchical manner** (i.e. Heading 1, Title, Emphasis, Outline, etc...).
- Additional requirement on descriptive text for complex charts or images that are part of the Word document.
- Do not allow table rows to break accross pages.



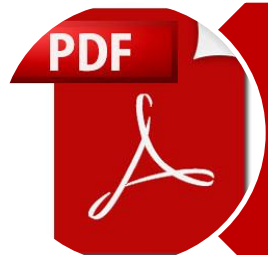
PowerPoint Checklist

- All slide text can be viewed in the Outline View.
- Additional requirement on descriptive text for complex charts or images that are part of the PowerPoint document.
- Do not copy charts/tables from Excel, create them using the Chart/Table tool available in PowerPoint.



Excel Checklist

- One sheet per table or graph
- Graphs should have sufficient contrast, even when printed in greyscale.
- If a tables spans multiple pages, header information should be repeated.



PDF Checklist

- Additional requirements for document properties.
- Also refer to the FDA's Portable Document Specifications Technical Guidance.
- All document functionality is available (receive focus and can be activated) using the keyboard.

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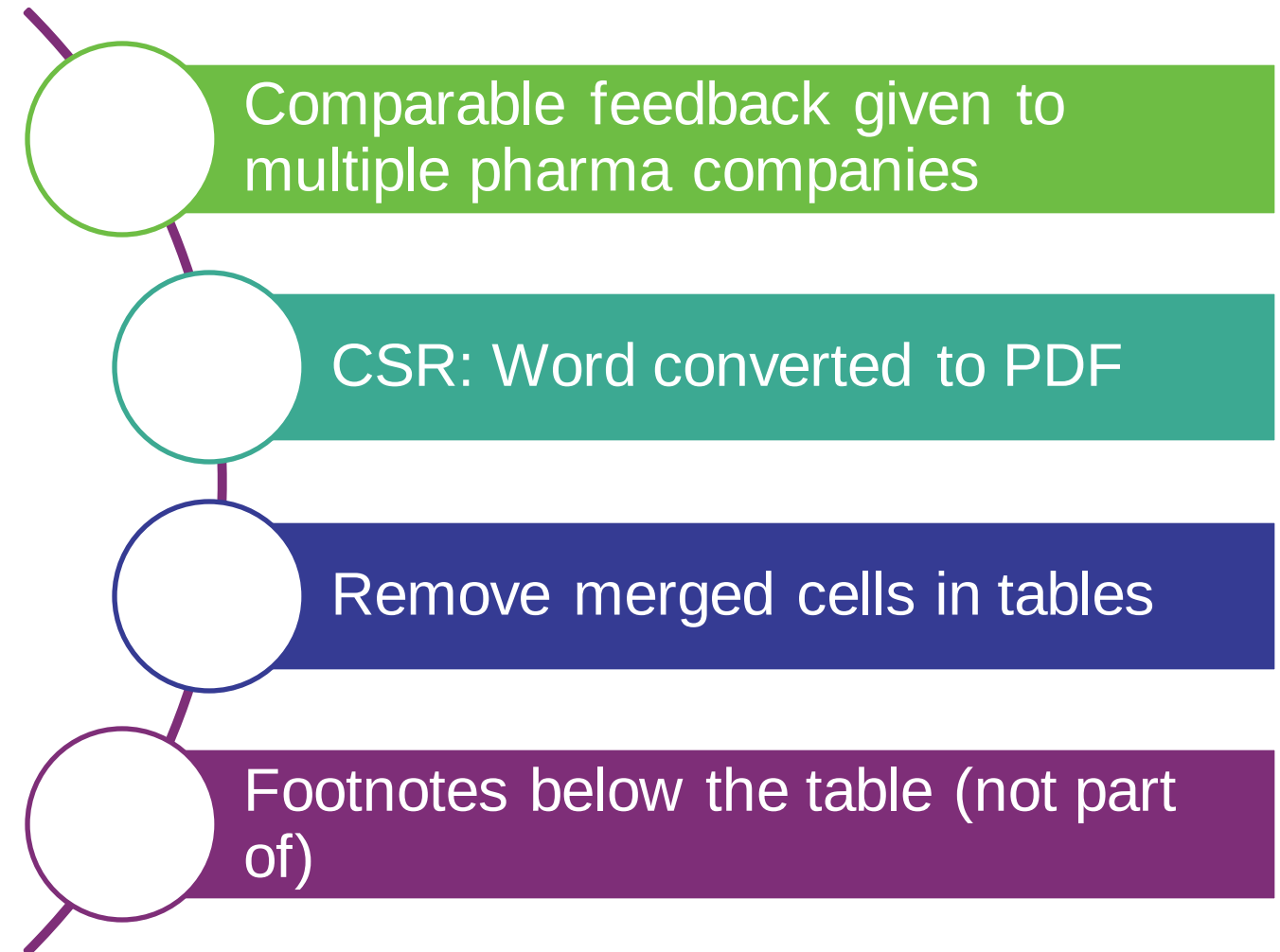
FDA feedback

Recent FDA feedback has the potential to cause significant rework

- CBER and CDER have confirmed that these requirements **will not be added to the Technical Conformance Guide** (for now).

However,

- Recommendation to **discuss with individual reviewer.**



Conclusion and Q&A

- **Diversity** should be taken into consideration at **all levels of clinical research**, from the team, to the patients and even the submitted package.
- **Checklists** for your submitted documents are available on the FDA website.
- **Engage with your reviewer** at the earliest opportunity.



