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# CSS 18 – Data Transparency

WG Presentation & Agenda

Jean-Marc Ferran (Qualiance)

WG Lead

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# PhUSE Data Transparency WG Vision from 2014...

**“Develop data de-identification standards  
for CDISC data models”**



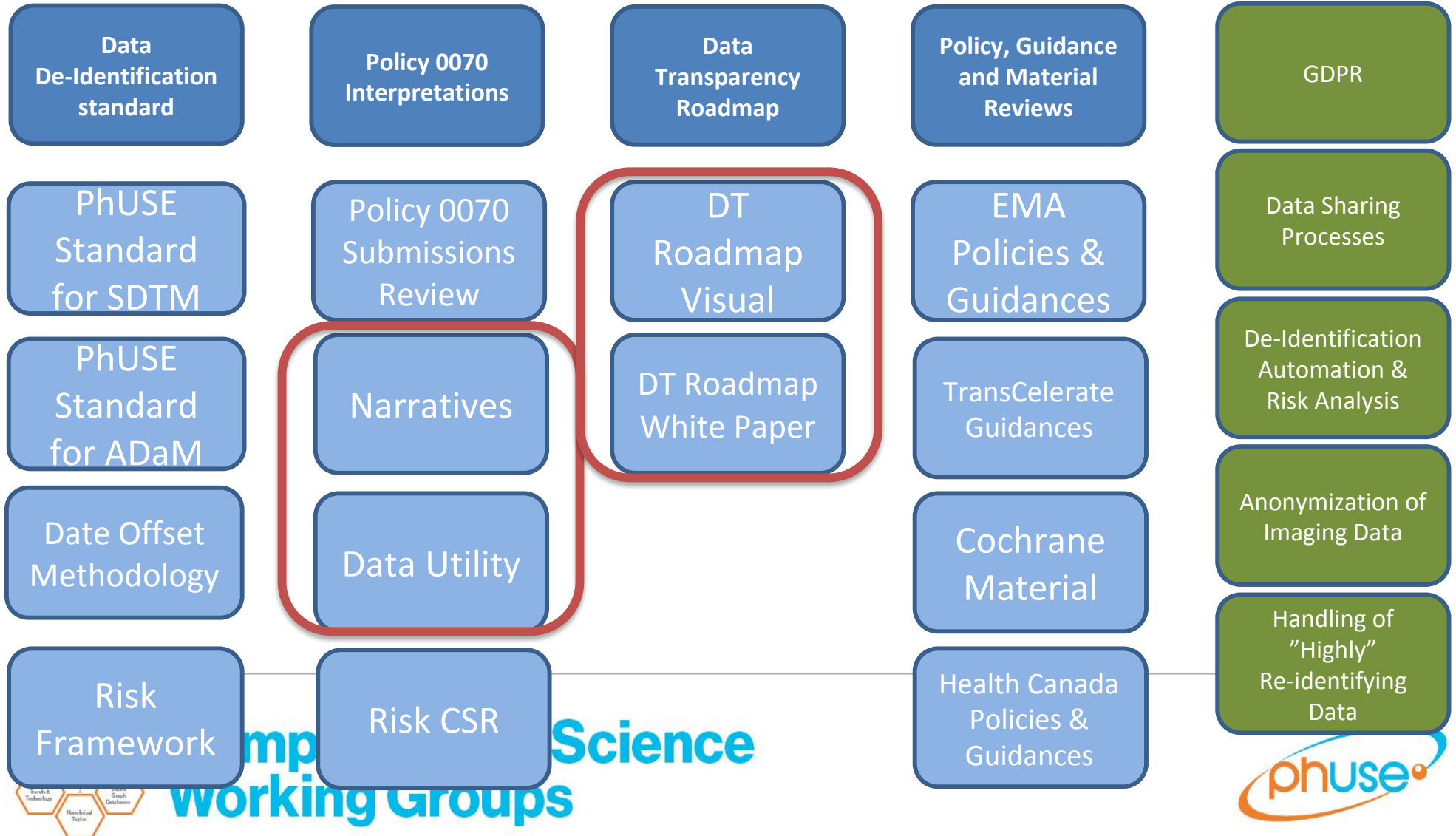


# Computational Science Working Groups



# PhUSE Data Transparency WG

## 2018 Projects



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# PhUSE Data Transparency WG

## Reviews & Collaborations so far...



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# PhUSE Data Transparency WG

## Agenda – Monday 5. March

Time (EST)	Topic
08:30 - 10:30	<b>“Be an FDA Reviewer for the Day: Take an Interactive Journey through the JumpStart Process”</b>
10:30 - 11:00	Coffee Break
11:00 – 12:00	<b>Session 1: Working Group Overview</b>
12:00 – 13:00	Lunch
13:00 – 14:00	<b>Session 2: Data Transparency, the FDA perspective</b>
14:00 – 14:30	Coffee Break
14:30 – 16:30	<b>Session 3: Review of Data Transparency Roadmap</b>
17:00 - 18:30	Poster Session



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# PhUSE Data Transparency WG

## Agenda – Tuesday 6. March

Time (EST)	Topic
08:30 – 10:00	<b>Session 4: Handling of Narratives in anonymized CSR</b>
10:00 – 10:30	Coffee Break
10:30 – 12:00	<b>Session 5: Data Utility</b>
12:00 – 13:00	Lunch
13:00 – 14:00	<b>Session 6: Wrap-up &amp; Next Steps</b>
14:30 – 16:00	<b>“Vision &amp; Collaboration: Integrating PhUSE, CDISC and Regulatory Stakeholders to ensure Public Health”</b>
16:00 – 16:30	Poster Awards and Closing Session



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Gregory Campbell (Gilead)	Jiaan Illidge (Caratherapeutics)	Stephen Bamford (J&J)
Nand Kishore Rawat (Cytel)	Stephen Baker (d-Wise)	Other?
Arlene Coleman (Pfizer)	Chris Connor (d-Wise)	Other?
Julie Holtzople (AstraZeneca)	Catherine Munera (Caratherapeutics)	Other?
Linda Gau (Pcyc)	Jack Zhang (FDA)	Other?
Alex Hughes (Roche)	Micaela Salgado-Gomez (Pharma Stat)	
Jean-Marc Ferran (PhUSE)	Ann Witt (FDA)	
Vasanthi Naidu (MMS Holdings)	Hima Bhatia (ICON)	
Veera Thota (MMS Holdings)	Rashmi Dodia (MMS Holdings)	

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