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# Nonclinical Topics

Jaga Virayah; Phil Drew



**Computational Science  
Working Groups**



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# Working Group Objective

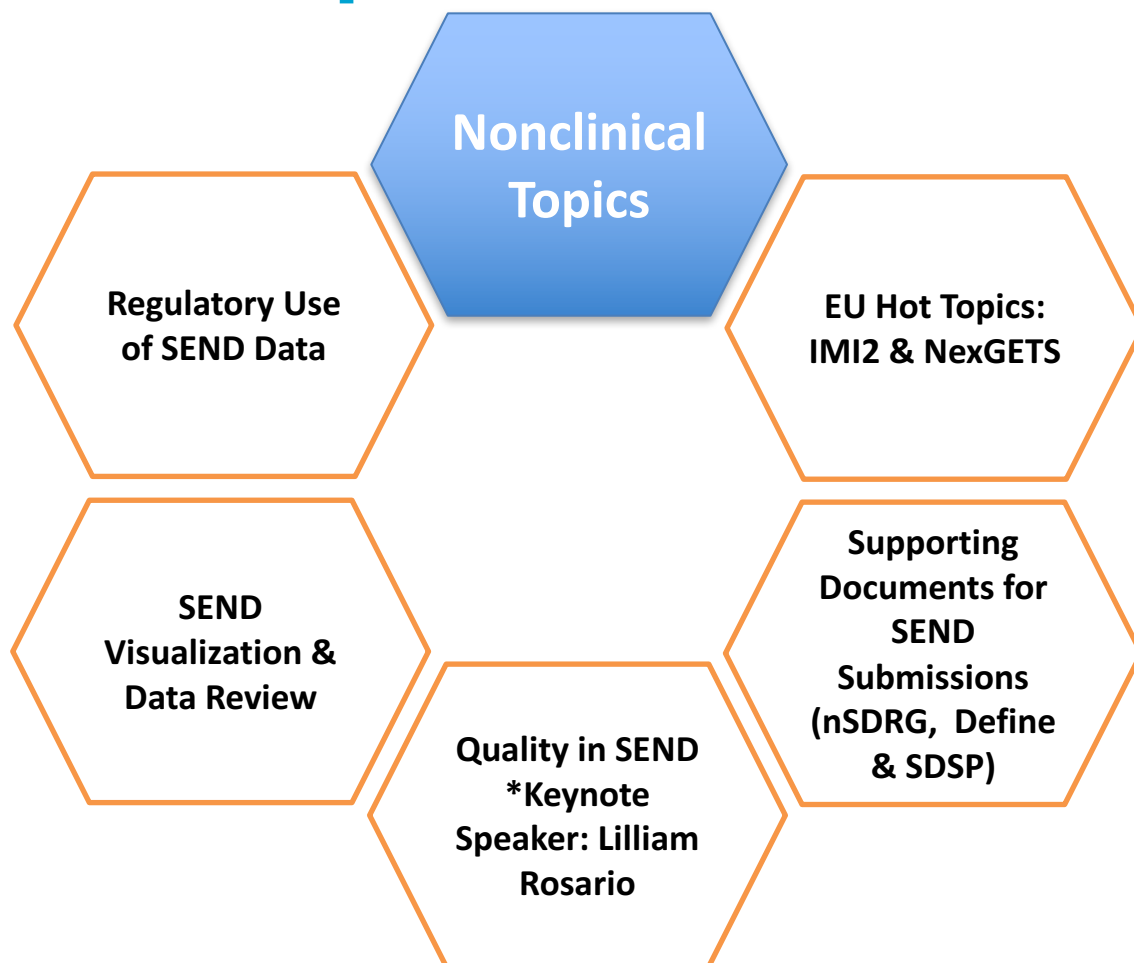
- Improve nonclinical assessments and regulatory science by identifying key needs and challenges in the field and then establishing an innovative framework for addressing them in a collaborative manner.



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# Nonclinical Topics



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# Key Themes

## Data that is fit for USE

- Fit-for-Use Pilot; Review template
- Conformance vs. Reviewability

## Voluntary/Pilot Submissions

- Feedback from FDA
- Support FDA workflow optimisation

## Visualisation of data for review/research purposes

- Going beyond the regulatory use of the data

## Industry Best Practices

- nSDRG; SDSP
- Open sharing of ideas & experiences



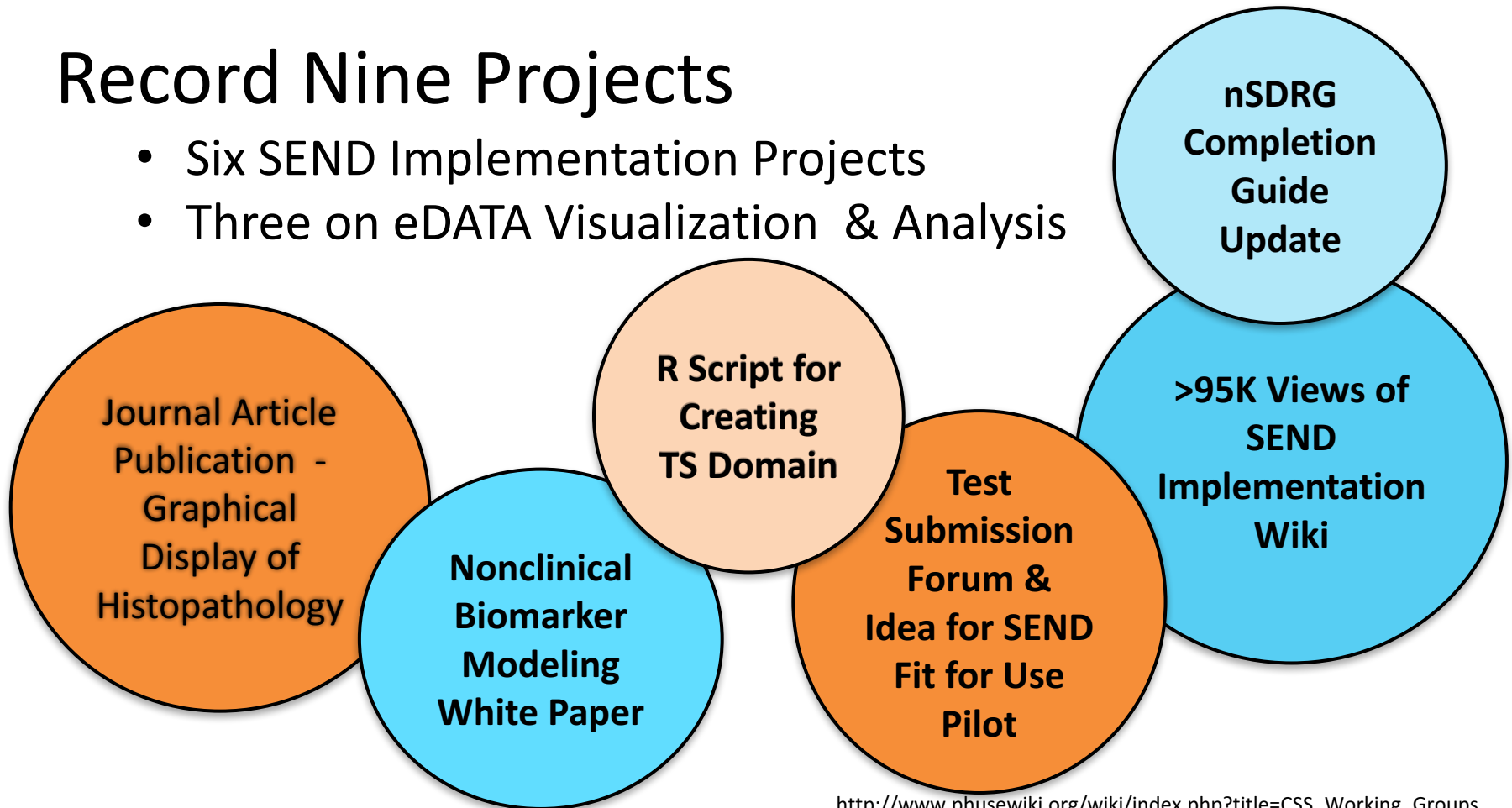
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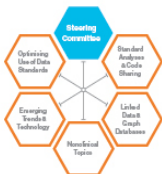
# Working Groups

## Record Nine Projects

- Six SEND Implementation Projects
- Three on eDATA Visualization & Analysis



[http://www.phusewiki.org/wiki/index.php?title=CSS\\_Working\\_Groups](http://www.phusewiki.org/wiki/index.php?title=CSS_Working_Groups)



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# Thank you!



## Working Group Co-leads

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