



PhUSE 2016 SDE – Frenchtown Integrated Clinical Systems

Chris Hurley, US Events Director
Thursday, August 04, 2016



Today's Sponsors – Thank you!



Thank You Volunteers

Co-Chairs

- Jennifer True, GSK
- Naveed Khaja, SW-T Consulting Group

Venue Contact

- Eric Herbel, Integrated Clinical Systems

PhUSE US Events Project Leads

- Suhas Sanjee, Merck
- Ramesh Satyavarapu, inVentiv Health

PhUSE Director

- Chris Hurley, MMS Holdings



2016 PhUSE Highlights

- 502+ registered so far for Annual Conference
- 313 attended CSS Conference in March
- 18 Single Day Events
- 5 Working Groups with 27 Active WG Projects
- US FDA, EU EMA, Japan PMDA Collaborations
- PhUSE-Industry Future Forum



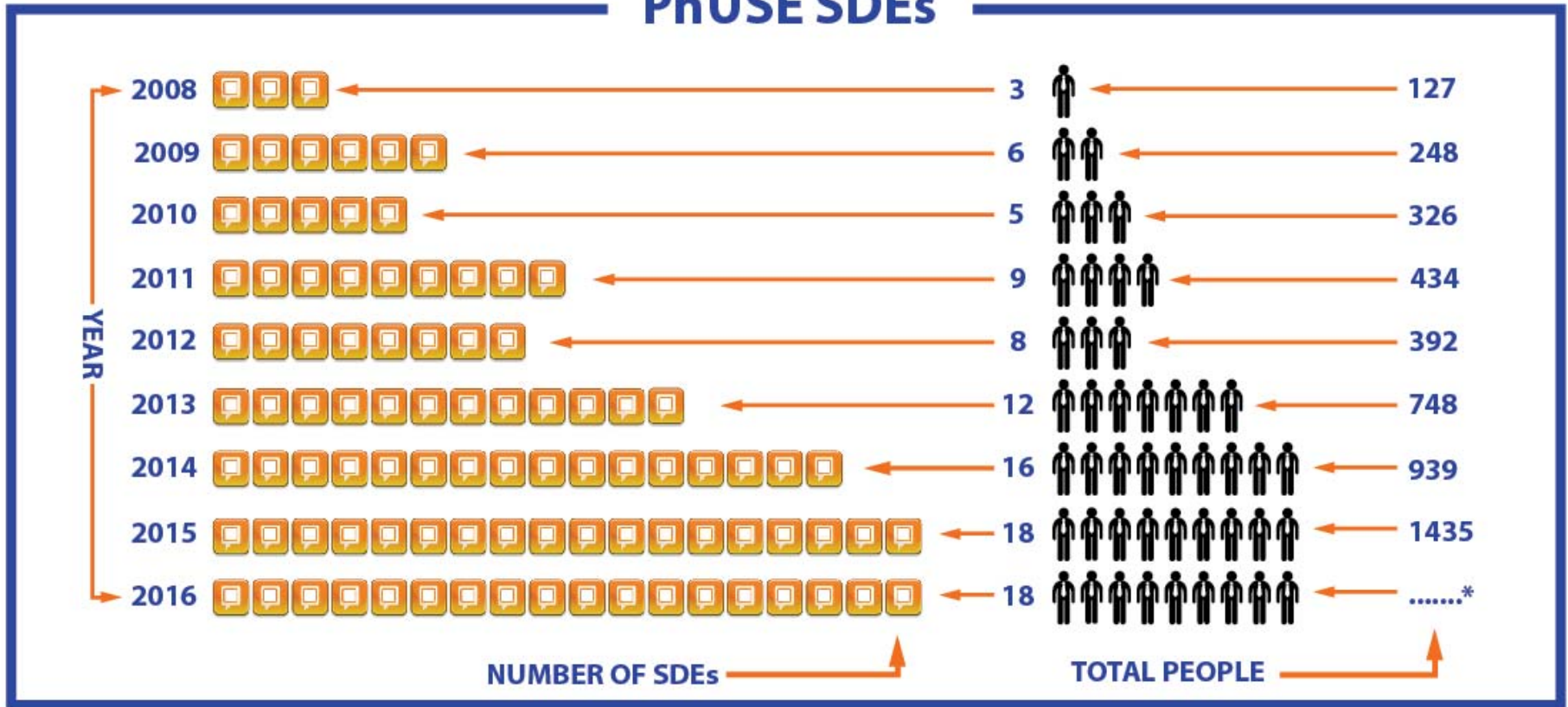
2016 European CSS

- 1st European CSS
 - Basel, Switzerland
 - 102 Attendees

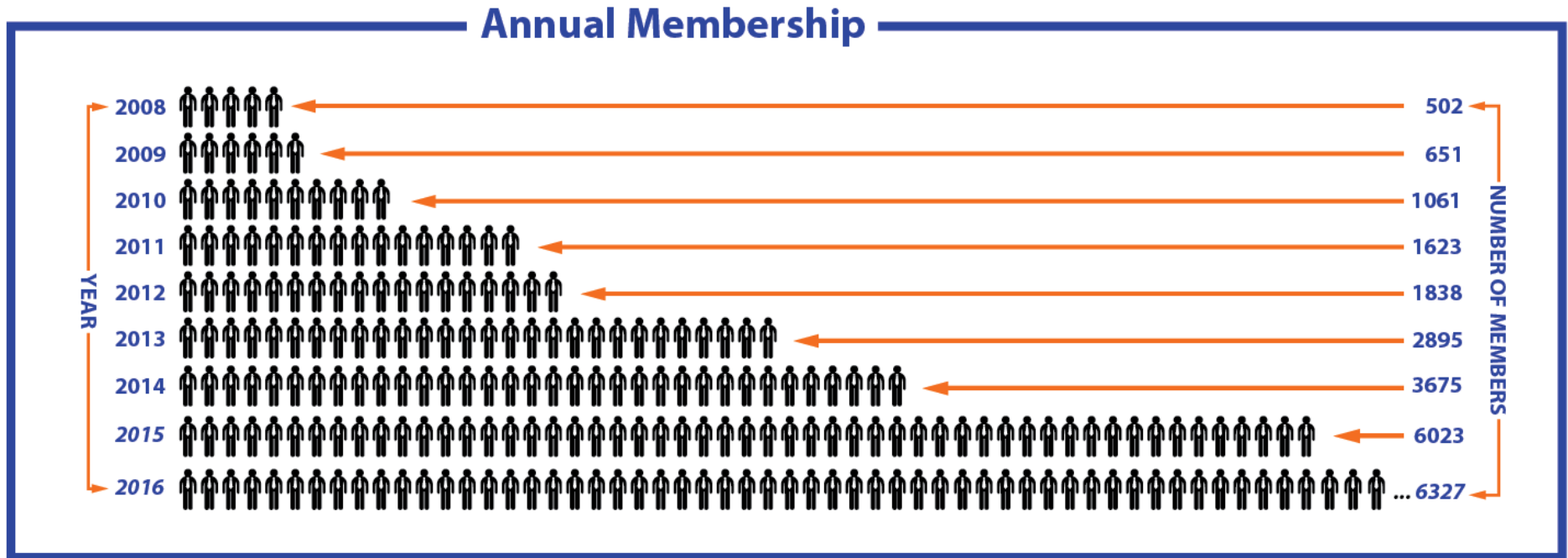
EU CSS 2016 - Basel		Novartis, Basel, Switzerland	21/06/2016	104	102
<u>Options</u>					
Evaluate and Prototype Alternative Transport Formats for Submission				10	
Experiences Statistical Computing Environments				24	
De-identification of ADaM Datasets				20	
Nonclinical Roadmap and Impact on Implementation Working Group				16	
SDTM Implementation FAQ				10	
PhUSE Future Forum: Process Optimization				18	

Global Single Day Events

PhUSE SDEs



World's largest biometrics society



Members as of 03AUG2016 ... 6990!

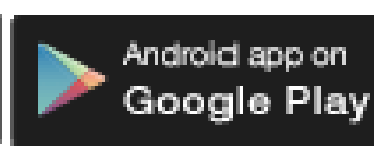
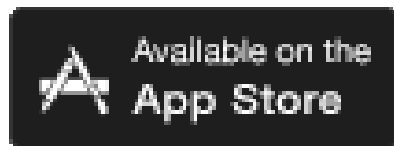
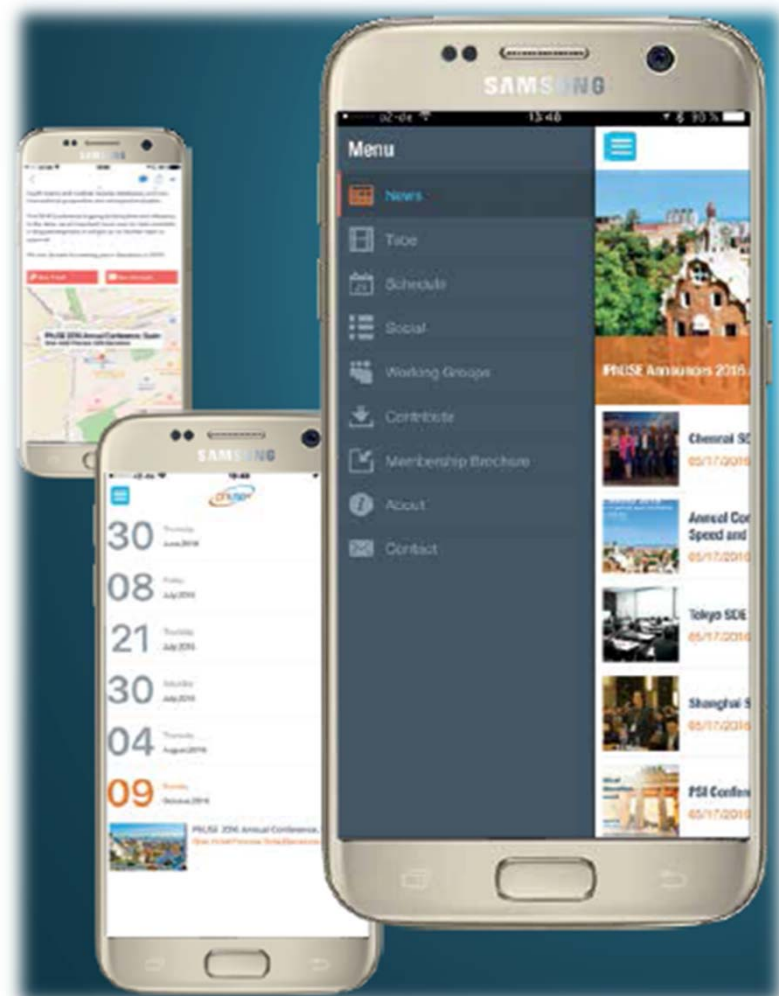
The new PhUSE App

Stay up to date with everything
going on at PhUSE

Mobile access to:

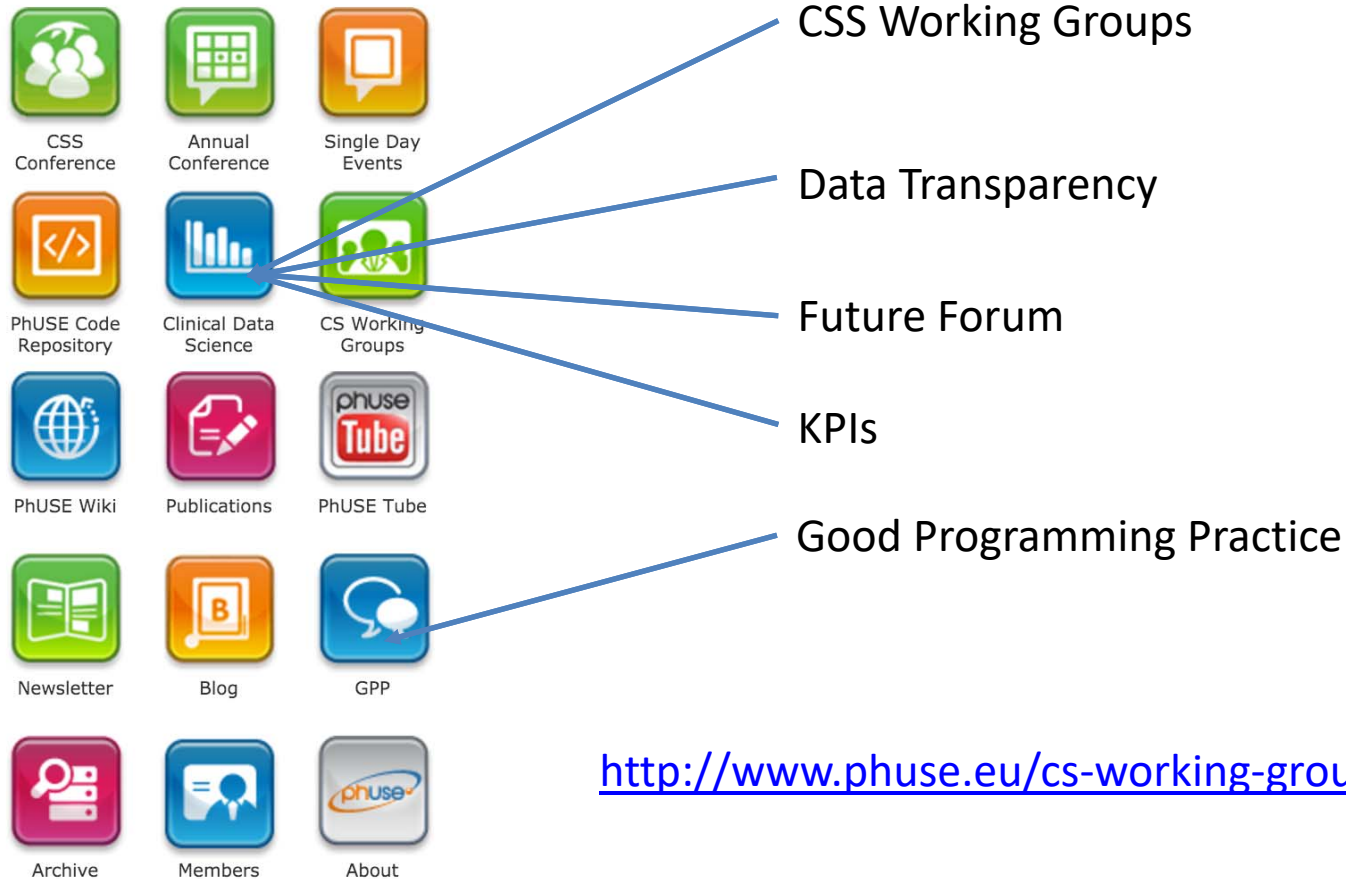
- News
- PhUSE Tube
- Event Schedule with options to register, add to own calendar, routes, etc.
- Social Media Channels
- ...

The next level to
Share – Contribute - Advance





Location of “working groups”

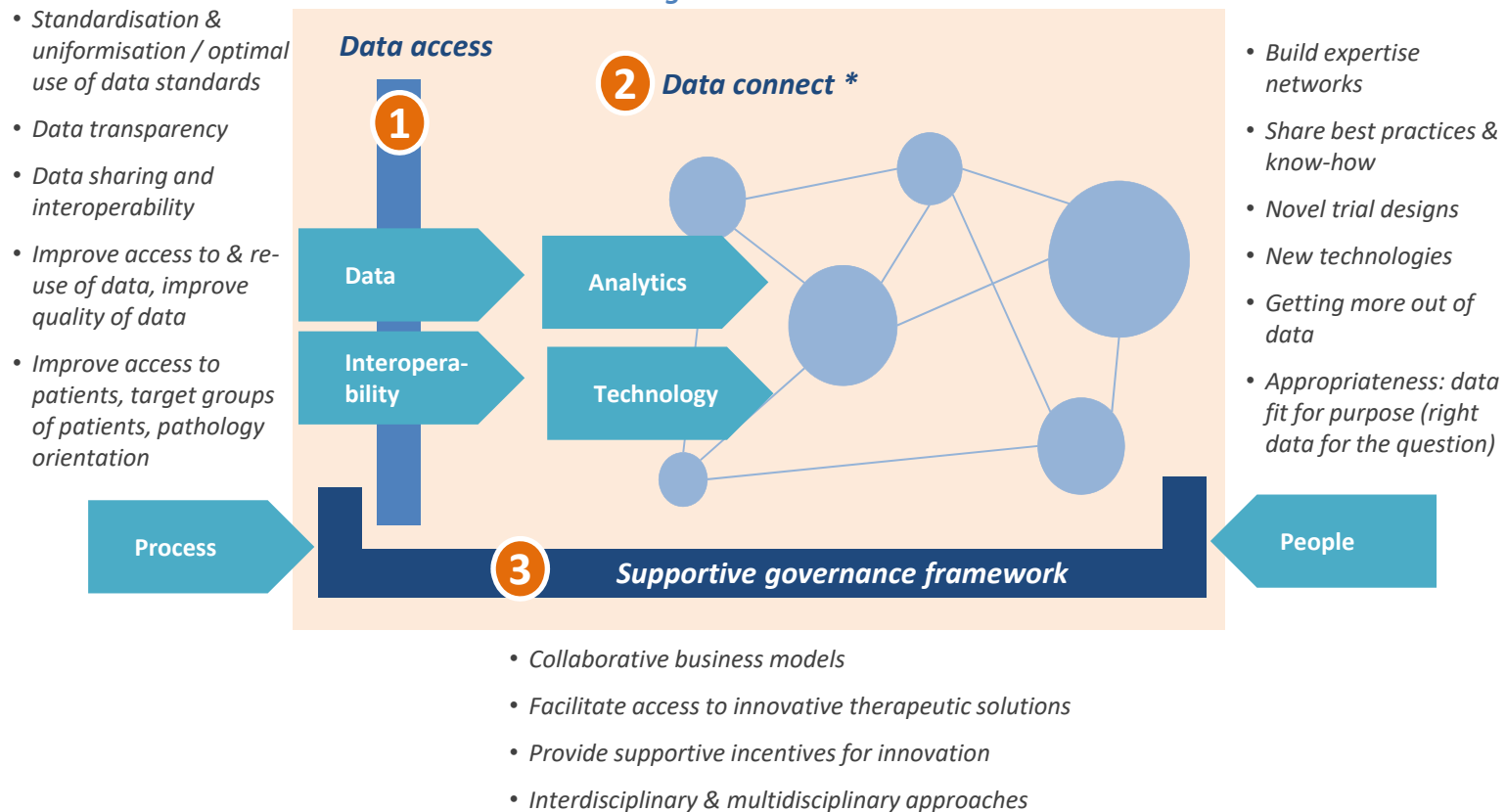


<http://www.phuse.eu/cs-working-groups.aspx>



PhUSE Future Forum - Enabling adaptability and flexibility that will bring more value

PhUSE FUTURE FORUM Strategic Initiatives



PhUSE Data Transparency Workgroups

- 4 Workgroups
 - EMA Policy 0070
 - De-identifying ADaM data
 - Complexities around de-identified partial dates
 - **Risk assessments** on de-identified data



New for
2016!

EMA Policy 0070

- External guidance on the implementation of the EMA policy on the publication of clinical data for medicinal products for human use
- Released March 2nd, 2016
 - References our PhUSE de-identification standards for anonymizing SDTM data
- Provides detailed guidance on document redactions
- Anonymization of Patient Narratives

EMA Policy 0070 - Data

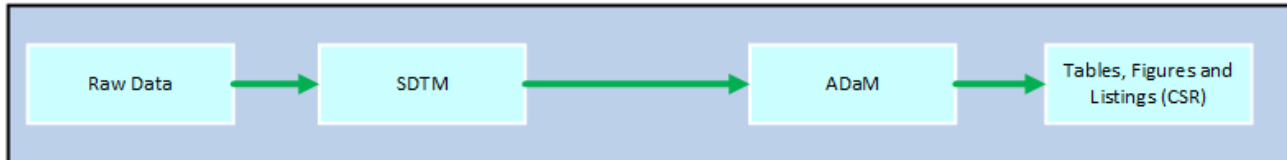
- Risk Assessment in semi-public context vs. controlled data sharing context
- Defining sample populations for anonymization
- Data utility
- Sensitive data and sensitive therapeutic areas
- Contents of Anonymization report

ADaM De-identification

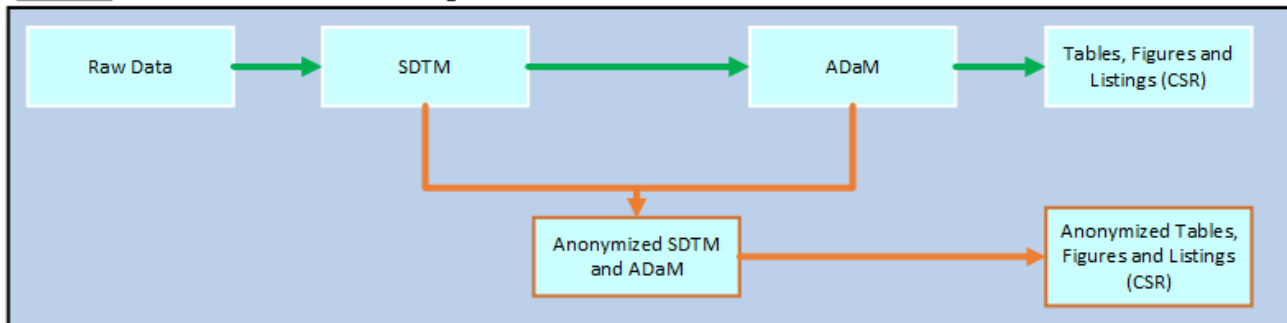
- Standards are still being worked out
- Expected release this year
- Existing SDTM 3.2 De-identification standards
 - [http://www.phuse.eu/Data Transparency download.aspx](http://www.phuse.eu/Data_Transparency_download.aspx)
- Various process scenarios are still being worked out

Current and Possible Future De-Identification Scenarios

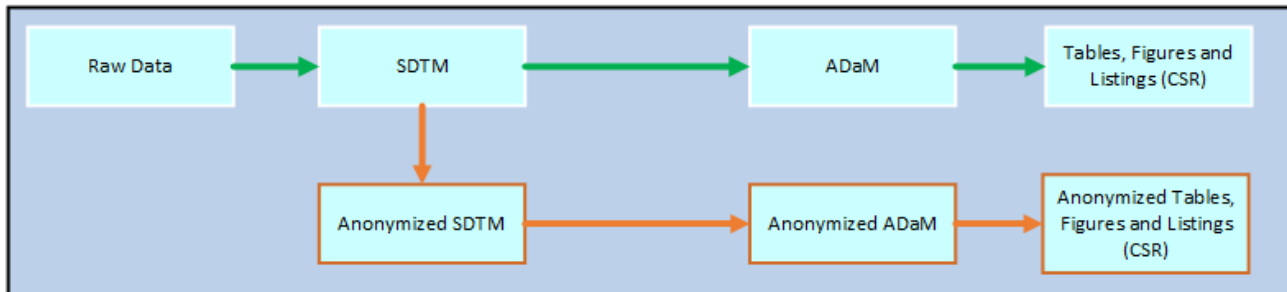
Clinical Data Flow



Current: DeID SDTM and ADaM Together



Future: DeID at SDTM



→ Clinical Data Analysis Code

→ Anonymization Code



ADaM De-identification

- Handling partial dates different than in SDTM
- Three common practices are being evaluated
 - Imputed using offset SDTM partial dates
 - Setting imputed ADaM dates (+flags) to missing
 - Only using relative days instead of date fields

Risk Assessment

- Grey area due to lack of guidance and expertise
- Looking at initial recommendations about risk to develop more comprehensive guidance
- EMA's [guidance](#) about risk assessment in semi-public context vs. controlled data sharing is a major driver

Looking Ahead: 2016 Single Day Events

	  	Beijing, China - 8th July Deerfield, IL - 21st July Trivandrum, India - 30th July
	 	Frenchtown, NJ - 4th August Tokyo, Japan - 4th August
	 	Shanghai, China - 4th November Durham, NC - 10th November
		Mumbai, India - 3rd December

2016 Annual Conference



Annual Conference 2016

Fast Track to Approval: Speed and Efficiency

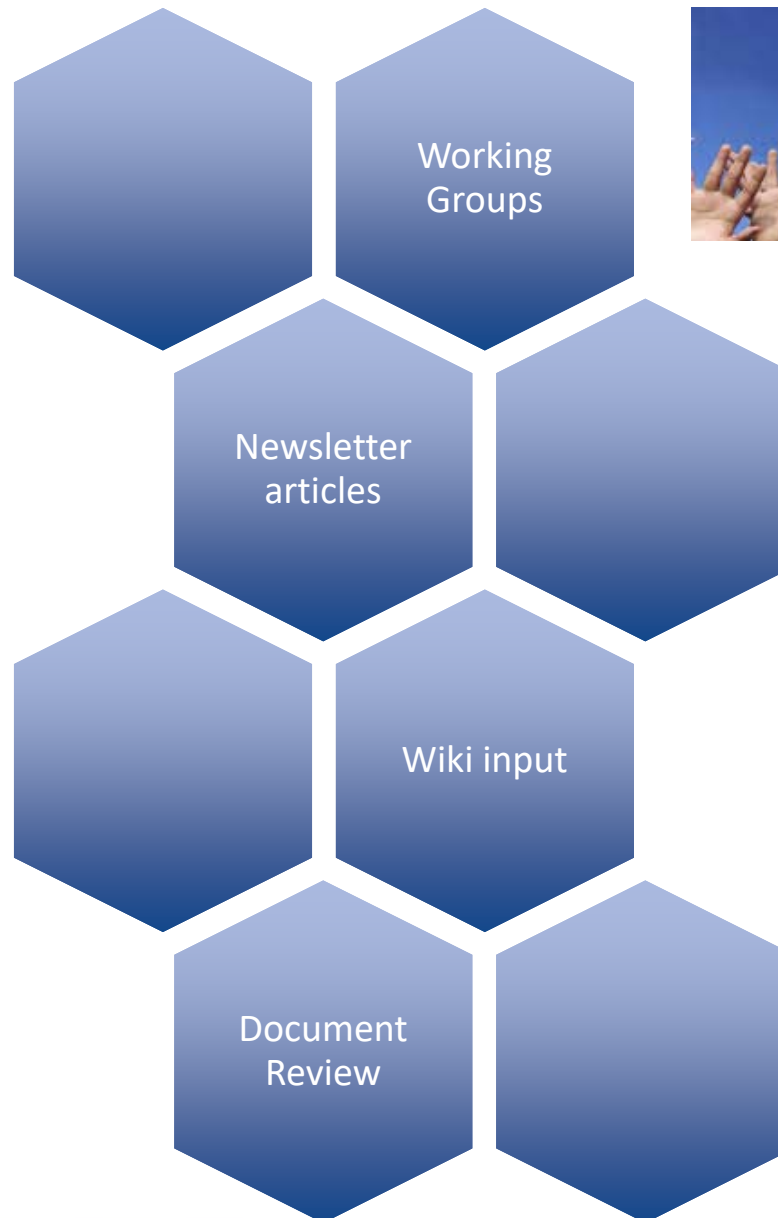
9th - 12th October 2016

****Registration Opens 1st March****





WE NEED YOU !





The premier community for people working in the biometric area



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PhUSE



www.phusewiki.org