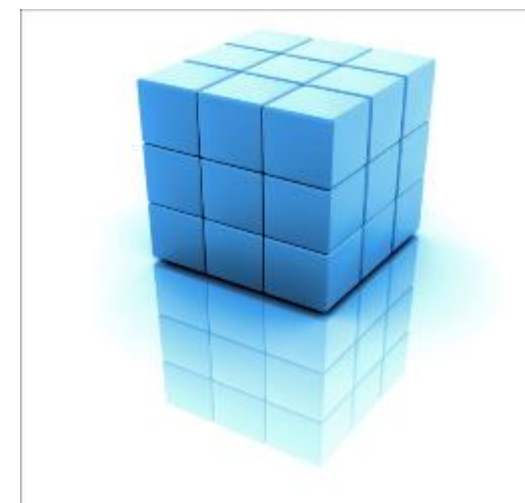


PhUSE Beerse SDE

Review safety signals from Interim or submittable SEND datasets using MySEND



11-SEP-2019

www.pointcross.com

Agenda

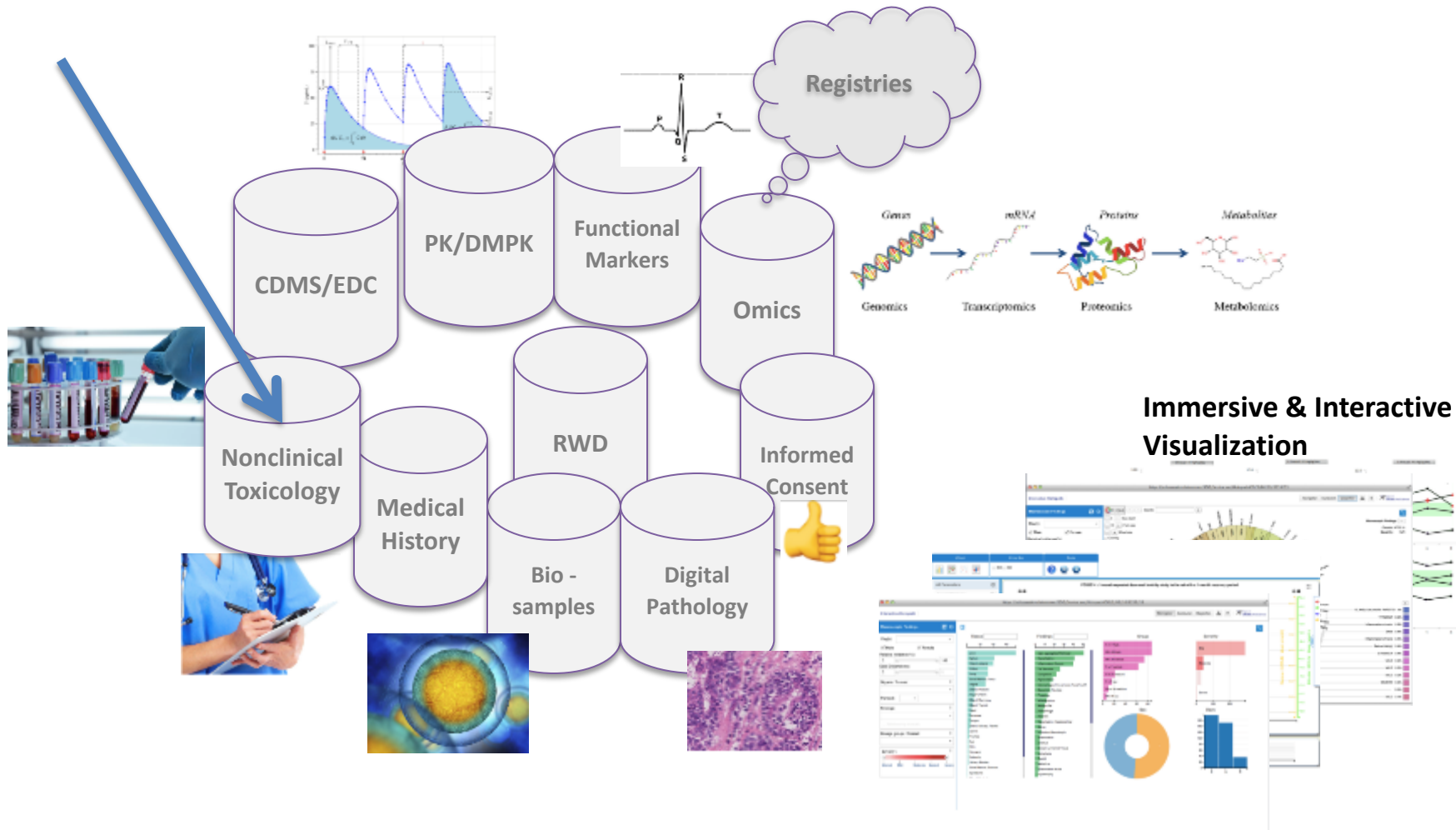
- Introductions – PointCross Life Sciences, Xbiom and MySEND
- MySEND – a review tool
- **Review safety signals from Interim or submittable SEND datasets using MySEND**
by Dr. Dragomir Ivanov Draganov, Roche

About PointCross Life Sciences

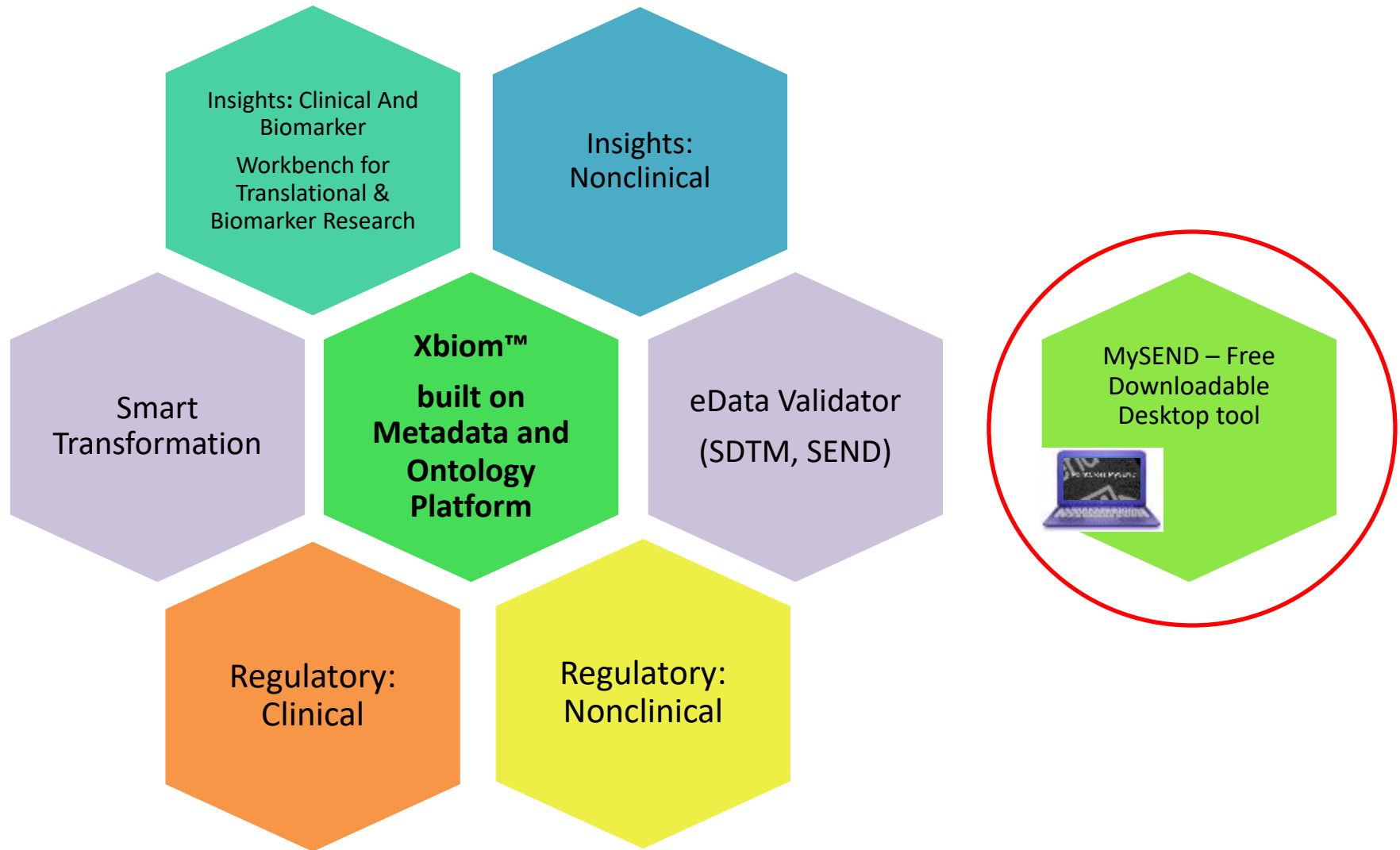
- PointCross Life Sciences is a wholly owned subsidiary of PointCross Inc.
- Serving Pharma and BioTechs since 2009
 - ✓ Xbiom Technology for Regulatory Submissions and Research Insights – Nonclinical, Clinical and Biomarkers for Translational Research
 - ✓ MySEND – a freely distributed downloadable SEND visualization version of Xbiom-NC
 - ✓ Automation for curation, transformation, standards management & governance, terminology ontology and harmonization of disparate c
- Global Clients: Roche, Sanofi, Bayer, Eisai, Ipsen, NGM,
- Contributor to PhUSE, CDISC, Industry Events
- FDA contractor and provider of technology
- Located at – Foster City - CA, Silver Spring - MD, Paris - France, Bangalore - India
- Gartner “Cool Vendor” in Life Sciences in 2013



Data from disparate sources from Nonclinical, Clinical Trials and Biomarker Assays



XbiomTM Suite for Research & Regulatory in Clinical & Nonclinical



MySEND visualizations

- MySEND concept :
 - Dataset Validation – eDataValidator for SEND, SDTM conformance to FDA, PMDA, CDISC rules
 - SEND Data visualization in SEND Trial Design as well as Dose Group
 - nSDRG generation
 - Trial Design generation
 - TS.xpt generation
 - Quality and consistency (with PDF report) checks
- Focus today : MySEND visualizations for Safety Review of interim or final SEND data
 - Templated Immersive and Interactive views
 - Cross Domain correlations
 - Exploring/Navigating the data for better understanding

Download MySEND from: <https://info.pointcrosslifesciences.com/mysend>

Dr. Dragomir Ivanov DRAGONOV, Data Science Lead, Roche

LIVE DEMO FROM MYSEND

Q&A

Thanks for attending

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