

# GUF

# 1st Session 2018

Espace Palissy, Boulogne-Billancourt (Paris)

29 Mai

# Welcome ! 😊

## Any newcomers?

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## To the veterans



GOOD TO SEE YOU AGAIN

# Special Thanks to



# And to our sponsors



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 medidata

THE  
ARCHITECTURE  
OF  
HOPE™

*About Us*

**1K**  
customers

**100+**  
industry  
partners

**18** of top 25  
pharma  
customers

**18** of top 25  
med device  
customers

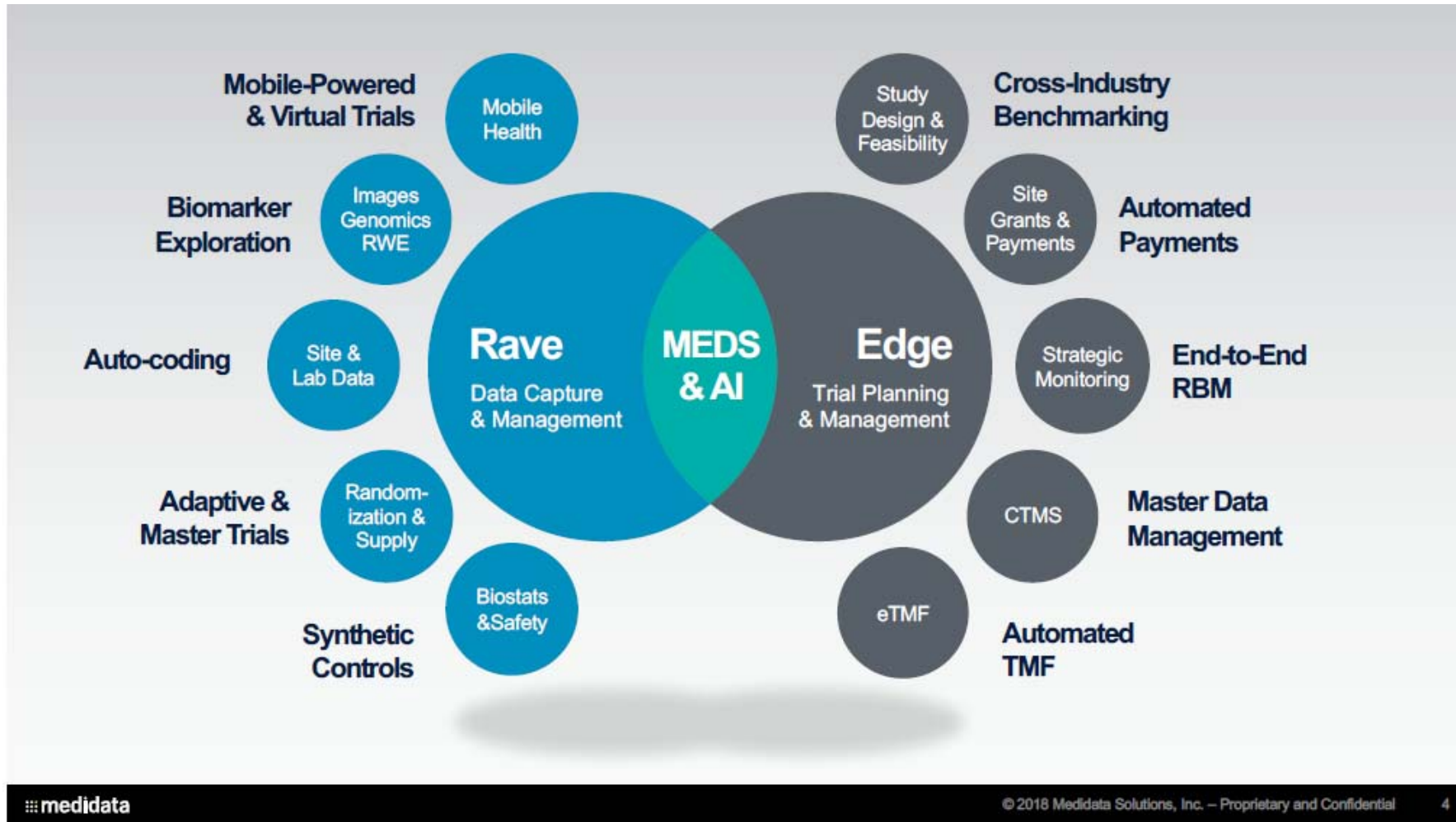
Opt-in to the industry's largest  
**Give to Get** repository

**>14K**  
studies

**>4M**  
trial  
subjects

**>500K**  
sponsor/site  
relationships

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## About PointCross Life Sciences

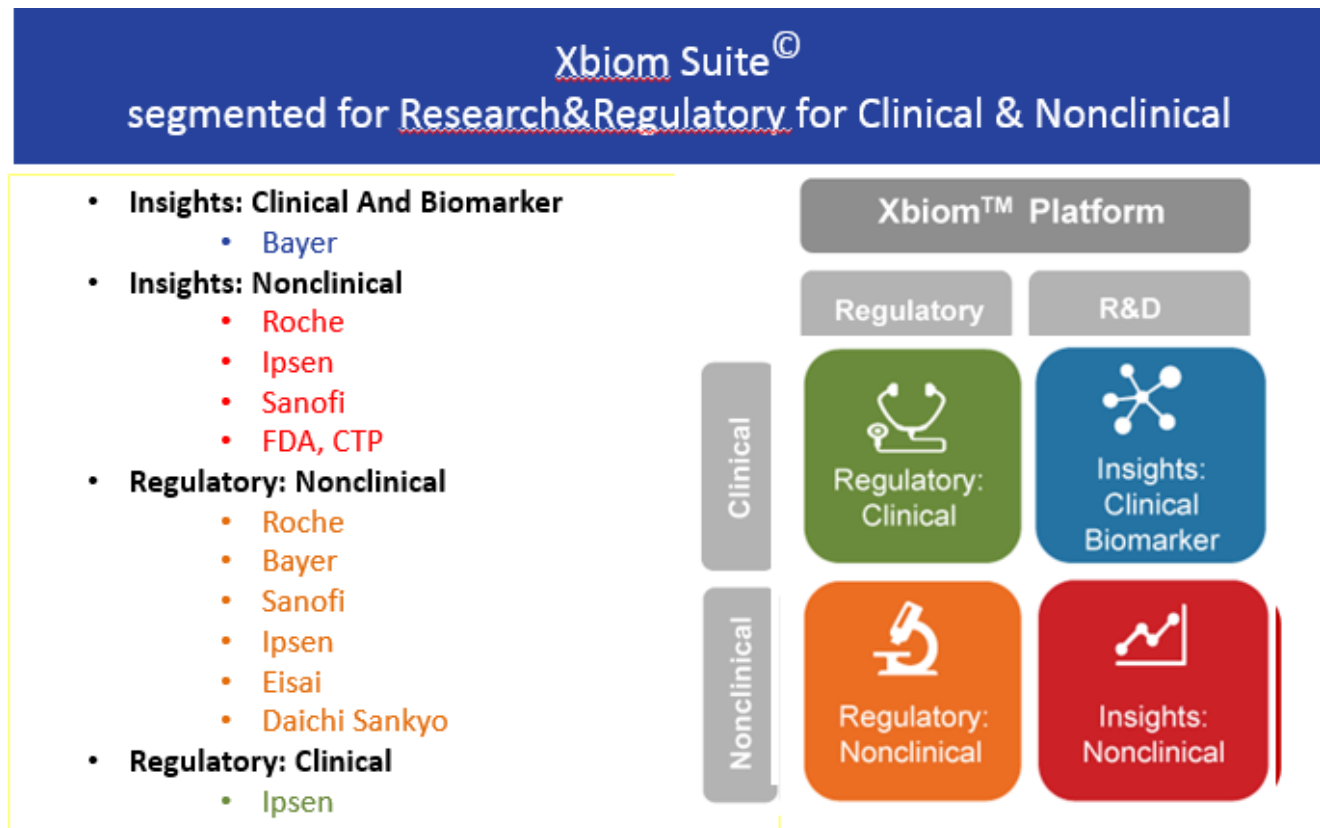
- BioPharma industry focus since 2009
- Global Clients: Roche, Sanofi, Bayer, Ipsen, Eisai, ....
- Contributor, Exhibitor at Industry Events

- FDA contractor and provider of technology



- Locations – Foster City, CA; Silver Spring, MD; Paris, France; Bangalore, India
- Gartner “Cool Vendor” in Life Sciences in 2013

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**Cognizant (NASDAQ-100: CTSH)** is one of the world's leading professional services companies, transforming clients' business, operating and technology models for the digital era. Our unique industry-based, consultative approach helps clients envision, build and run more innovative and efficient businesses. Headquartered in the U.S., Cognizant is ranked 205 on the Fortune 500 and is consistently listed among the most admired companies in the world.

## OUR OVERVIEW

 **Founded**  
in 1994 (CTSH, Nasdaq)

 **Headquarters**  
Teaneck, NJ

 **Revenue Mix**  
NA: 76.1%  
Europe: 17.5%  
RoW: 6.4%

 **~261,400**  
Employees

 **100+ Global**  
Delivery Centers

 **Revenue**  
**\$14.81B in 2017**  
**\$3.91B in Q1 2018**  
**\$13.49B in 2016**

*\*Digital Revenue ~23% of total in 2016*

## ACCOLADES

**9** **Fortune's**  
Most Admired Companies  
Years in a Row

**18** **Forbes**  
Fast Tech 25

**101** **Newsweek's**  
2015 World  
Green Rankings

**281** **Financial Times**  
Global 500

**205** **Fortune**  
500

**529** **Forbes**  
Global 2000



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## Cognizant Life Sciences & Healthcare Practice Highlights



*Acquired TriZetto, a provider of care management and administration of benefits for \$2.7B*



*An industry consortium selected Cognizant to develop a industry utility for clinical trials collaboration*



*Acquired Cadient, a provider of digital strategy, marketing, and technology and analytics solutions for LS industry*

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## Advantages of working with XClinical



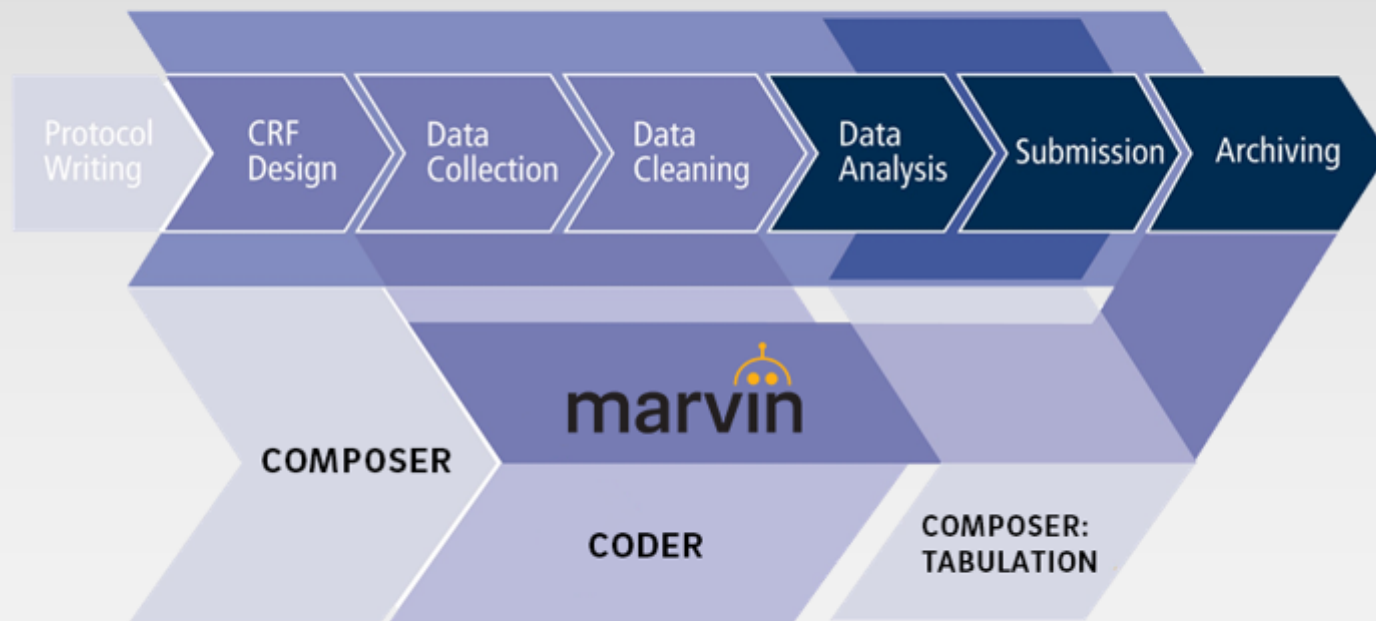
xclinical

- ⊗ is an international EDC software vendor with European Headquarters
- ⊗ facilitates the whole eCRF set-up without programming
- ⊗ offers all functions on every browser and in every language: EDC, DDE, CDM, IWRS, ePRO, Safety Reporting, Coding, customized reporting, a study portal, etc.
- ⊗ provides audit trail and archive files in XML format as recommended by authorities
- ⊗ implements your requirements **within weeks**, not months

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## Product Portfolio

XClinical's products cover the complete clinical trial process



# Agenda

09H30-10H00: Accueil des participants

10H15-11H00: CDISC Update (*Bureau du GUF + Membre de l'E3C S.Rogiers*)

11H00-11H45: Process gestion des données cliniques CDISC (*C.Boulard & V.Roubert for IPSEN, J.Mambrini for Pierre Fabre*)

11H45-12H30: SEND Overview & Requirements (*G.Frausing, Data Standards Decisions*)

12H30-13H45: Pause Déjeuner

13H45-14H15: Benefit Analysis of using Standards in setting up a trial (*P. Van reusel & J.Kestemont, Innovion*)

14H15-14H45: Metadata Versioning (*N. de St Jorre, XClinical*)

14H45-15H15: Controlled Terminology: How to implement? (*R. Gagali Angoh , Mel Consulting*)

15H15-15H45: Pause Networking & Café

15H45-16H30: Data Mapping using Machine Learning (*S.Rogiers, SAS*)

16H30-17H00: Forum : Discussion ouverte & Conclusion

# Congratulations to the board

- ❑ Catherine Boulard (Ipsen)
- ❑ Karen Fanouillere (Sanofi)
- ❑ Nathalie Sabin (Oxmocdm)
- ❑ Michelle Vandenberg (SGS)
- ❑ Wafaa Jabert (Glenmark)
- ❑ Xavier Gobert (Président GUF, MyData-Trust)
- ❑ Fabien Maugard (Vice-Président GUF, APHP)
- ❑ Jonathan Riches (SAS)
- ❑ Yoanni Matsakis (Telemedecine Technologies)
- ❑ Khaled Mostaguir (Hôpitaux de Genève)
- ❑ Simon Lebeau (IVIDATA, Danone Nutrition)
- ❑ Nicolas de Saint Jorre (Quanticsoft)
- ❑ Jeremy Mambrini (Secrétaire GUF, Pierre Fabre)

