GUF CDISC 2nd Session 2019

Biotrial, Rennes

03 Octobre 2019

Flashback

A : 24 Octobre 2016

B : 04 Novembre 2016

C : 04 Octobre 2016

D : Never happened

Here we are !

Le GUF CDISC vous invite le
3 Octobre 2019
pour sa prochaine conférence
à Rennes dans les locaux de
BIOTRIAL
GUF
Groupes des Utilisateurs Francophones des standards CDISC
30 years!
BIOTRIAL

Special Thanks to

And to our sponsors

Any newcomers?

Who are we?

- French User Network of CDISC
- Created in 2007 and 1st day of conference in 2008
- Objective : Awareness and feedbacks about hot topics of CDISC implementation in French or in English on French-speaking areas (France, Belgium, Switzerland)
  - 2 conference days per year

  --> Free of charge for attendees
  - Awareness on standards evolution
  - Webinar
  - Sharing news
- 13 volunteers in the board
- Connexion with other organizations

Robert Adriaansen

VP Global Business Development

robert.adriaansen@anjusoftware.com

Anju Software Product Overview

anju LIFE SCIENCES SOFTWARE

anjusoftware.com

ZEPHYR | IRMS | OpenQ | ClinPlus | PUBSTRAT | ta-Scan | OmniComm

CLINICAL OPERATIONS

Conduct clinical trials and submit results to regulatory bodies (e.g. FDA)

- EDC, CTMS, Coding, Reporting, eTMF
- Clinical Disclosure, Patient Screening
- Trial Feasibility, Country & Site Selection, Disease Landscaping

PRE-MARKET

MEDICAL AFFAIRS

Communicate safety information and results of drug interactions to external stakeholders

- Medical info management, Adverse Events/Complaints
- KOL segmentation & engagement
- Publication Planning, conference/journal selection
- KOL identification and profiling

POST-MARKET

COMMERCIAL

Reach and engage end customers (e.g. hospitals, physicians, drug wholesalers, etc.)

- KOL segmentation
- Sales & Marketing Analytics & Optimization

POST-MARKET

DATA INSIGHTS FOR LIFE SCIENCES

OmniComm Systems is a leading strategic software solutions provider to the life sciences industry.

OmniComm®
eClinical Solutions for Life™
an anju software company

OmniComm Systems provides a critical role in enhancing patient lives by shortening time to market of essential life-saving treatments. OmniComm Systems is dedicated to providing the latest eClinical technology enabling the world's life science organizations to maximize the value of their clinical research investments. OmniComm's solutions provide better trial oversight and study delivery, connecting patients to better healthcare.

AB-Cube

Making Safety Easy

Our Expertise

« A quick, easy and fully validated solution,
for entry, import, tracking and electronic submission
of adverse events »

AB Cube in Numbers

100

DIRECT CLIENTS

270

INDIRECTS + DIRECTS CLIENTS

1000,000

RECORDED ICSRs

1800

USERS

500

DATABASES

13

YEARS

Our solutions

AB-Cube E2B (R3) Native

CosmEthics™

Your Cosmetic database software

SafetyEasy™ PV

Your E2B (R3) Pharmacovigilance database software

SafetyEasy™ MD

Your Medical Device vigilance database software

SafetyEasy™ MI

Your Medical Information Management database Software

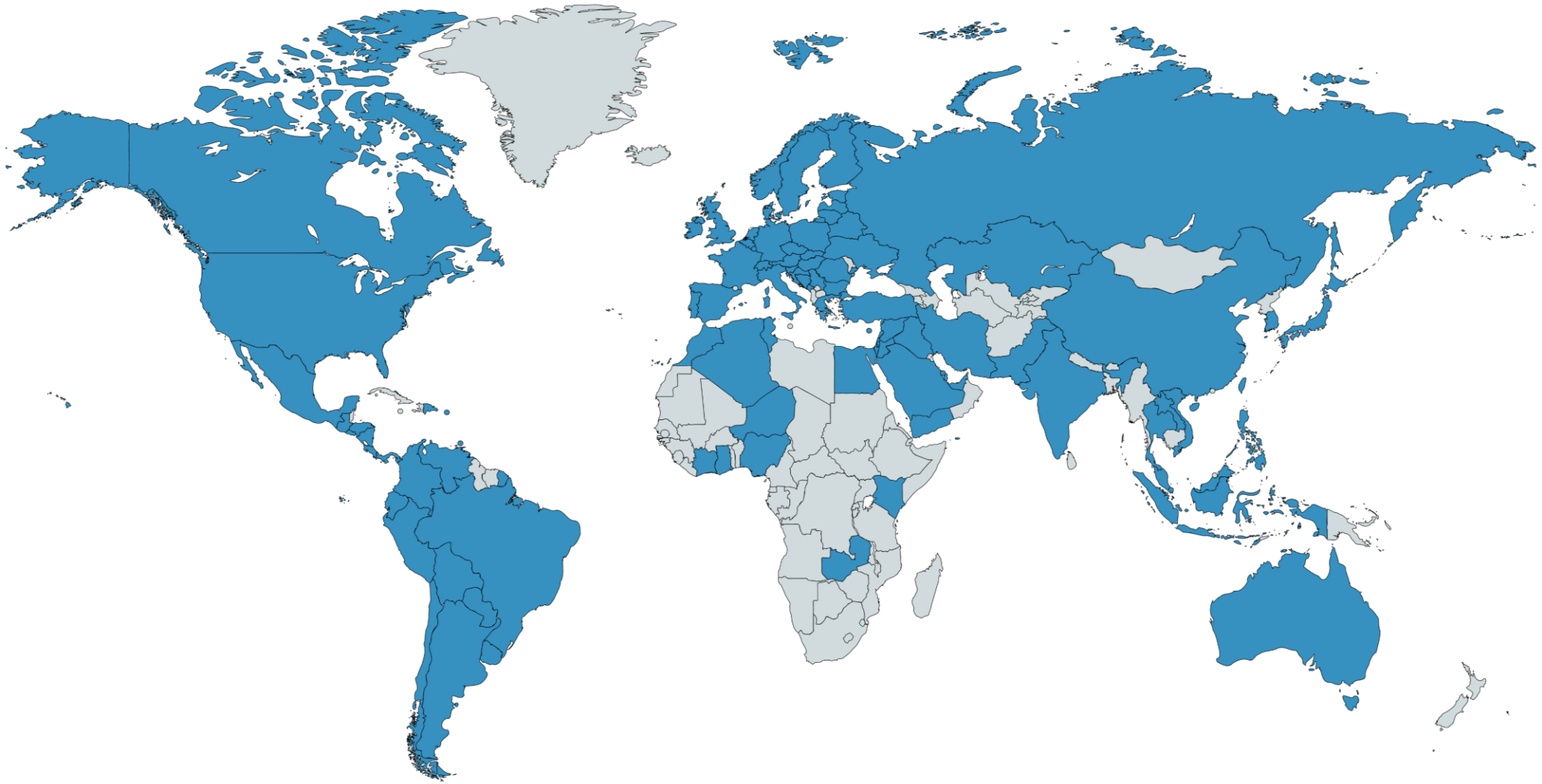
SafetyEasy™ Nutri

Your Nutrivigilance database software

iTAP™ – TRIAGE

Your ISCR Triage and Assessment Processing tool

We support vigilance from over the world…



They trust us

Pioneers of SaaS

Since 2006, AB Cube is the pioneer in the field of vigilance databases delivered as a SaaS

Flexible

- The same version for all, but **highly and easily configurable**
- Adapts to your processes: from few cases to hundreds of thousands cases

Evolutive

- Quarterly evolutions
- Always compliant with the latest regulation
- **No extra costs for upgrades !**

Easily Implemented

- Full Web SaaS: no need for program installation
- **Implemented in less than 2 weeks**

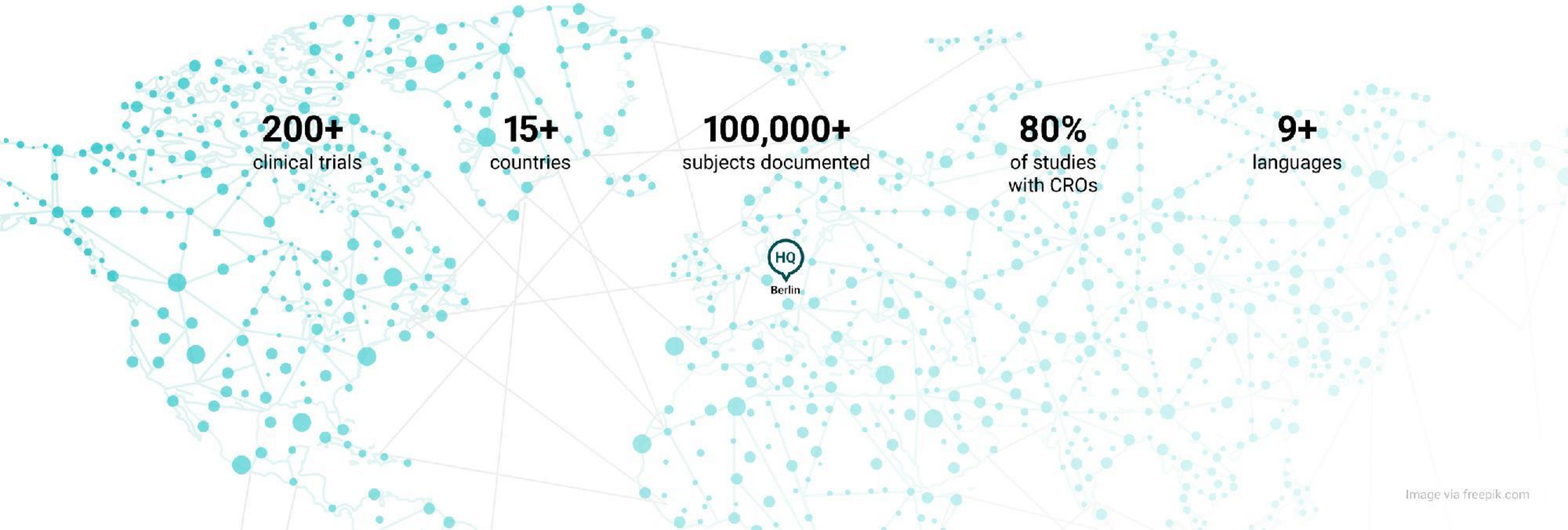
CLINCASE

CLINCASE

Quadratek

15 years
of experience

Our Mission is to create the best e-Clinical solution that would transform data management and simplify the way clinical trials are conducted.



200+
clinical trials

15+
countries

100,000+
subjects documented

80%
of studies with CROs

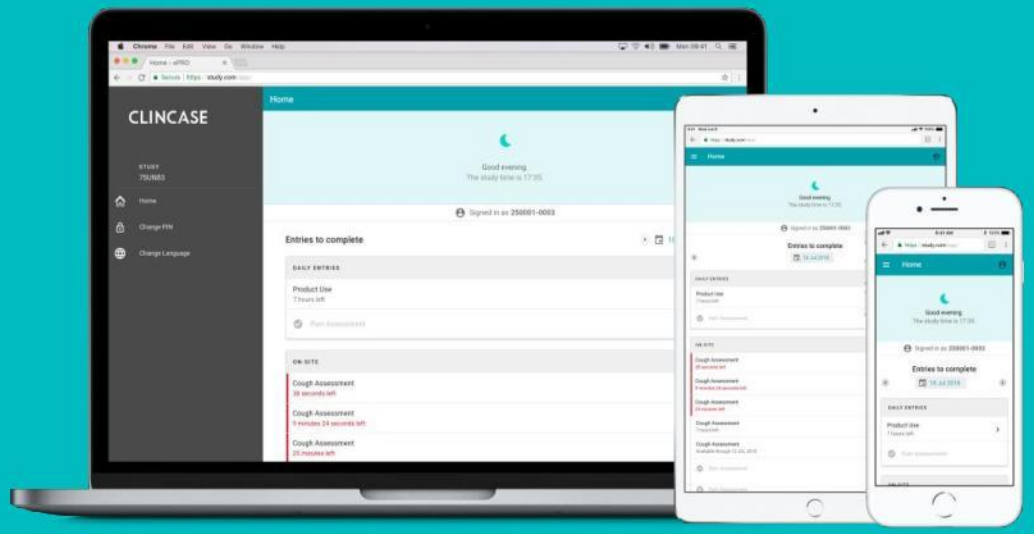
9+
languages

Image via freepik.com

CLINCASE Quadratek

What We Do

- EDC
- ePRO / eCOA
- Clinical Supply System (IWRS)
- Dashboard
- eLearning
- Encoding Meddra / WHODD



Agenda

09.30 – 10.00	Accueil des participants
10.00 – 10.15	Introduction & Sponsors présentation ***Jérémy Mambrini, Pierre Fabre & GUF Président*** ***Représentants des sponsors***
10.15 – 11.00	Update CDISC ***Jérémy Mambrini, GUF***
11.00 – 11.45	Balade dans le monde des Graphs et de l'API CDISC Library ***Nicolas de Saint Jorre, Quanticsoft***
11.45 – 12.15	REX sur la validation de l'outil Pinnacle 21 Community pour le SDTM IG 3.2 ***Karine Provost, Biotrial***
12.15 – 13.45	**Pause déjeuner**

13.45 – 14.15	Forum – Open Discussion ***Bureau du GUF et participants***
14.15 – 14.45	Using CDISC QRS Supplements for the implementation of eCOA ***Henning Lux, Quadratek Data Solutions Ltd***
14.45 – 15.15	CDISC pour la PK : du SEND au ADaM en passant par le SDTM ***Helène Tribodet, Biotrial***
15.15 – 15.45	**Pause café**
15.45 – 16.15	Impacts GDPR concernant les données cliniques et le CDISC ***Pierre-Yves Lastic***
16.15 – 16.45	Data Transformation: Best Practices to When to Transform Your Data ***Olivier Bouchard, SAS***
16.45 – 17.00	Conclusion

anju LIFE SCIENCES SOFTWARE

Quadratek

AB-Cube More than softwares

Biotrial

- CRO internationale, siège à Rennes
- Partenaire global de l'industrie pharmaceutique
- 2 Unités Cliniques de Phase I (260 lits)
  Rennes – New Jersey
- Service Biométrie couvrant les métiers de Data Management, Biostatistiques, Programmation et Medical Writing
- De la phase non-clinique jusqu'à la Phase IV

International CRO

- Non-Clinical
- Phase I/IIa

- Phase II Patient Studies
- Biometrics
- Oncology
- Core Lab
- Bioanalysis
- Regulatory Services

Biotrial Biometrics

SEND

Preclinical

GLP safety pharmacology & toxicology

SDTM / ADaM

Phase I

FiH SAD&MAD

TQT & PD

BA/BE

FE, AlcI, DDI, RI, HI

Umbrella protocols

Phase II

Ph IIa / IIb

Dose finding

Specific populations

Phase III

Non-inferiority

Safety/Efficacy endpoints

Meta-analyses

Phase IV / PMS

Registries

Observational / NIS

PASS

ADS and TFL programming: SAS

EDC, ePRO/eCOA: Clincase, Rave

PK analysis: Phoenix WinNonlin

Coding: MedDRA and WHO-DRUG Enhanced+Herbal