Biotuesday

Réunion 10 Septembre 2013

Olivier Humbey

Head of BD

Murielle Carré

Head of Medical & Scientific Dev

ICTA

R & D CLINIQUE

“ A Decisive breakthrough in Clinical R&D ”

www.tuv.com TÜVRheinland ID:9105039269

About Us

- ICTA is an **international full service** CRO in clinical & epidemiological R&D

  Contract

  Research

  Organization

- Private mid-sized company (± 500 international team members)
- A successful 30 year-experience since its setup in 1983
- Key partner for the Top 20 Pharmas, Mid-sizes, Biotechs, Medtechs, Academics..
- ISO certified company since 2006

ICTA R & D CLINIQUE

ICTA, a comprehensive experience in drug development

Drugs, Medical devices, Diagnostics, Cell/gene therapies, Vaccines

Clinical studies
Pharmacokinetic studies

Traditional frequentist Phase I/II/III studies
Bayesian, frequentist adaptive and seamless Phase I, II, III studies

E A Ps

Post-marketing studies
Phase IV studies
PASS studies
Epidemiological studies
Observatories
Registries
R T U

EAP: Early Access Programs
PASS: Post-Authorization Safety Studies
RTU: Recommandations Temporaires d'Utilisation

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Study conduct: Key steps

DESIGN	FEASIBILITY	PREPARATION	STUDY MANAGEMENT	DATA MANAGEMENT	STATISTICS	MEDICAL WRITING
• Analysis of the scientific context • Bibliography • Study rationale • KOLs • Protocol drafting • Statistical methodology	• Countries and sites identification • Recruitment potential • Logistics • Final selection	• Study documents • Regulatory submissions • Teams training • Logistics • Database preparation	• Monitoring • IMP management • Coordination of all study stakeholders • Drug safety	• Data processing • Medical coding • Medical reviews • DB cleaning	• Data reviews • DB lock • Statistical analysis	• Clinical study report • Abstracts • Posters • Publications

Deployment of ITMS
Development of eCRFs - IWRS

Quality Assurance

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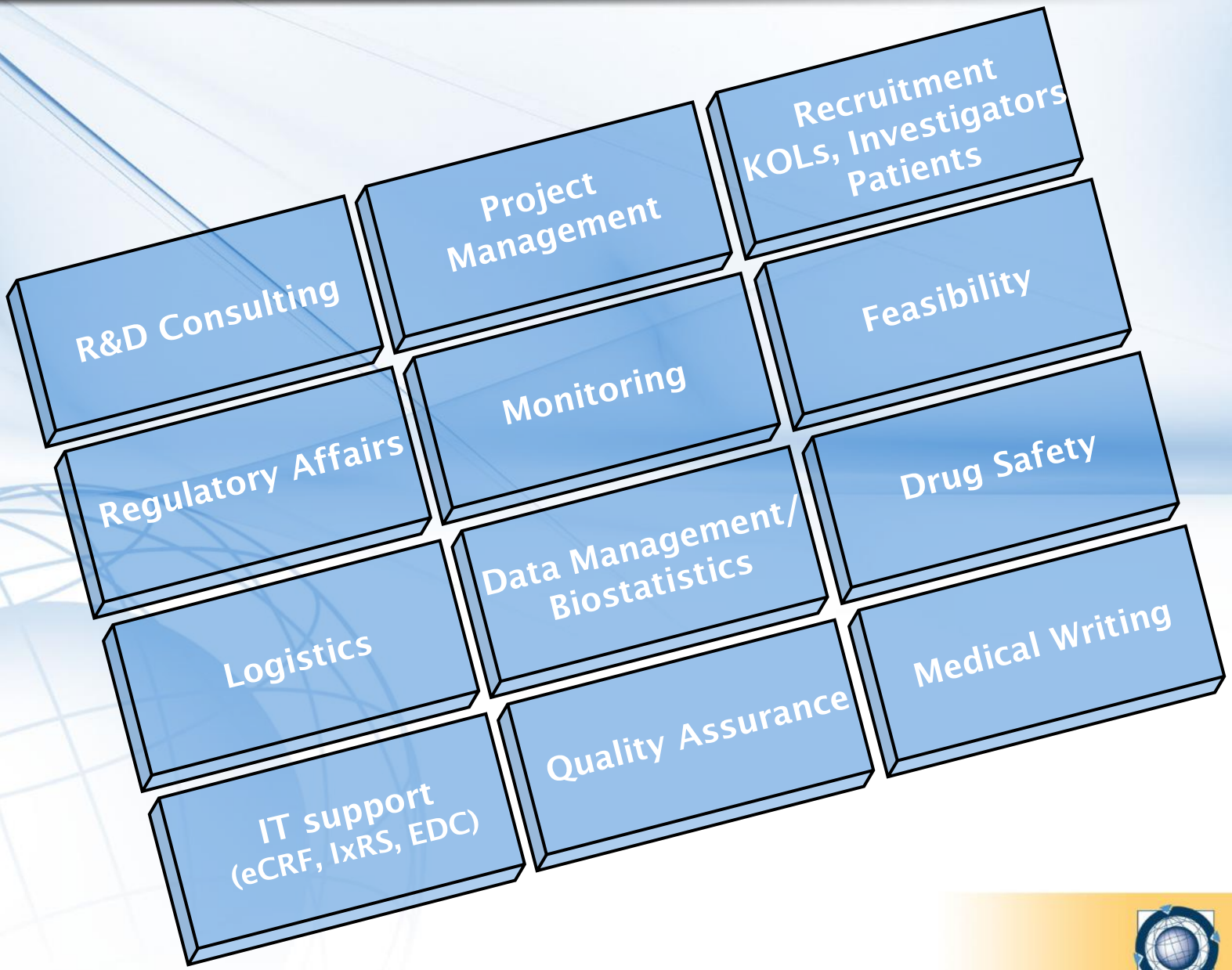
FULL SERVICE / « A LA CARTE » SERVICES



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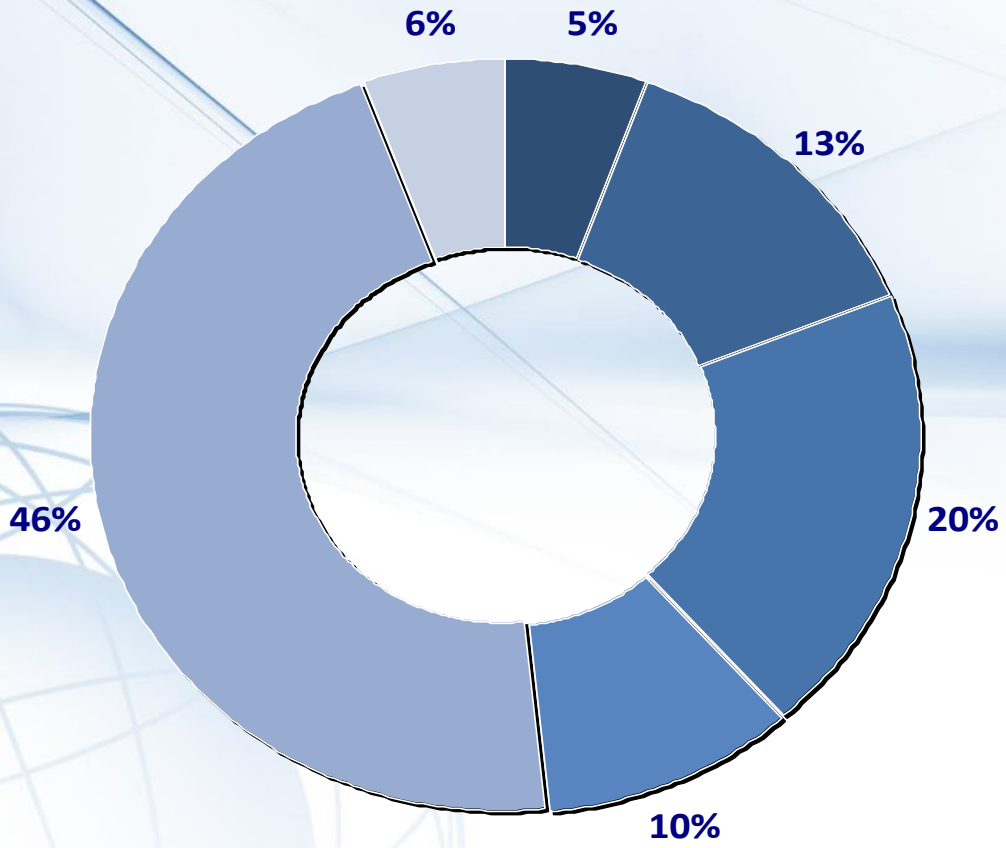
Experience by phase

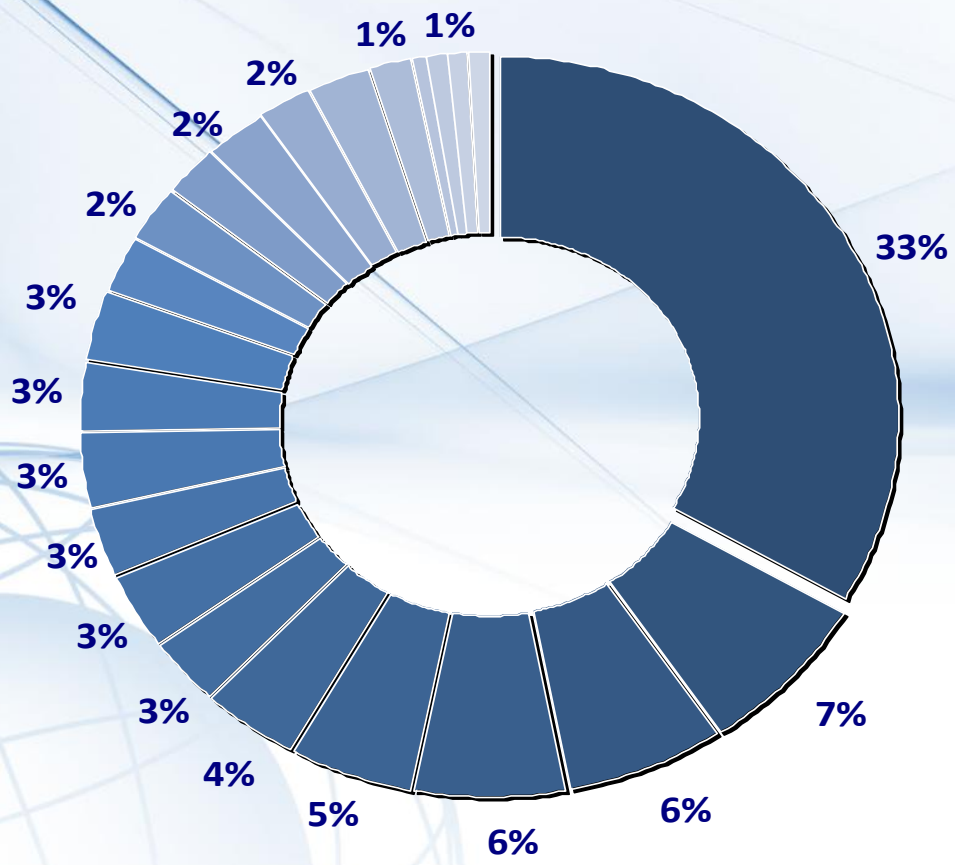
Over the last 3 years*



*Number of studies N=128

Therapeutic experience*

Over the last 3 years



- Oncology (solid/liquid)
- Cardiology
- Urology and Nephrology
- CNS
- Endocrinology
- Pneumology
- Dermatology
- Gynaecology
- Infectiology
- Ophtalmology
- Pain
- Rhumatology
- Angiology
- Diagnostics
- Gastro-enterology
- Hematology and hemostasis
- Immunology
- Metabolism, Diabetology and Nutrition
- Hepatology
- Neurosurgery
- Psychiatry
- Spermiology
- Transplantation

*encompassing phases I to IV and pharmaco-epidemiology (N=128)

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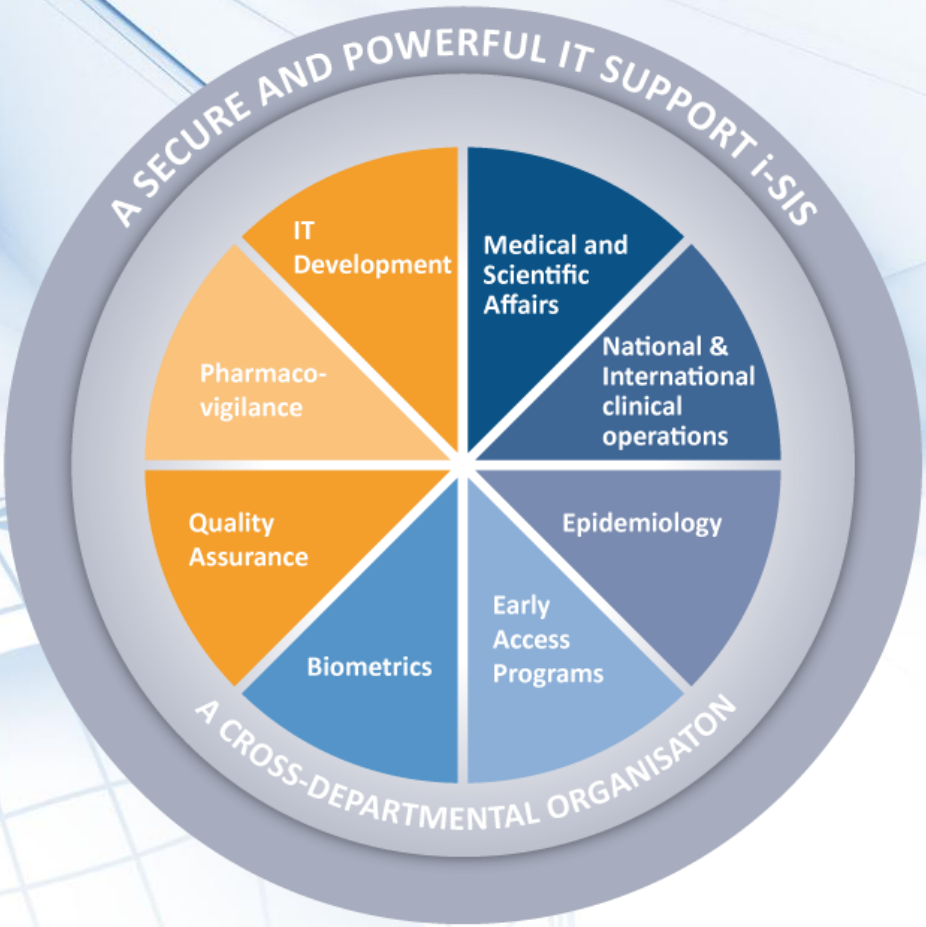
Our organisation



- A matrix organisation to boost responsiveness
- A cross-departmental organisation with a cross-functional validation
- I-SIS, to share information, optimize study conduct, control data and make informed decisions

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ICTA, the secure hub to conduct international studies

" Local experience to support Global trials"

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ICTA R & D CLINIQUE

I-SIS®: ICTA-Secured Information System

Firewall

I-Cloud

An immediate access
- → Anytime / Anywhere
- → Via Internet
- → No software installation required
- → User-friendly solution

A secure e-Platform (I-SIS)

7 i-modules
For a Complete Project Management Support

ICTA Trial Master File

I-TMF

CROs

I-TMS

ICTA Trial Management System

Sponsor

I-Study Portal

I-REPORT

ICTA Report
- → Decision-making
- → Proactive management

Investigators

Interactive Web Response Services

I-WRS

I-CRF

ICTA Case Report Form
- → CDISC standards

On Line Secured Real Time Communication

*21 CFR part11 compliance

ICTA R & D CLINIQUE

As a conclusion…

Our guarantees

- Durability and sound finances (no debts)
- Experience and expertise (senior)
- Low personnel turnover and strong partnerships
- Flexibility and Responsiveness (adaptive trials)
- Quality of work (outcomes / external audits)
- Repeat Business (preferred provider)
- Transparency of work (report / communication)
- Regular Training (medical / operational / regulatory..)
- Certification IPM ISO 9001- 2008 (Renewal)
- French Tax Refund accreditation (Europe)

ICTA R & D CLINIQUE

ICTA ready to serve you

Thank you for your attention!

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