

TUNECT

Corporate Presentation

TUNED to support clinical development



Our Mission

We support global clinical development industry by providing transparent, traceable, and cost-efficient biometrics services and solutions.

We tune clinical trials with passion to bring anticipated medications to life, improve their quality and earn trust of our clients and patients around the world. That's our mission. That's TUNECT.

Fast-growing team, experience
built project by project

More than 15 years of
TUNECT staff professional
experience



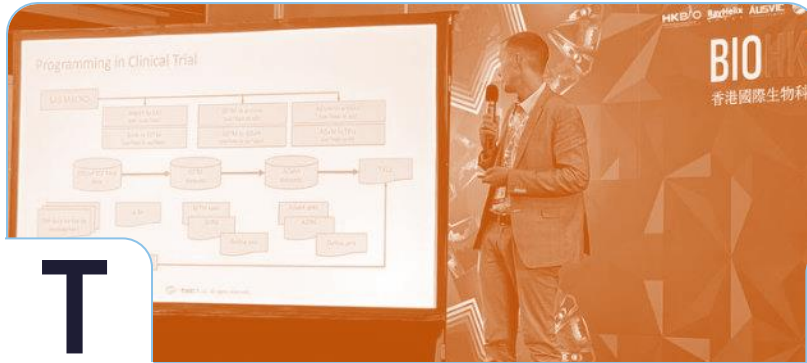
Our Vision

Our vision is clear. Together with our partners from pharmaceutical, biotechnological, and CRO companies, we support clinical development by evolving the environment of biometrics professionals who believe in honesty at each step of our work.

We are tuned to evolve traceability and transparency in clinical development. That's our vision for the industry.

TUNECT values & principles

All these 6 basic values and principles together are the core of our corporate spirit:



T

Transparent and Traceable Workflow

We don't do "black boxes." Every step in our process is visible, logical, and explainable - from budget to submission.



U

Unique and Innovative Solutions

No two studies are the same. We approach each challenge with fresh eyes to find the best path forward.



N

Noticeable Quality

Quality is the attention to detail, clean structure, traceable datasets, validated code, and clear deliverables.



E

Evolving Professional Development Environment We don't just deliver services - we grow experts. Inside TUNECT, people become great experts and leaders.



C

Credible Vendor

Trust is earned through consistency; we deliver what we promise - every time.

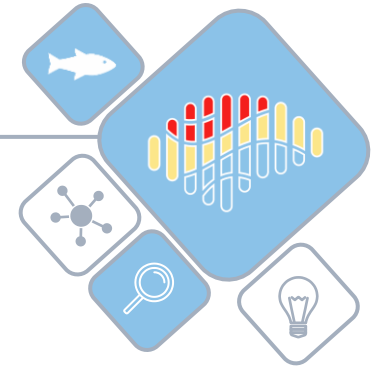


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Team Spirit

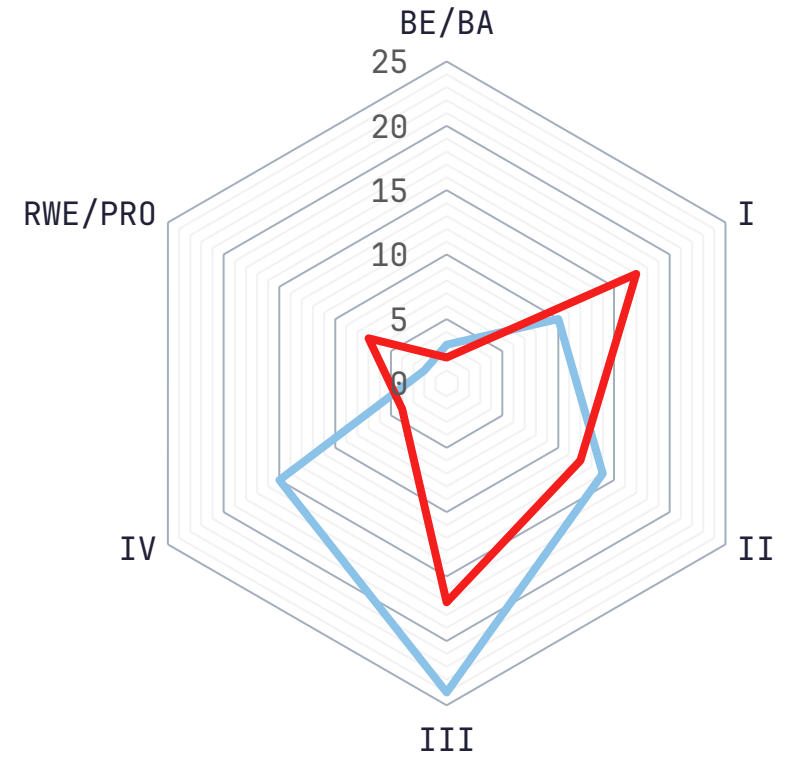
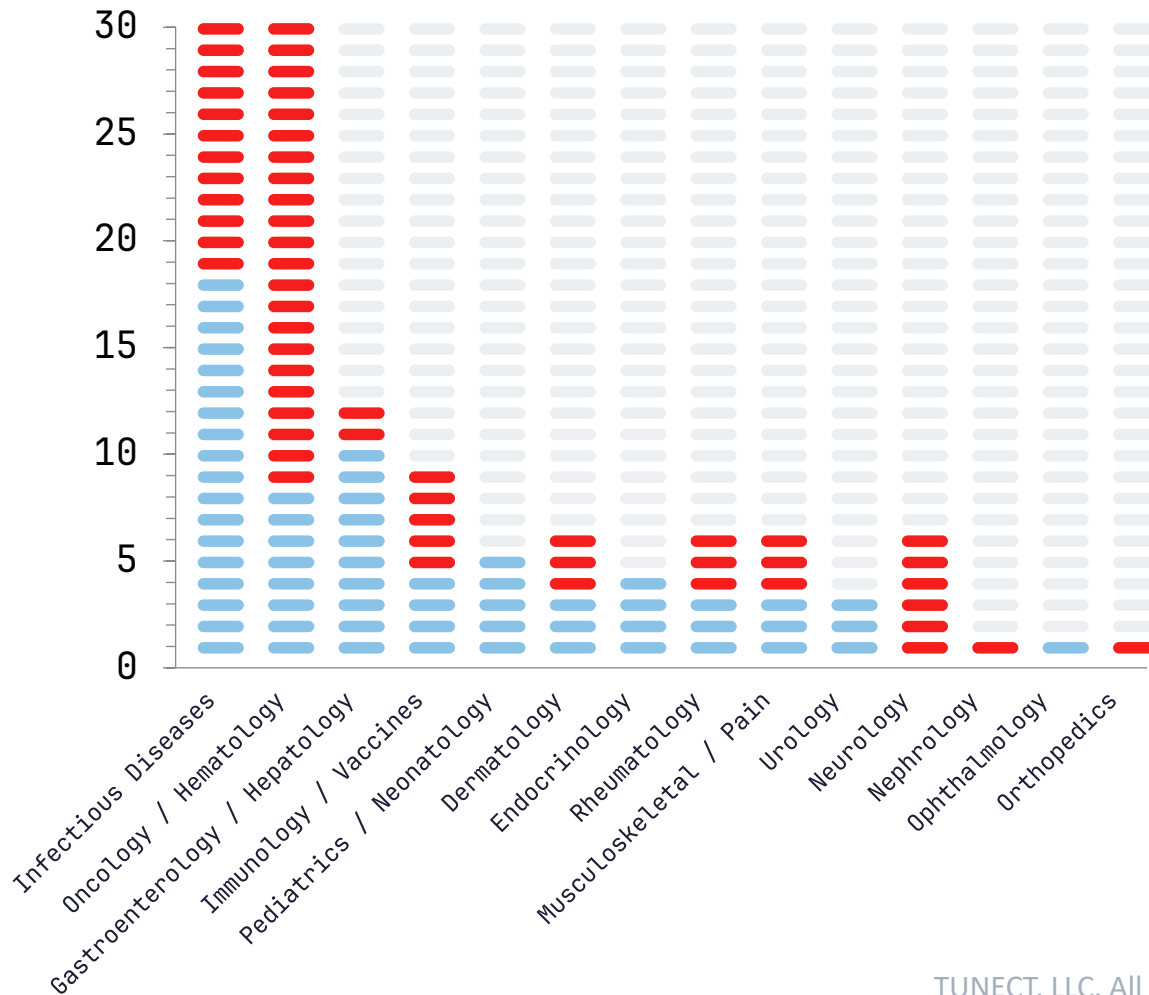
Clinical research is team work. The TUNECT team integrates seamlessly into your team - collaborating proactively and adapting fast to become part of your success.

TUNECT - clinical trials



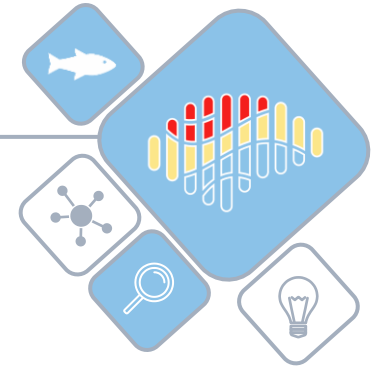
THERAPEUTIC AREA

STUDY PHASE



■ Staff Experience
■ TUNECT Experience

TUNECT - medical devices



THERAPEUTIC AREA

STUDY PHASE

Endocrinology
Cardiology (Arrhythmia)
Ophtalmology
Tobacco Heating System
Inflammatory Diseases

0

3

Post-Market

Pivotal

Pilot

4

3

2

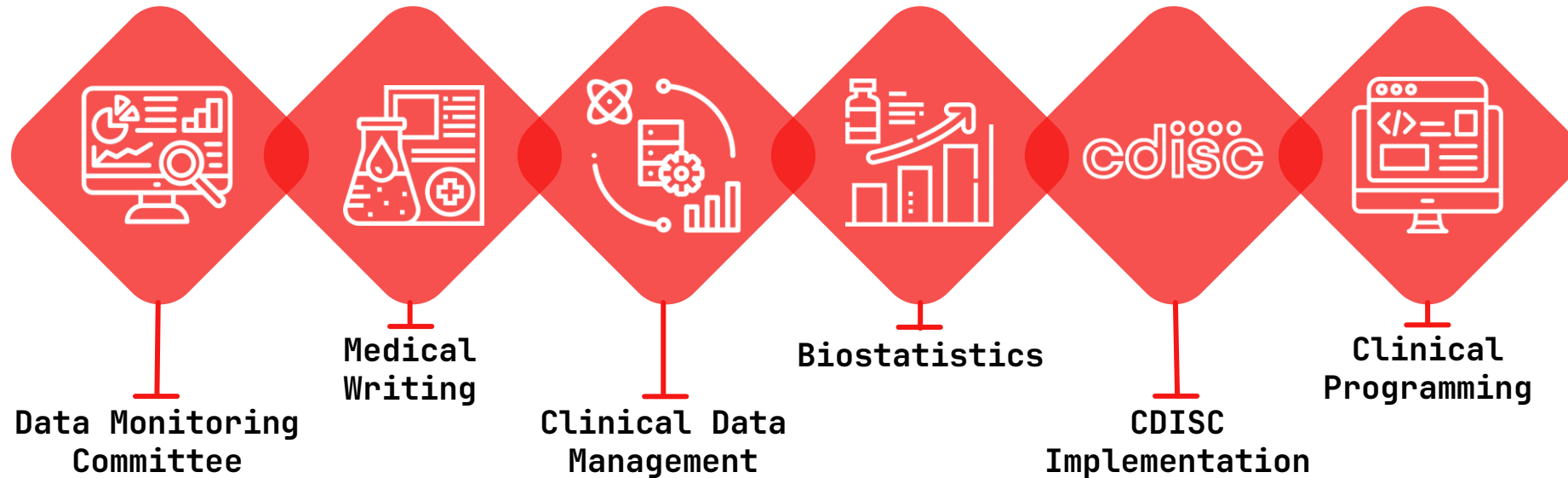
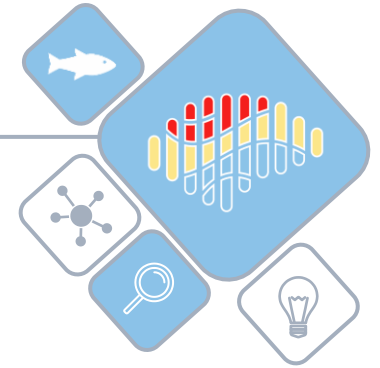
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Traditional
Feasibility

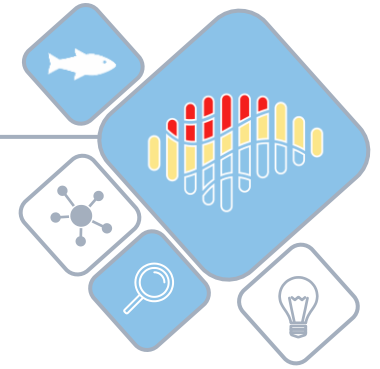
Staff Experience
TUNECT Experience

Our Services

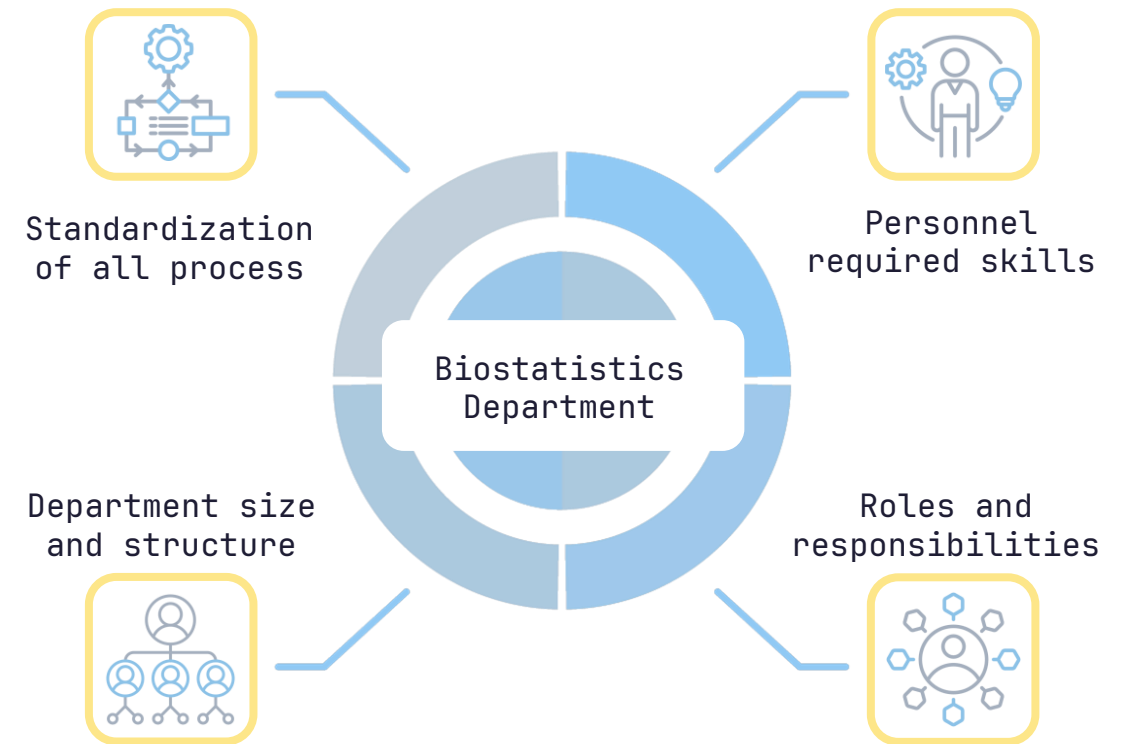


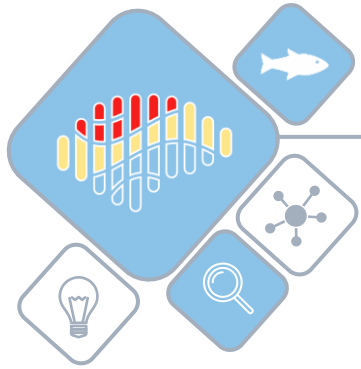
Functional Service Provider (FSP)	Project-Based (SOW / Deliverables)
• Embedded capacity within your Team • Work under Client credentials and system • Day-to-day priorities by Client managers • FTE / Time and Materials	• Scope and acceptance fixed in SOW • Governed by TUNECT SOPs and QA • Day-to-day priorities by TUNECT • Milestones / Fixed price

Biostatistics

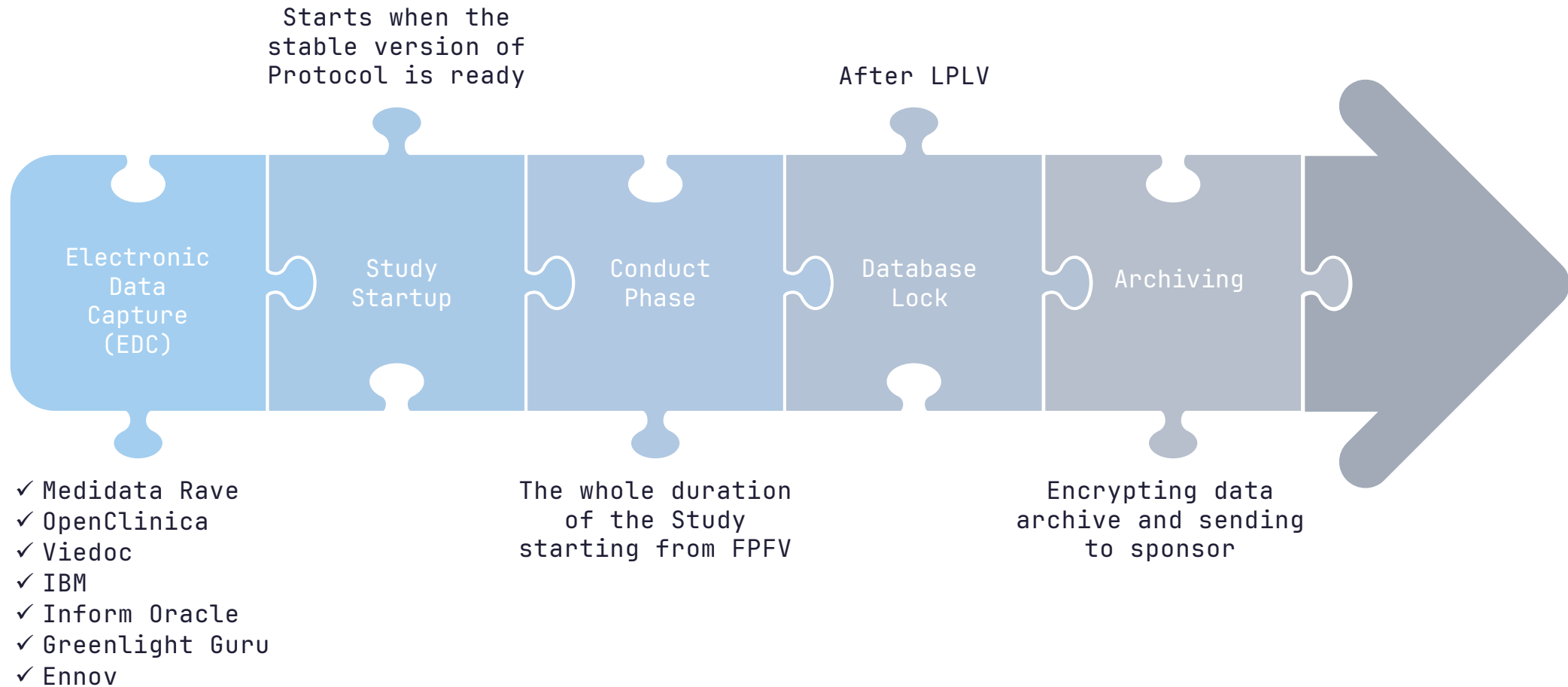


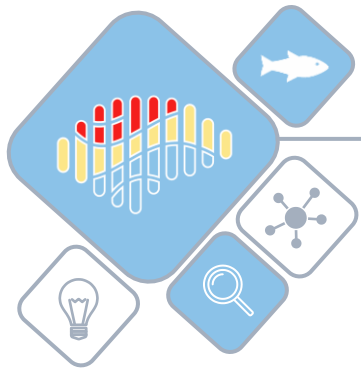
- Statistical Input into Protocol Development
- Generation of Randomization Schedules
- Development of SAP (Statistical Analysis Plan)
- PK/PD Analysis
- Tables, Figures and Listings (TFLs) shells
- Interim analyses and reports
- Statistical Analysis Report (SAR)
- Statistical input to Clinical Study Report (CSR)
- Statistical support for regulatory submissions





Data Management and EDC experience

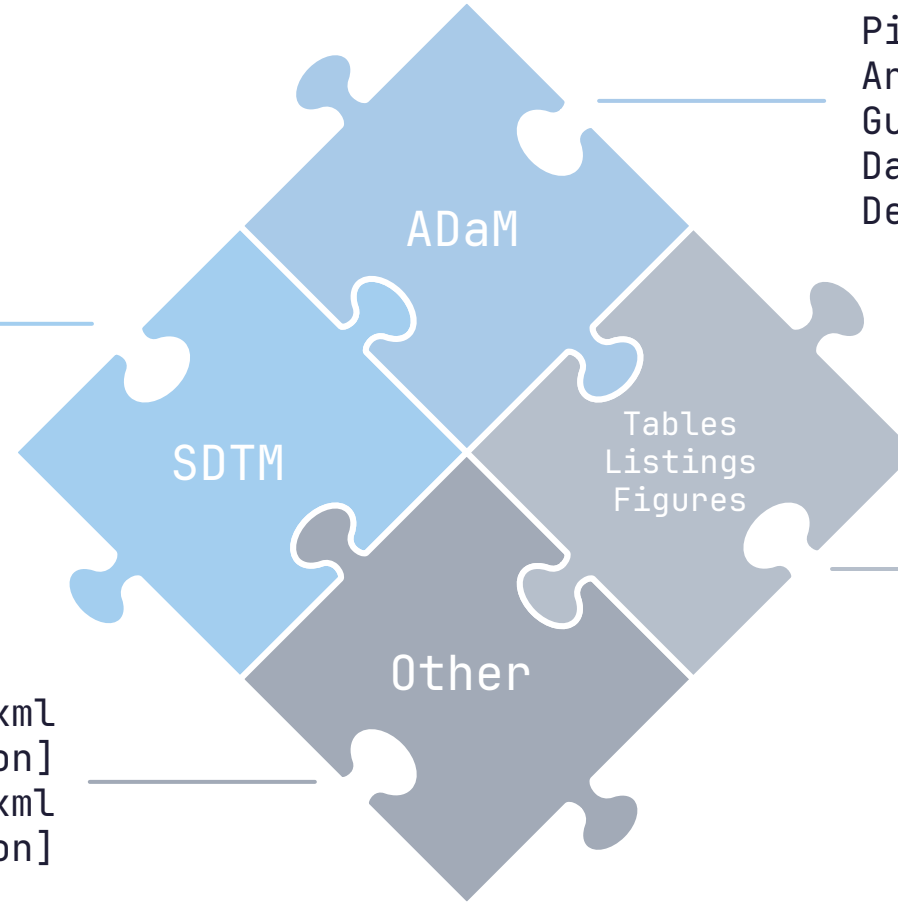




SAS Programming services

CRF annotation
SDTM Specification
Pinnacle 21 Review
Study Data Reviewer's Guide
Dataset Development and QC
Define.xml

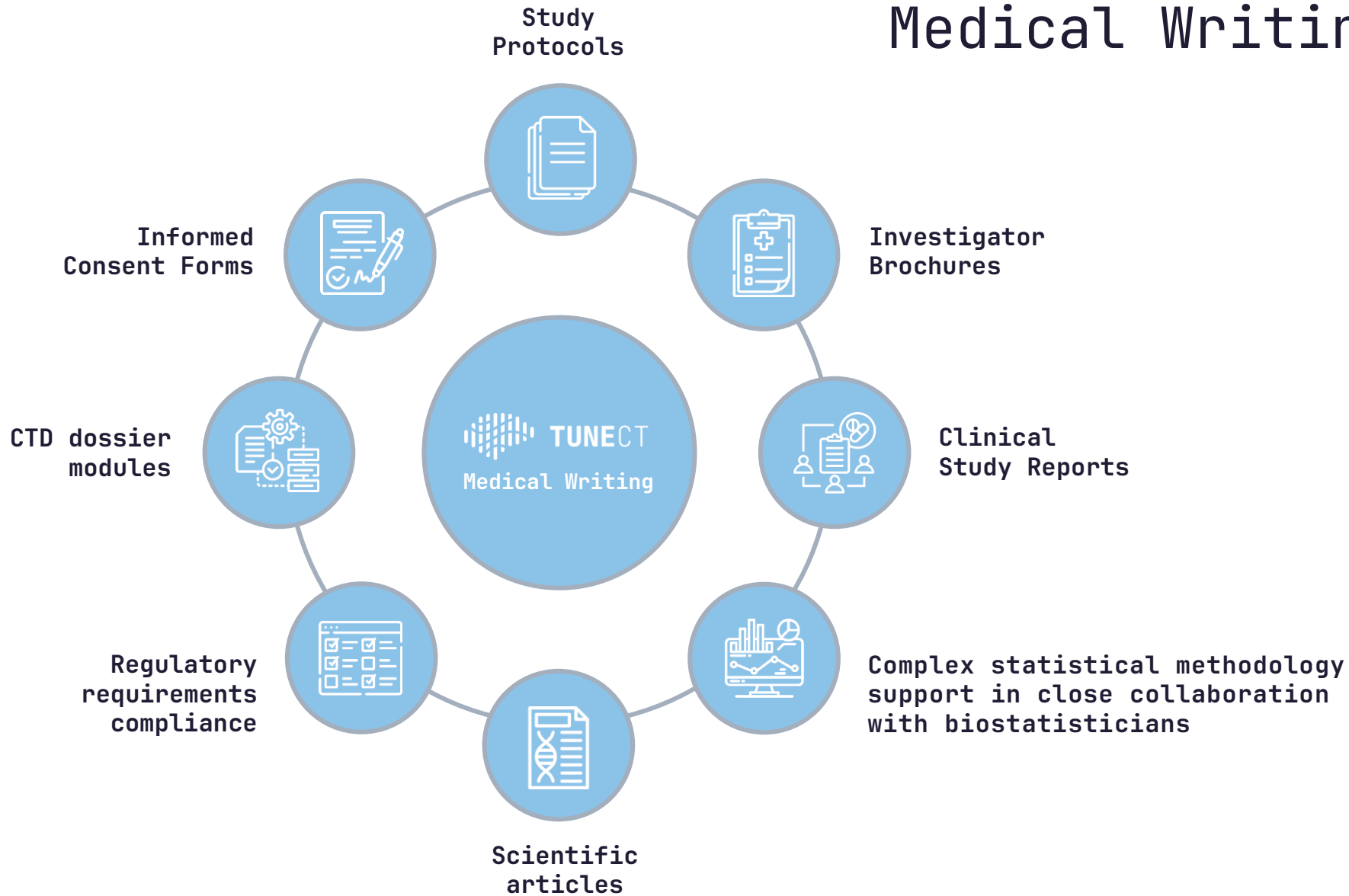
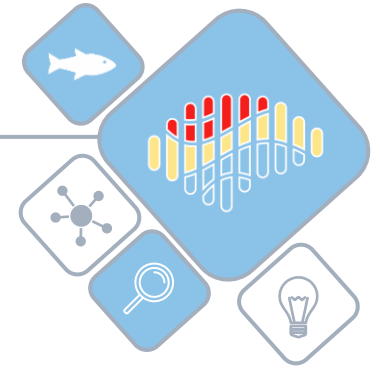
ADaM Specification
Pinnacle 21 Review
Analysis Data Reviewer's Guide
Dataset Development and QC
Define.xml



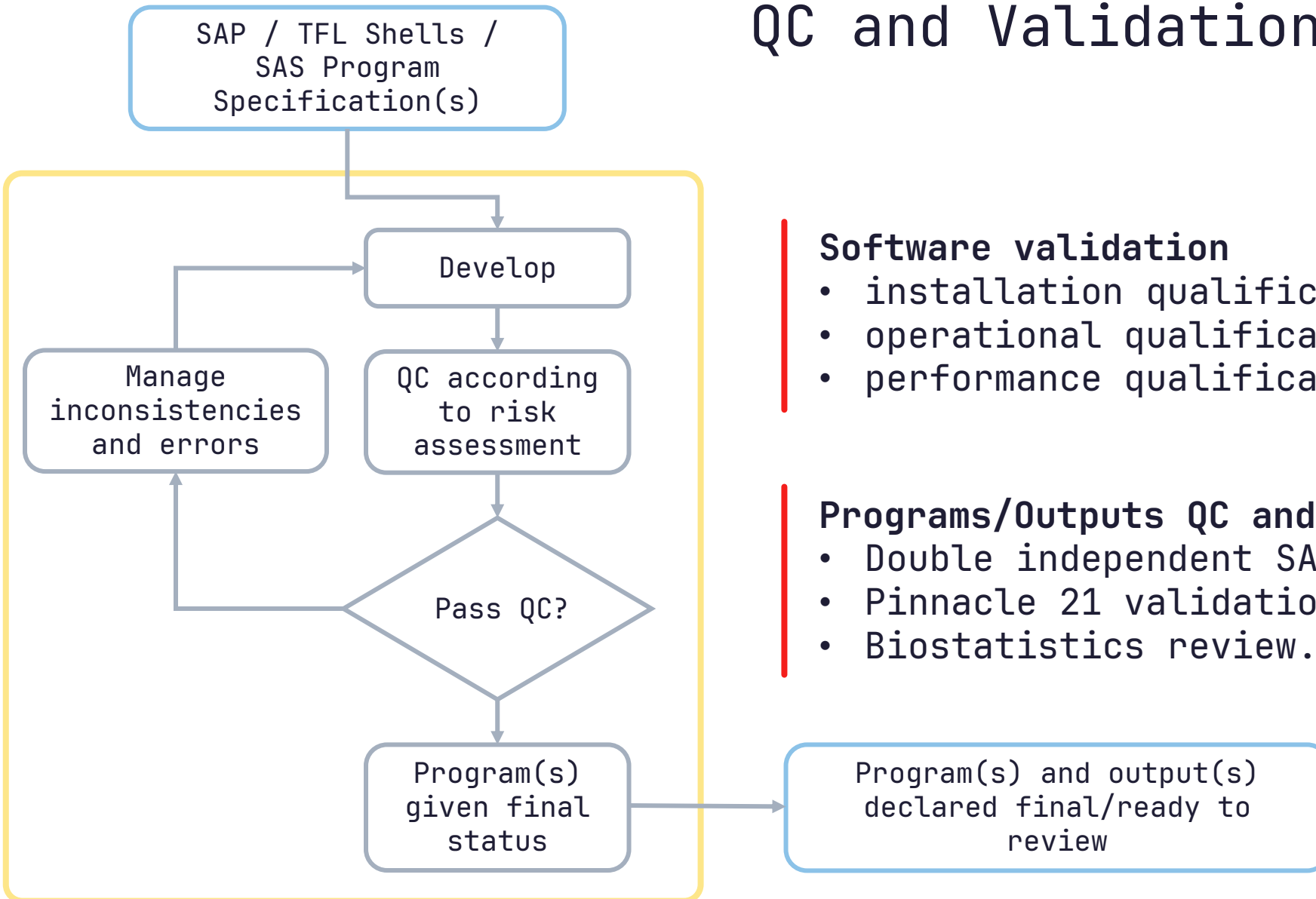
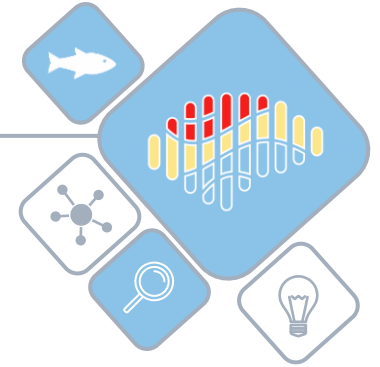
TLFs
Programming
and QC

EudraCT.xml
[EEA Clinical Trial Application]
CT.GOV.xml
[ClinicalTrial.gov Application]

Medical Writing



QC and Validation

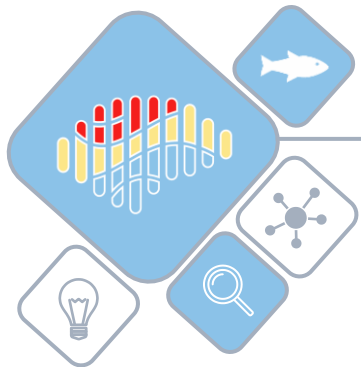


Software validation

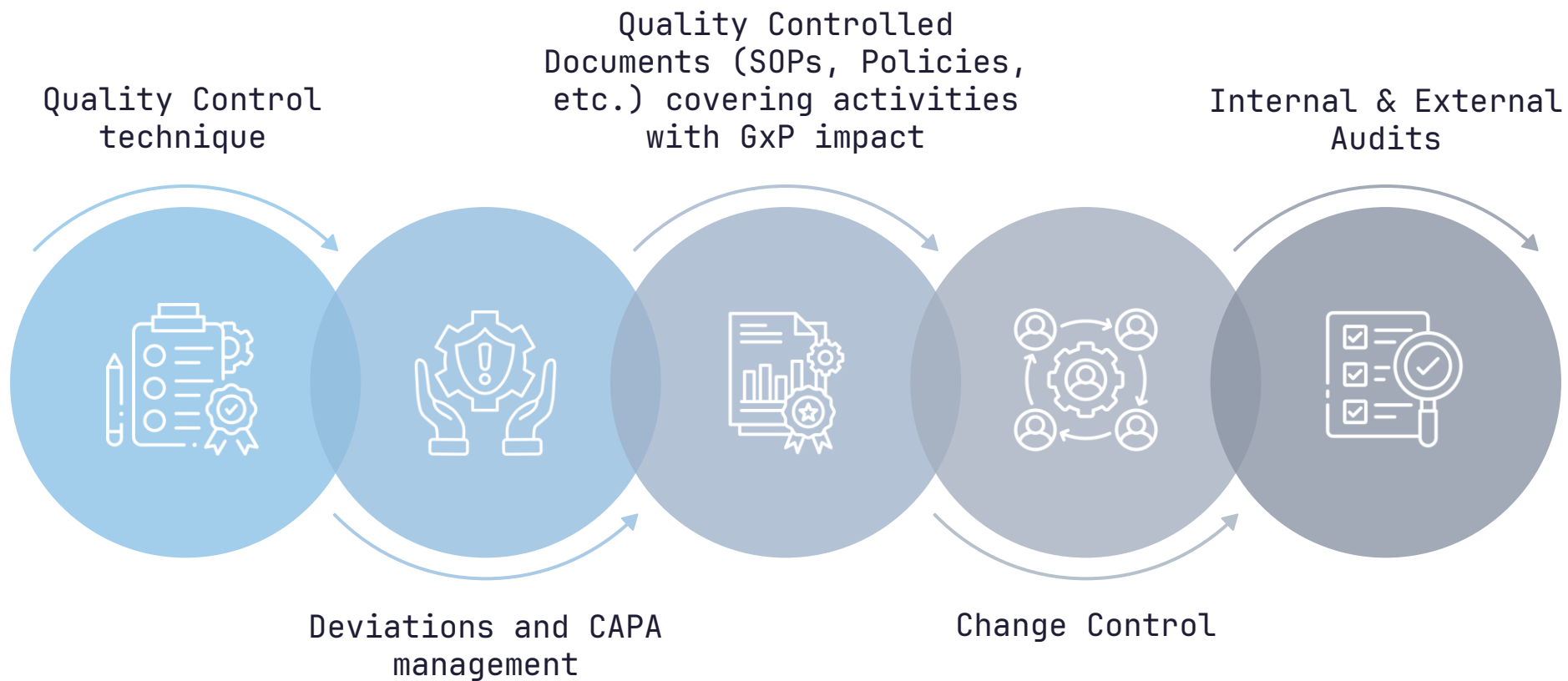
- installation qualification (IQ),
- operational qualification (OQ),
- performance qualification (PQ).

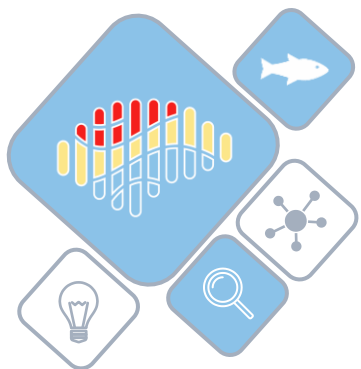
Programs/Outputs QC and Validation

- Double independent SAS programming,
- Pinnacle 21 validation,
- Biostatistics review.



Quality Management





Quality Assurance Guarantee: Our Commitment to Excellence

At TUNECT, we stand behind the quality of our services. Our commitment to excellence drives us to ensure that every project we undertake meets the highest standards.

We guarantee the quality of our work, and in the rare event an error is found within 12 months of delivery, we will correct it promptly at no additional cost.

Your satisfaction and peace of mind are our top priorities.



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tune-ct.com