Flexible and Accurate Biometrics Solutions

Delivery with High Quality and Data Integrity
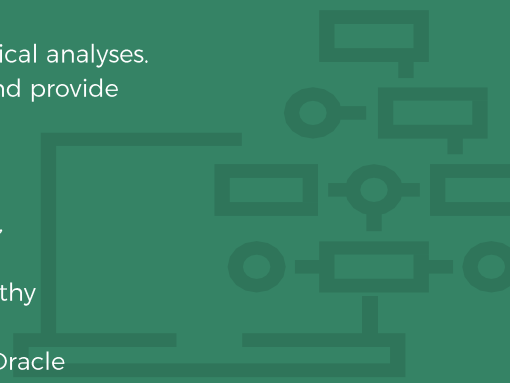
Data Management
Biostatistics
Statistical Programming

Tigermed | www.tigermedgrp.com

Global, Reliable and Flexible

Tigermed Biometrics team offers more than data management and statistical analyses. We bring a deep understanding of every aspect of clinical development, and provide flexible and accurate solutions from start-up to close-out.

- Teams in APAC and US for global customer reach
- Deep understanding of therapeutic areas like Oncology, Immunology, Endocrinology, Neurology, Infectious Diseases, etc.
- Well known industry reputation for being highly reliable and trustworthy
- Excellent tracking record of quality and on-time deliverables
- 100+ employees capable of using Medidata Rave, Clinflash EDC and Oracle Clinical

Customers Testimonials

"I don't know how you do it. You guys are our strategic partner, have always delivered on time and accurately over the last 10 years we have worked together. You outperform all the other biometrics CROs we work with. That is why we continue to collaborate with you."

Head of Biometrics at one of the top 10 global pharma companies in US

1,000+
Global Biometrics Experts
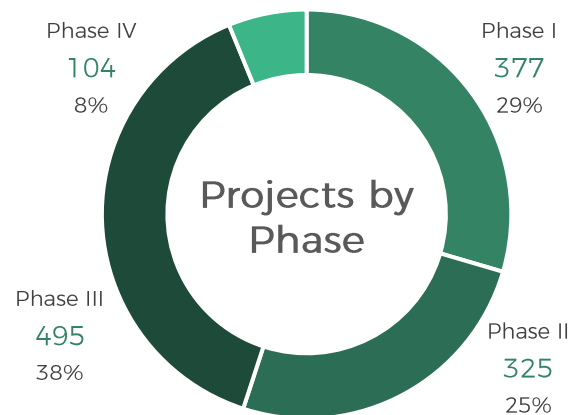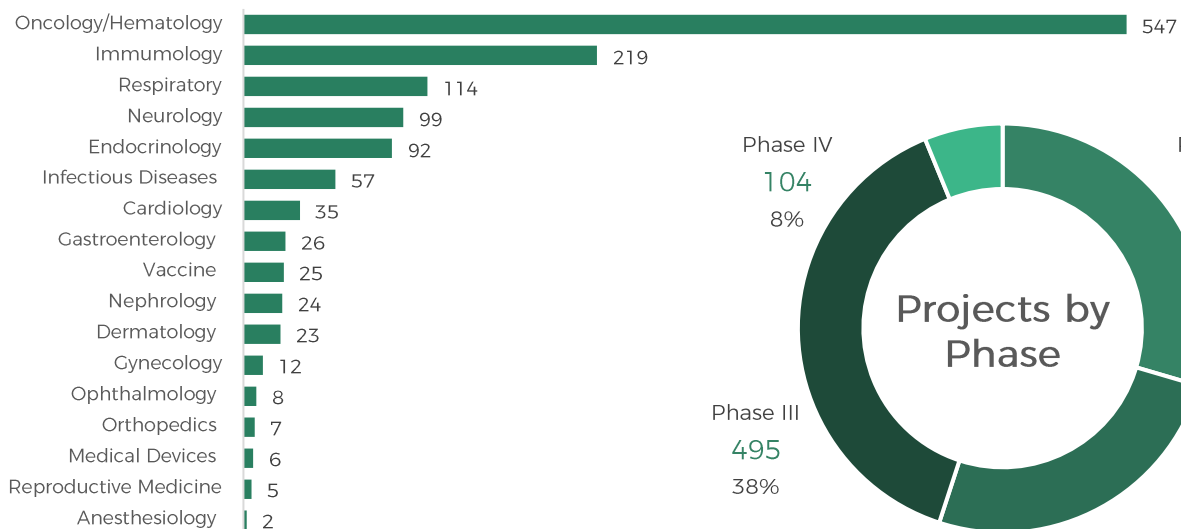
1,300+
Biometrics Projects (2018-2022)

600+
CDISC Projects

28
NDA/BLA Submissions to FDA with new indications

Projects by Therapeutic Areas (2018-2022)

Therapeutic Area	Projects
Oncology/Hematology	547
Immumology	219
Respiratory	114
Neurology	99
Endocrinology	92
Infectious Diseases	57
Cardiology	35
Gastroenterology	26
Vaccine	25
Nephrology	24
Dermatology	23
Gynecology	12
Ophthalmology	8
Orthopedics	7
Medical Devices	6
Reproductive Medicine	5
Anesthesiology	2

Projects by Phase

- Phase I: 377 (29%)
- Phase II: 325 (25%)
- Phase III: 495 (38%)
- Phase IV: 104 (8%)

Quality Management

- Well-established SOPs
- Comprehensive Training Program
  New employee orientation training, SOP/ WPD/Policy training, Regulation training, Advanced professional skills training, Project training

- Solid Internal and External Audit Program
- Effective Corrective Action and Preventative Action Process
- 300+ audits passed by 100+ customers from 20+ countries

Data Security and Privacy

- Data access controlled with Microsoft Active Directory
- Well-established SOPs/Polices to protect data:
  - Policy-01 Information Protection Policy
  - Policy-05 Protection of Personal Data
  - SOP-G-05 Protection of Subject Privacy
  - SOP-G-13 Personal Data Breach Response

- Data Processing Addendum in accordance with GDPR to adduce adequate safeguards with respect to the protection of privacy

Data Management ▶

- Dictionary management after coding
- Risk Based Quality Management
- Close collaboration with clinical and biostatistics
- Data capture and management using EDC systems
- CRF/eCRF design
- Database design, development, and maintenance
- Data validation specifications and edit check programming & testing
- SAE reconciliation
- External data handling and reconciliation
- Data management status reports
- Data extraction and transfer

◀ Biostatistics

- Expertise in Estimands and ICH E9 R1
- Conform to FDA and EMA current requirements
- Review of approved product FDA Statistics reviews
- Analysis of prior trials and public databases to determine placebo response
- Design your trial and SAP with deep therapeutic expertise
- Optimize statistical aspects of trial design for greatest likelihood of success
- Exploratory analysis specification
- Rapid regulatory response

Statistical Programming ▶

- Development of submission-ready datasets and supporting documents in CDISC format: Annotated CRF, SDTM, ADaM, Define.xml and Reviewer's Guide
- Generation of Analysis Datasets
- Production of Tables, Figures and Listings (TFLs)
- Data Monitoring Committees, Evaluation Committees and interim analyses outputs
- Generation of pooled datasets and TFLs for Integrated summary of efficacy and safety (ISE/ISS)
- Rapid regulatory response outputs
- Publication and ad hoc analysis outputs
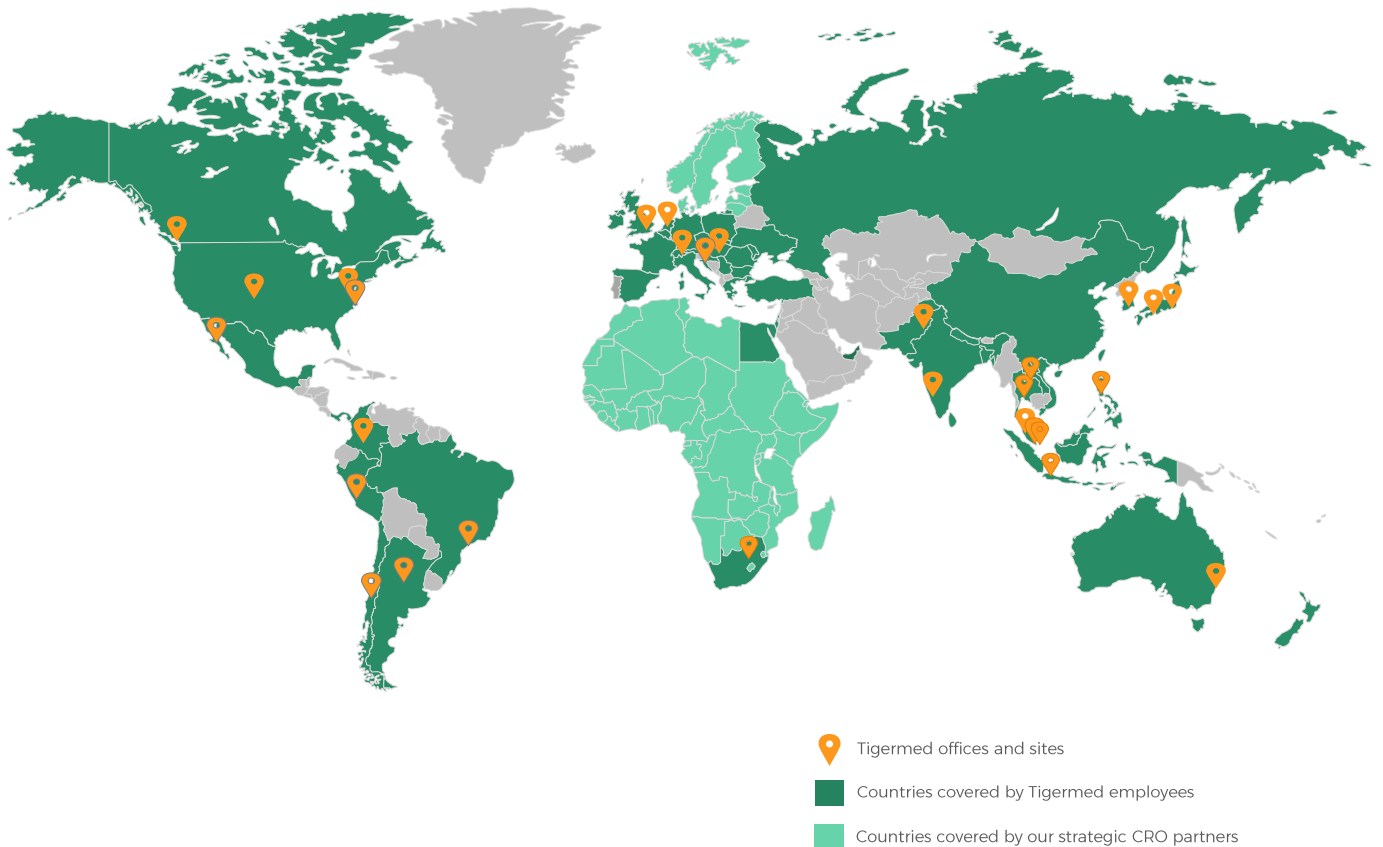- Exploratory data analysis outputs

Tigermed is a leading global provider of integrated research and development solutions for biopharmaceutical and medical device industry. With a broad portfolio of services and a promise of quality, from preclinical development to clinical trial to commercialization, we are committed to moving our customers through their development journey efficiently and cost-effectively.

10,000+
Global Employees

50
Countries

29
Offices & Sites

3,300+
Clinical Studies

Tigermed offices and sites

Countries covered by Tigermed employees

Countries covered by our strategic CRO partners

Contact

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