AVANIA
ADVANCING YOUR MEDICAL TECHNOLOGY

When You Need to Advance Your Data Analytics, It Takes Avania

Avania's analytical services team is vital to your clinical trial optimization

Your trial is important, and it takes a team with data analytics expertise to move it forward. **It Takes Avania.**

Avania's data analysts are a vital part of advancing your products through:

- Case report form (CRF) development
- Certified database builders in iMedNet, DFdiscover, and IBM platforms
- Modular development of randomization, device and IP tracking, site payments, and ePRO
- EDC-agnostic data management team who can support data cleaning, interrogation, and analysis in most leading EDC platforms
- Data validation and discrepancy management
- Data lock for prompt data resolution

Avania analytics is supported by a global team of experienced professionals from the data management, biostatistics, and eClinical areas. Our team holds advanced degrees (master's and Ph.D.) and are uniquely cross-trained across Avania's service offerings to streamline communication, facilitate collaboration, and ensure efficiencies.

Database Development and Trial Data Management

Avania brings knowledgeable experts together to form a unique CRO that can advance the research of your medical technology. Avania's team of dedicated data managers and analysts keep your trial streamlined and up to date by continually adapting to technological advancements to apply to your research.

Full-Service Data Analytics

Avania's experts are known for providing transparent, open communication to ensure that you will always have complete project visibility whenever you need it. Our data analysts work closely with cross-functional teams from clinical, regulatory, medical writing, and statistics to understand the needs and requirements of your study to develop effective case report forms and cutting-edge electronic clinical databases.

- We hand-select the best platform to suit your study and offer customized database development that utilizes electronic data capture, ePRO, eSignature, API, and more
- To proactively manage data validation and discrepancies, we manually and automatically review, confirm, and clean your data for consistency and clarity
- Avania structures your data to accelerate regulatory review by applying CDISC standards with flexibility to convert legacy data
- For prompt data resolution, we extensively plan and manage your site to safeguard data through the end of your study and clean database lock within days of last patient visit to save you time
- Certified medical coders can help with the application of MedDRA, WHODrug/WHO DDE, and WHOCC ATC coding to your data
- Statistical programming in SAS and R to carry out planned analyses which include creation and QC of analysis datasets, tables, figures, and listings (TFLs)

Through these services, our analysts ensure your data is well-structured, clean, consistent, and in the correct format to support the claims in your clinical study report. Avania is committed to delivering analytics within set timelines, and routinely accomplishes clean database lock within days of last patient last visit.

Customized Data Visualization

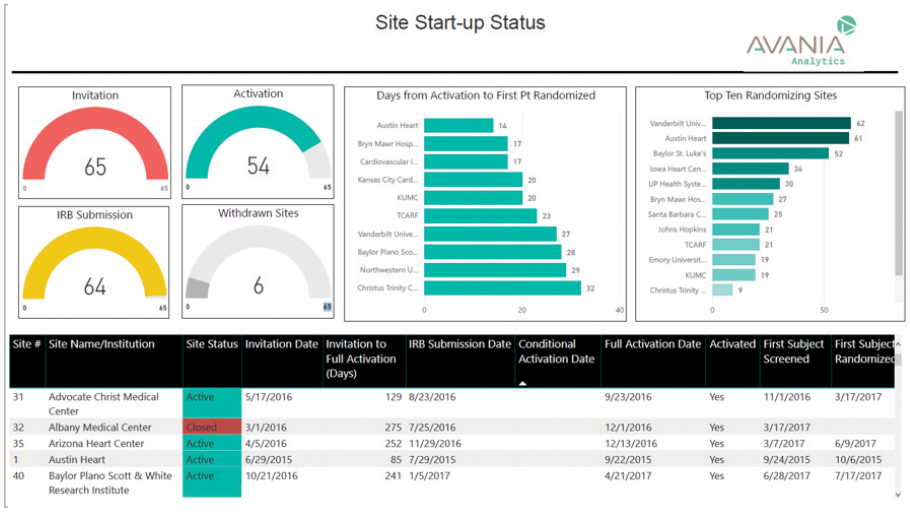
Avania analytics' data visualization platform provides one central location for all your study data to give insight into your clinical trial metrics while ensuring efficient and effective trial management. These customized study dashboards include interactive figures, tables, and displays of trial data in an easy-to-understand, easy-to-use format. Our data visualization services provide you with the study data insight and clinical trial execution metrics needed to ensure efficient and effective trial management. Avania's analysts will customize the dashboard to your clinical trial and design it to suit your data visualization needs by providing:

- Current project overviews with cross-tab filtering capabilities
- Site feasibility and site startup status metrics to aid site selection and study startup activities
- Enrollment tracking against projected enrollment to gauge study and site progress
- Safety reporting tools to review safety outcomes in real time

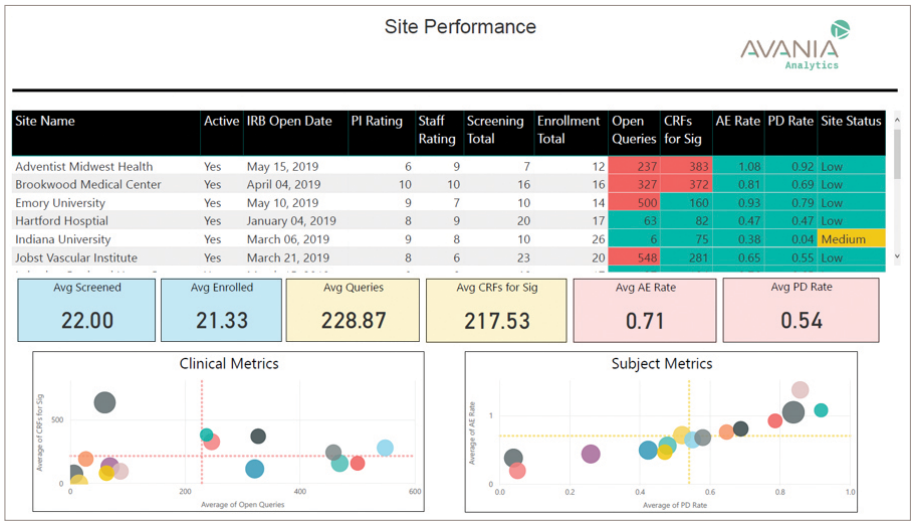
These customized visualization tools facilitate key decision-making by providing you with current summaries of critical study metrics. All data sources are kept in a protected data lake with planned data extracts set to refresh at an established frequency from one or more study databases.

Why is data visualization valuable?

- Up-to-date reporting at your fingertips providing insight into your study
- Detects data trends across sites
- Determines why an outlier or trend is present
- Tracks study progress easily while identifying potential risks
- Facilitates decision-making
- Aids risk assessment and critical variable monitoring



Site #	Site Name/Institution	Site Status	Invitation Date	Invitation to Full Activation (Days)	IRB Submission Date	Conditional Activation Date	Full Activation Date	Activated	First Subject Screened	First Subject Randomized
31	Advocate Christ Medical Center	Active	5/17/2016	129	8/23/2016		9/23/2016	Yes	11/1/2016	3/17/2017
32	Albany Medical Center	Closed	3/1/2016	275	7/25/2016		12/1/2016	Yes	3/17/2017	
35	Arizona Heart Center	Active	4/5/2016	252	11/29/2016		12/13/2016	Yes	3/7/2017	6/9/2017
1	Austin Heart	Active	6/29/2015	85	7/29/2015		9/22/2015	Yes	9/24/2015	10/6/2015
40	Baylor Plano Scott & White Research Institute	Active	10/21/2016	241	1/5/2017		4/21/2017	Yes	6/28/2017	7/17/2017



Benefits of an adaptive design:

- Greater ability to customize based on trial data
- Mid-study opportunities for course correction
- Provide early information for KOLs
- Increased likelihood of endpoint success
- More labeling options available
- Well-powered trials save costs on patient count

Biostatistics

Avania biostatisticians work closely with our data analysts to implement best practices that ensure clean, uncompromised data. We support preclinical and clinical program consultation, sample size analysis, justification, statistical analysis plans, and more to provide the most strategic statistical designs and analysis plans for your trial.

Avania's biostatisticians are a vital part of advancing your products through:

- Adaptive design clinical trial planning, simulation, and implementation using frequentist and Bayesian techniques
- Study powering and endpoint justification
- Regulatory submissions, guidance, planning, and meeting representation
- Randomization schemes
- Statistical analysis plans (SAP)
- Pharmacokinetic and pharmacodynamic analyses
- SDTM and ADaM dataset preparation (submission-ready dataset packages)
- Data monitoring committee (DMC), safety committee, and endpoint committee support
- Statistical tables, data listings, and figures for clinical study reports (CSRs)
- Consolidated, in-house approach of regulatory, clinical, reimbursement, and statistic consultants to develop a program pathway best suited to expedited market adoption

Avania is an integrated global, full-service CRO with specialized expertise in medical device, novel technology, and combination products. They advance products from feasibility all the way through post-approval in analytics, clinical trials, consulting, regulatory, reimbursement, and more.

AvaniaClinical.com | info@AvaniaClinical.com

AVANIA
ADVANCING YOUR MEDICAL TECHNOLOGY