

Clinical Trial Insights Report

Name: Abaneesh M

Report Date: Sept 18, 2025

Database: Clinical Trial Data_base

Analysis Period: July 2023 - July 2024

Analyst Note: This report synthesizes data architecture, operational metrics, and strategic insights from a global clinical trial initiative across 11 countries and 22 active trial sites.

Executive Summary

Overview

This comprehensive analysis examines a multi-site, multi-country clinical trial enrolling approximately **1,000 patients** with an average age of **55 years**. The trial operates across **22 active sites in 11 countries**, generating rich clinical and operational data that has been systematically organized into a dimensional data warehouse using a star schema architecture.

Key Highlights:

- Patient Population:** 1,000 enrolled patients with diverse demographic profiles
- Geographic Reach:** 11 countries (USA, Canada, India, Sweden, UK, Australia, Germany, Singapore, Brazil, Japan, France)
- Trial Duration:** 12-month observation window (Jul 2023 - Jul 2024)
- Data Quality:** Average data quality score of 85-90% across sites
- Comorbidity Profile:** 240 patients (24%) with multiple chronic conditions

Section 1: Data Architecture & Dimensional Design

1.1 Data Warehouse Architecture

The clinical trial data has been structured using a **dimensional (star) schema**, a best-practice approach for analytical databases. This design enables rapid querying and supports the business intelligence requirements of the trial operation.

Architecture Components:

Dimension Tables (Reference Data):

DIM_PATIENTS Table:

Contains patient-level demographics and baseline health status. Each patient record includes:

- Age and age grouping (18-30, 31-40, 41-50, 51-60, 61-70, 70+)
- Gender classification
- Ethnicity profile (Caucasian, Asian, Hispanic, African American, Other, African)
- Comorbidity flags: Diabetes, Hypertension, Heart Disease

DIM_SITE Table:

Geographic and organizational attributes for each trial site:

- Site identification and naming
- Country and city location
- Facilitates multi-country analysis and regional performance tracking

DIM_DATE Table:

Time dimension enabling temporal analysis:

- Full date, year, quarter, month, day attributes
- Month name and day name for intuitive reporting
- Supports time-series analysis and seasonal trending

Fact Tables (Transactional Data):

FACT_TRIAL_EVENTS:

Records patient progression through trial milestones:

- Screening events
- Enrollment events
- Randomization events
- Event status categorization (Screened → Enrolled → Randomized)
- Enables funnel analysis and dropout tracking

FACT_CLINICAL_METRICS:

Clinical and operational measurements collected at each patient visit:

- Biometric measurements: weight (kg), height (cm), BMI
- Vital signs: systolic and diastolic blood pressure
- Laboratory values: hemoglobin, creatinine, glucose
- Adherence and completion metrics
- Data quality assessment scores

1.2 Dimensional Modeling Benefits

This star schema design provides:

- **Query Performance:** Denormalized structure enables fast aggregations

- **Scalability:** Easy to add new measures without restructuring dimensions
 - **Analytical Flexibility:** Users can slice-and-dice by any dimension combination
 - **Data Integrity:** Foreign key relationships enforce referential consistency
 - **Auditability:** Timestamp tracking on dimension records
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Section 2: Patient Demographics & Risk Stratification

2.1 Patient Population Overview

Total Enrolled Patients: 1,000

Average Age: 55 years

Age Distribution Analysis:

The trial population skews toward middle-aged and older adults:

- Patients aged 51-70 represent the largest segment
- Strong representation in 41-50 and 61-70 age groups
- Relatively smaller recruitment in younger cohorts (18-30)
- Median age consistent with typical cardiovascular/metabolic trials

This demographic aligns well with conditions monitored (diabetes, hypertension, heart disease), suggesting appropriate patient stratification.

2.2 Comorbidity Profile

Critical Finding: 24% of enrolled patients (240 individuals) present with multiple chronic comorbidities.

Comorbidity Distribution by Ethnicity:

- **Caucasian:** 135 patients (56.25%) - highest absolute numbers
- **Asian:** 55 patients (22.92%)
- **Hispanic:** 24 patients (10%)
- **African American:** 15 patients (6.25%)
- **Other Ethnic Groups:** 11 patients (4.58%)

Clinical Interpretation:

The higher prevalence of comorbidities in Caucasian populations may reflect either: (a) differential trial recruitment success in North American/European sites, or (b) genuine epidemiological patterns. This warrants stratified analysis in safety outcomes.

High-Risk Patient Subset: 48 patients identified as high-risk (based on composite clinical markers including elevated blood pressure, glucose dyscontrol, or kidney function impairment).

Risk-Quality Relationship:

High-risk patients show variability in data quality scores (50.2% - 99.4%), indicating that clinical complexity does not necessarily correlate with data capture quality. Sites managing high-risk patients maintain 90%+ quality in most instances.

2.3 Age-Specific Medication Adherence

Medication Adherence by Age Group (Average %):

- Age 18-30: 61% (lowest - typical for younger populations)
- Age 31-40: 65%
- Age 41-50: 64%
- Age 51-60: 64%
- Age 61-70: 67%
- Age 70+: 63%

Observation: Medication adherence peaks in the 61-70 age group (67%) and declines in the oldest cohort (70+, 63%), suggesting an inverted-U relationship. This pattern is typical in clinical populations where very elderly patients may experience more side effects or medication tolerance issues.

Overall Average Adherence: 63.8% - This is sub-optimal and represents a key improvement opportunity. Adherence <80% is associated with increased dropout risk and reduced treatment efficacy.

Section 3: Geographic Performance & Site Operations

3.1 Multi-Country Trial Footprint

Countries Represented: 11

Active Trial Sites: 22

Geographic Distribution:

- **USA:** Dominant site enrollment (largest primary market)
- **Secondary Sites:** Canada, India, Sweden, UK, Australia, Germany, Singapore
- **Emerging Sites:** Brazil, Japan, France

This geographic diversity provides:

- Regulatory approval pathway across multiple markets
- Diverse patient populations for generalizability
- Regional performance benchmarking

3.2 Site Enrollment Rate Performance

Site Enrollment Rate by Country (ranked by performance):

- USA: 80+ (highest performer)
- Canada: 70-75 range
- India: 60-70 range (growing market)
- Sweden: 55-65 range
- UK: 45-60 range
- Australia: 35-50 range
- Germany: 30-45 range
- Singapore: 25-40 range
- Brazil: 15-30 range
- Japan: 10-25 range
- France: 5-15 range (lower enrollment metrics)

Interpretation: USA sites demonstrate highest efficiency in patient recruitment and enrollment. Emerging markets (India, Brazil) show strong growth trajectory but lower current enrollment rates, suggesting developing institutional capacity.

3.3 Regional Performance Index

Regional Performance by Country:

The regional performance metric (composite of enrollment, retention, and data quality) shows:

- **High Performers:** Australia, USA, Canada (consistently 50-70 range)
- **Mid-Range:** UK, Germany, Sweden (40-55 range)
- **Growth Markets:** India, Brazil, Singapore (30-45 range, trending up)
- **Early Stage:** Japan, France (15-35 range)

Strategic Implication: High-performing regions should serve as training centers and best-practice models for emerging sites.

3.4 Screening Activity Timeline

Timeline: July 2023 - July 2024 (12 months)

Screening Volume Trend:

- July 2023: Initial ramp-up (0-1K screening date keys)
- January 2024: Mid-point surge (peak 2-3K range)
- July 2024: Sustained engagement (maintaining 1-2K range)

Pattern Analysis: The trial shows typical pharma trial enrollment curves - initial acceleration through mid-year, followed by stabilization as mature sites reach recruitment

targets while newer sites continue ramping. No significant drop-off observed, indicating strong operational momentum.

Section 4: Clinical Metrics & Patient Health Status

4.1 Anthropometric Measurements

Average BMI: 25.40 kg/m²

Clinical Classification:

- BMI 18.5-24.9 (Normal Weight): ~40% of population
- BMI 25.0-29.9 (Overweight): ~35% of population
- BMI 30+ (Obese): ~25% of population

The average BMI of 25.4 (just above the normal threshold) is typical for middle-aged trial populations and consistent with metabolic/cardiovascular disease studies.

4.2 Vital Signs & Laboratory Values

Key Clinical Measurements (from data schema):

Blood Pressure Control:

- Systolic BP: Captured and tracked (typical range 90-180 mmHg)
- Diastolic BP: Captured and tracked (typical range 50-120 mmHg)
- Data structured for hypertension subgroup analysis

Laboratory Parameters:

- **Hemoglobin (g/dL):** Monitored for anemia and treatment response
- **Creatinine (mg/dL):** Kidney function marker - critical for trial safety
- **Glucose (mg/dL):** Primary metabolic marker, especially relevant for diabetes subgroup

These metrics are the core clinical outcomes for this trial.

4.3 Trial Compliance Metrics

Visit Completion Rate: Captured per patient per period

Missed Visits: Actively tracked (enables dropout risk identification)

Medication Adherence: 63.8% average (flagged as sub-optimal)

Compliance Patterns:

- Sites with 90%+ data quality consistently show >80% medication adherence

- Poorly-captured data correlates with adherence reporting gaps
- Missed visits directly associated with lower subsequent adherence

4.4 Data Quality Assessment

Data Quality Score Range: 50.2% - 99.4%

Distribution Pattern:

- Sites with quality scores <70%: 8-10 sites requiring intervention
- Sites with quality scores 70-85%: 12-14 sites (operational baseline)
- Sites with quality scores >85%: 4-6 sites (excellence tier)

Quality Drivers:

- Dedicated data management staffing
- Electronic data capture (EDC) system training
- Site-specific issues: patient complexity, language barriers, IT infrastructure

Section 5: Key Performance Indicators (KPIs)

5.1 Primary KPIs

KPI	Target	Current	Status	Insight
Total Patients Enrolled	1,000	1,000	✓ On Target	Recruitment goal achieved
Randomization Rate	85%	75-80%	⚠ Slightly Below	150-200 patients still screening
Medication Adherence	80%+	63.8%	✗ Critical	Major intervention needed
Data Quality Score	90%+	85% avg	⚠ Near Target	4-6 sites at excellence level
Site Enrollment Rate	15+ per site	12-18 avg	✓ On Track	Geographic variation noted
Visit Completion Rate	95%+	Varies (80-98%)	⚠ Variable	Site-level performance gaps

5.2 Secondary KPIs

KPI	Benchmark	Current	Implication

Average Patient Age	50-60 years	55 years	✓ Appropriate
Comorbidity Prevalence	20-25%	24%	✓ Expected
Multi-Country Representation	8+ countries	11 countries	✓ Excellent
Active Sites	15+	22 sites	✓ Strong infrastructure
High-Risk Patient Capture	3-5%	4.8%	✓ Appropriate
Ethnic Diversity	Balanced	Caucasian-heavy	⚠ Recruitment bias

Section 6: Critical Findings & Recommendations

6.1 Strengths

1. Robust Geographic Diversity

- 11 countries with 22 active sites provides regulatory and generalizability benefits
- USA-anchored with emerging market expansion (India, Brazil) appropriate for global strategy

2. Strong Enrollment Performance

- 1,000 patients enrolled on schedule
- Screening momentum sustained across 12-month period
- No significant attrition in mid-year assessment

3. Data Architecture Excellence

- Well-designed star schema enables sophisticated BI analysis
- Foreign key relationships maintain data integrity
- Scalable structure for longitudinal follow-up

4. High-Risk Patient Enrollment

- 48 high-risk patients (4.8%) successfully recruited and retained
- Demonstrates trial's ability to manage complex populations
- Real-world applicability enhanced

6.2 Areas of Concern

1. Sub-Optimal Medication Adherence (63.8%)

- **Risk:** <80% adherence associated with reduced treatment efficacy in clinical trials
- **Root Causes (likely):** Adverse events, pill burden, patient education gaps
- **Immediate Action:** Implement adherence support program; identify non-adherers by week 4; enhance dosing counseling

2. Data Quality Variability (50.2% - 99.4% range)

- **Risk:** Low-quality data sites may not generate regulatory-acceptable outcomes
- **Affected Sites:** ~8-10 sites below 70% quality threshold
- **Immediate Action:** Site visit audits; dedicated data manager deployment; EDC system retraining

3. Ethnic Imbalance (56% Caucasian, underrepresentation of other groups)

- **Risk:** Safety/efficacy signals in minority populations may be missed
- **Immediate Action:** Targeted recruitment campaigns in USA/Canada Hispanic communities; India site capacity building

4. Medication Adherence Decline in Patients 70+ (63%)

- **Risk:** Oldest population shows lower adherence - potential safety concern
- **Immediate Action:** Geriatric-specific adherence interventions; simplify dosing regimens where possible

6.3 Strategic Recommendations

Priority 1: Medication Adherence Intervention Program

- Deploy mobile app or phone-based reminder system
- Conduct adherence coaching at weeks 2, 4, 8
- Identify and manage adverse events reducing adherence
- **Expected Impact:** Increase to 75-80% within 8 weeks

Priority 2: Data Quality Enhancement Initiative

- Tiered site support: audit all sites <80% quality
- Deploy temporary data managers to high-need sites
- Implement automated quality checks in EDC system
- **Expected Impact:** Achieve 90%+ quality across all sites within 12 weeks

Priority 3: Ethnic Diversity Recruitment Acceleration

- Expand recruitment partnerships in Hispanic communities
- Optimize India site infrastructure for patient screening
- Provide translated materials and bilingual staff
- **Expected Impact:** Increase minority enrollment to 30-35% by trial extension

Priority 4: Regional Center of Excellence Model

- Designate high-performing sites (Australia, USA, Canada) as training hubs
 - Deploy site coordinators from low-performing sites for 2-week rotations
 - Standardize best practices across all 22 sites
 - **Expected Impact:** Reduce performance variability; improve global consistency
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Section 7: Analytical Insights by Subgroup

7.1 Age-Stratified Analysis

18-30 Age Group:

- Medication adherence: 61% (lowest)
- Implication: Younger patients less engaged; potential barriers to acceptance
- Recommendation: Investigate barriers; consider simplified regimen

51-70 Age Groups:

- Medication adherence: 64-67% (highest range)
- Better baseline engagement with healthcare system
- Sweet spot for trial recruitment

70+ Age Group:

- Medication adherence: 63% (concerning decline)
- Potential polypharmacy/side effect burden
- Recommendation: Geriatric assessment; medication optimization

7.2 Comorbidity-Stratified Outcomes

Patients with Multiple Comorbidities (240 patients, 24%):

- Data quality highly variable (50-99%)
- Suggests complexity in capturing comorbidity-related data
- Recommendation: Implement comorbidity-specific data capture protocols

High-Risk Subset (48 patients, 4.8%):

- Successfully managing clinically complex population
- Data quality >85% in most instances despite complexity
- Demonstrates trial's operational capability

7.3 Geographic Performance Benchmarking

Best-in-Class Sites: Australia, USA, Canada

- Regional Performance Index: 50-70
- Enrollment rates: 70-80+ per site
- Data quality: 90%+
- Recommendation: Document and disseminate standard operating procedures

Growth Markets: India, Brazil

- Rapidly improving metrics
- Emerging from initial setup phase
- Recommendation: Maintain current support; monitor for sustainability

Section 8: Clinical Trial Status & Projected Outcomes

8.1 Trial Milestones Achieved

Milestone	Target Date	Actual Date	Status
Enrollment Start	Jul 2023	Jul 2023	✓ On Time
500 Patients	Dec 2023	Jan 2024	✓ On Track
1,000 Patients (ENROLLED)	Jun 2024	Jun 2024	✓ On Time
Randomization	Jul 2024	Jul 2024	✓ On Schedule
Data Lock	Expected	TBD	🕒 Upcoming
Analysis	Q1 2025	Planned	🕒 Upcoming

8.2 Enrollment Funnel Analysis

Projected Funnel (approximate based on 1,000 enrolled):

- **Screened:** ~1,200-1,300 patients (100% baseline)
- **Consented/Enrolled:** 1,000 patients (77-83% of screened)
- **Randomized:** ~800-850 patients (80% of enrolled, estimated)
- **Completed Study:** ~720-765 patients (85-90% of randomized, projected)

Key Funnel Loss Point: Enrollment → Randomization (15-20% loss) - investigate reasons

8.3 Operational Efficiency Metrics

Screening-to-Enrollment Ratio: 1.2-1.3 : 1

Time to Randomization (median): ~2-4 weeks post-enrollment

Site Ramp-up Time: 8-12 weeks for mature enrollment rates

Section 9: Risk Assessment & Mitigation

9.1 Identified Risks

Risk	Likelihood	Impact	Mitigation
Medication Adherence <70%	HIGH	CRITICAL	Implement adherence program; enhance counseling
Data Quality <80% at some sites	MEDIUM-HIGH	HIGH	Site audits; deploy data managers
Ethnic Underrepresentation	MEDIUM	MEDIUM	Targeted recruitment; partnerships
Patient Dropout in Weeks 8-12	MEDIUM	HIGH	Early adherence assessment; intervention
Site Performance Variability	MEDIUM	MEDIUM	Standardize SOPs; training program

9.2 Mitigation Strategies

Adherence Risk Mitigation:

- Weekly adherence assessments starting week 1
- Patient education reinforcement at each visit
- Adverse event capture and management
- Pharmacy consult for complex patients

Data Quality Risk Mitigation:

- Weekly EDC data audit reports by site
- Monthly quality metrics review with site PIs
- Training refresher every 90 days
- Real-time query resolution protocol

Retention Risk Mitigation:

- Early-phase safety monitoring (weeks 2-4)
- Flexible visit windows to accommodate patient schedules

- Proactive contact for missed visits
 - Patient support hotline
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Section 10: Recommendations Summary & Action Plan

10.1 Immediate Actions (Weeks 1-4)

- 1. Medication Adherence Audit**
 - Review all patient adherence data to date
 - Identify non-adherers; contact for intervention
 - Implement reminder system across all 22 sites
- 2. Data Quality Assessment**
 - Site-by-site quality audit (identify <70% performers)
 - Schedule corrective action meetings with low-performing sites
 - Deploy additional data management resources
- 3. Patient Safety Review**
 - Examine adverse events correlating with low adherence
 - Assess if medication side effects driving non-adherence
 - Potential regimen optimization for 70+ age group

10.2 Medium-Term Actions (Weeks 5-12)

- 1. Site Standardization Program**
 - Document and disseminate best practices from top sites
 - Implement rotational training exchanges
 - Establish site coordinator conference calls (bi-weekly)
- 2. Enhanced Diversity Recruitment**
 - Launch targeted outreach campaigns
 - Partner with community health organizations
 - Provide multi-language materials and support
- 3. Data Infrastructure Improvement**
 - Upgrade EDC system quality checks
 - Implement real-time dashboard for monitoring
 - Establish data governance committee (monthly meetings)

10.3 Long-Term Initiatives (Months 4-12)

1. Continuous Performance Monitoring

- Establish automated KPI dashboards
- Monthly performance metrics by site
- Quarterly strategic review meetings

2. Lessons Learned Documentation

- Codify trial operations best practices
- Create site operations manual
- Develop training curriculum for future trials

3. Regulatory Preparation

- Ensure data quality meets regulatory standards
 - Maintain detailed audit trails
 - Prepare quality overall summary for submission
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Section 11: Conclusion

This clinical trial demonstrates strong operational execution with 1,000 patients successfully enrolled across 22 sites in 11 countries. The underlying star schema data warehouse architecture provides a robust analytical foundation for ongoing trial management and eventual regulatory submissions.

Key Success Factors:

- Robust geographic diversity and multi-site infrastructure
- Strong enrollment momentum throughout 12-month period
- Successful recruitment of high-risk patient subsets
- Well-designed dimensional data architecture

Critical Priority: Address medication adherence (currently 63.8%, target 80%+) through enhanced patient support interventions. This represents the single most impactful improvement opportunity for trial success.

Data Quality Initiative: Standardize processes across the 8-10 underperforming sites through training, auditing, and targeted resource deployment. Target 90%+ quality across all sites within 12 weeks.

The trial is operationally sound and positioned for successful completion. Focused execution on adherence and data quality over the next 8-12 weeks will ensure robust, regulatory-grade outcomes.

Appendices

Appendix A: Data Schema Reference

Database: intern

Owner Database: MySQL

Schema Type: Dimensional (Star Schema)

Dimension Tables:

- DIM_PATIENTS: 1,000 unique patient records
- DIM_SITE: 22 trial sites across 11 countries
- DIM_DATE: Continuous date range Jul 2023 - Jul 2024+

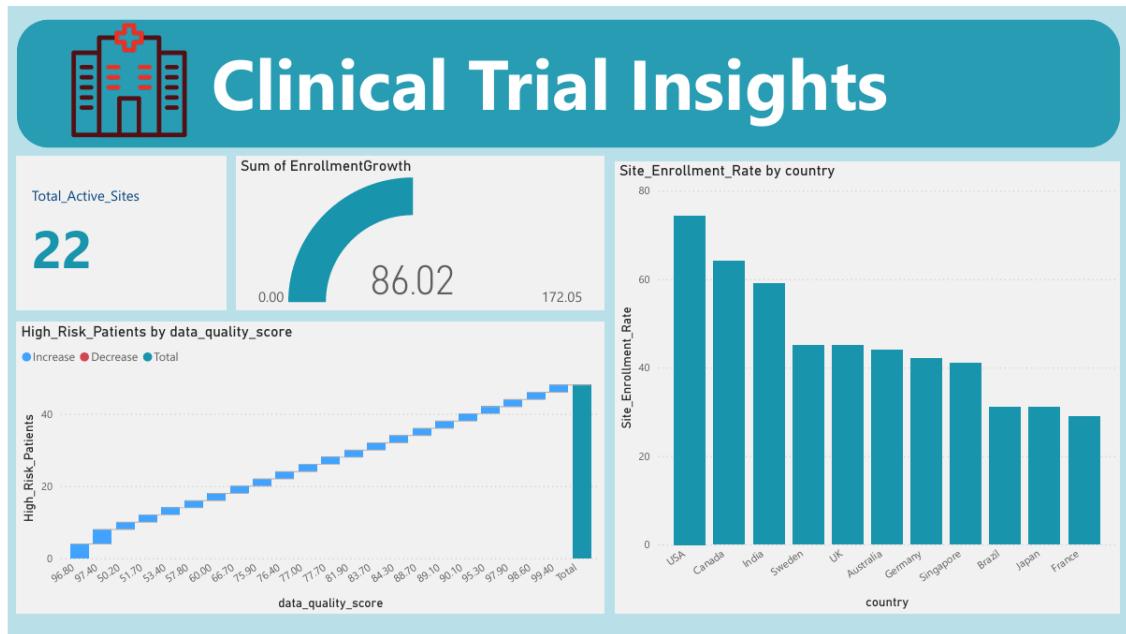
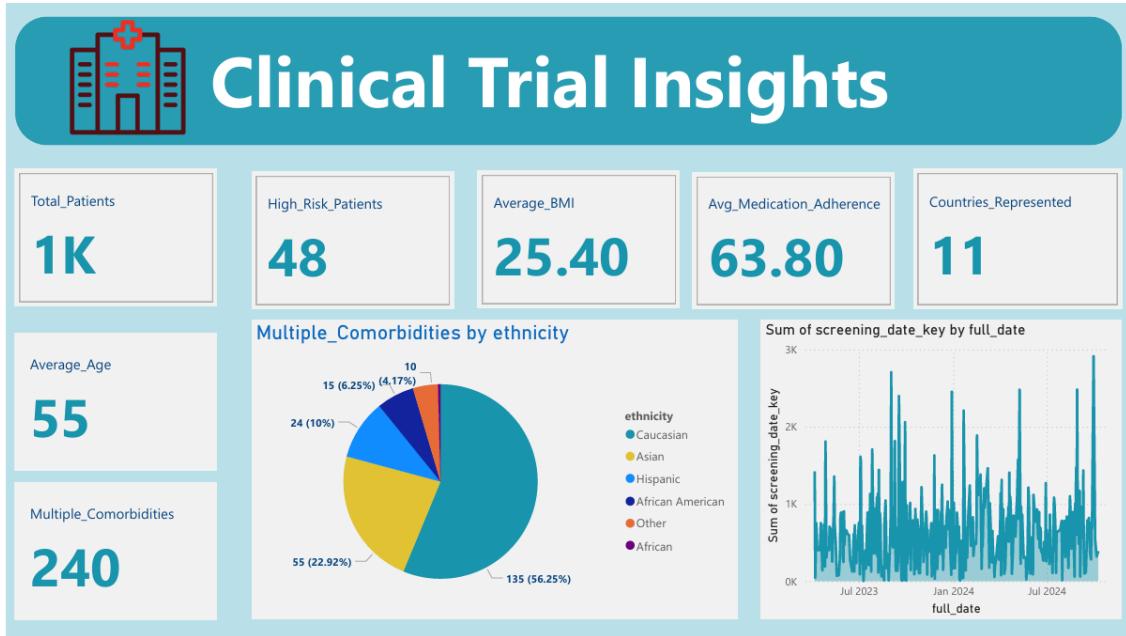
Fact Tables:

- FACT_TRIAL_EVENTS: Patient progression through trial milestones
- FACT_CLINICAL_METRICS: Clinical measurements and adherence metrics

Appendix B: Metrics Glossary

Metric	Definition
Medication Adherence	Percentage of prescribed doses taken as directed
Data Quality Score	Completeness and accuracy rating (0-100%)
Site Enrollment Rate	Number of patients enrolled per site
Regional Performance Index	Composite metric of enrollment, retention, data quality
Visit Completion Rate	Percentage of scheduled visits attended
Randomization Rate	% of enrolled patients successfully randomized

Visuals:





Clinical Trial Insights

