

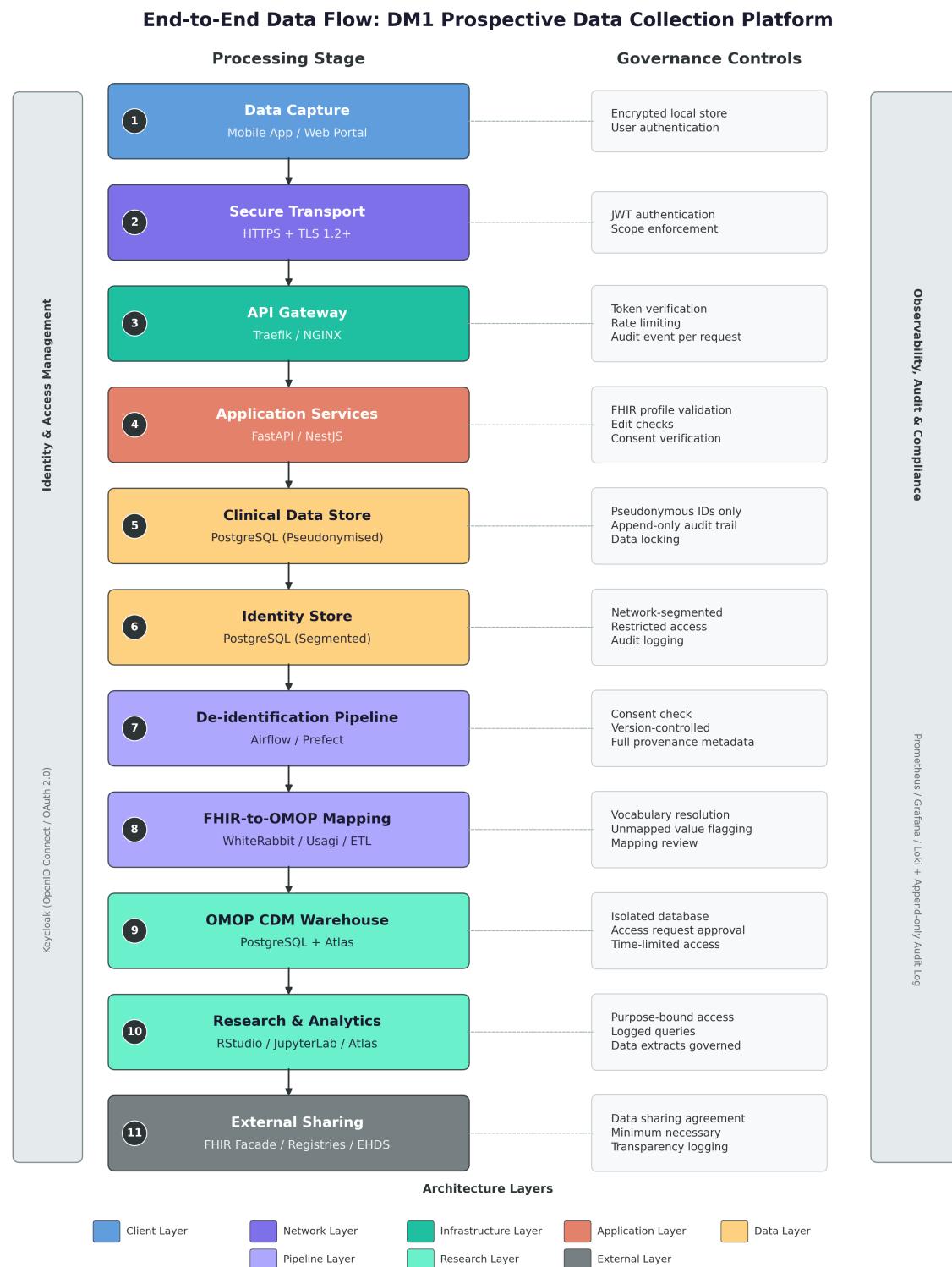
# Annex - Supporting Figures and Tables

Clinical Data Management for DM1 - IGTP

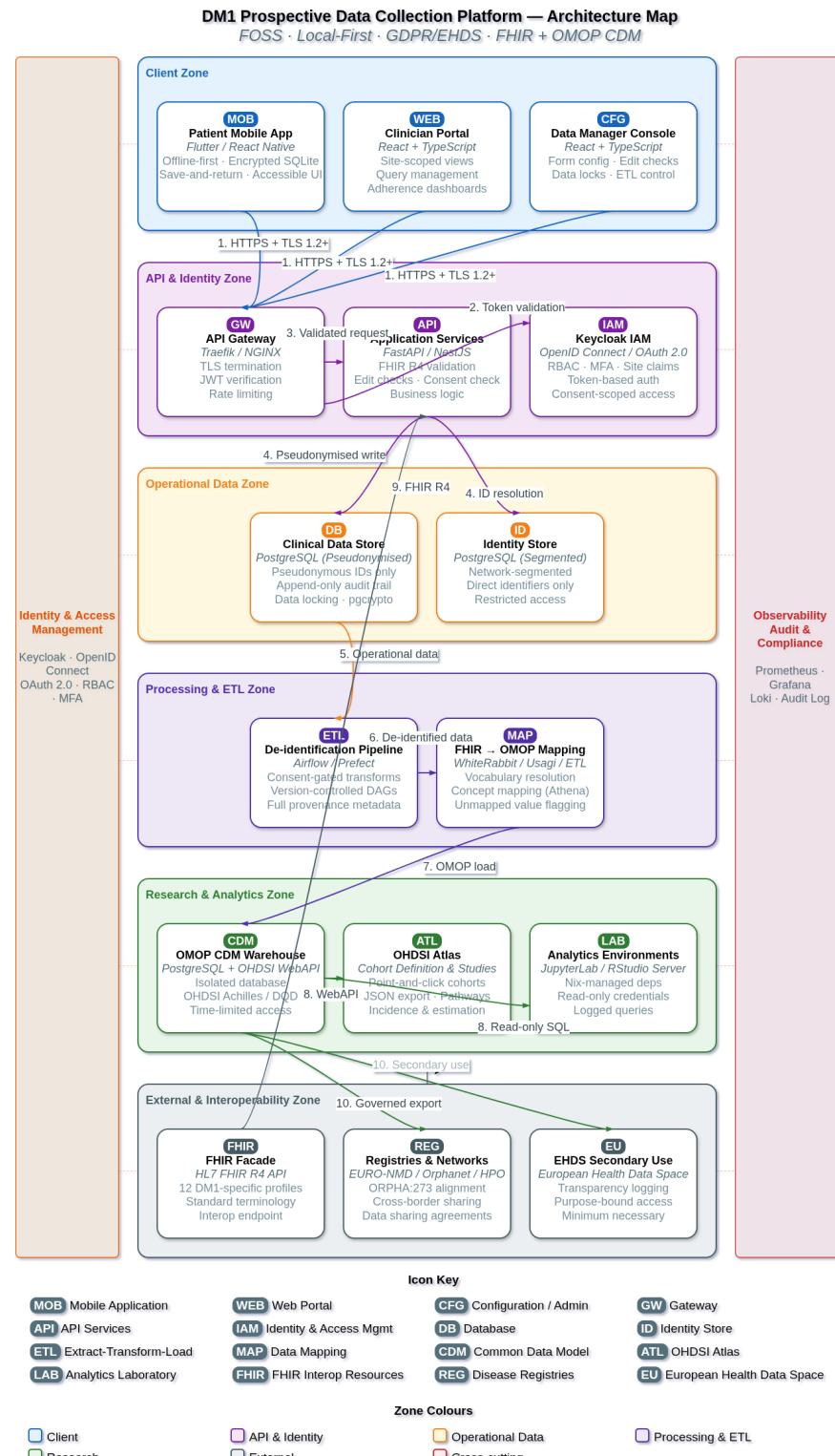
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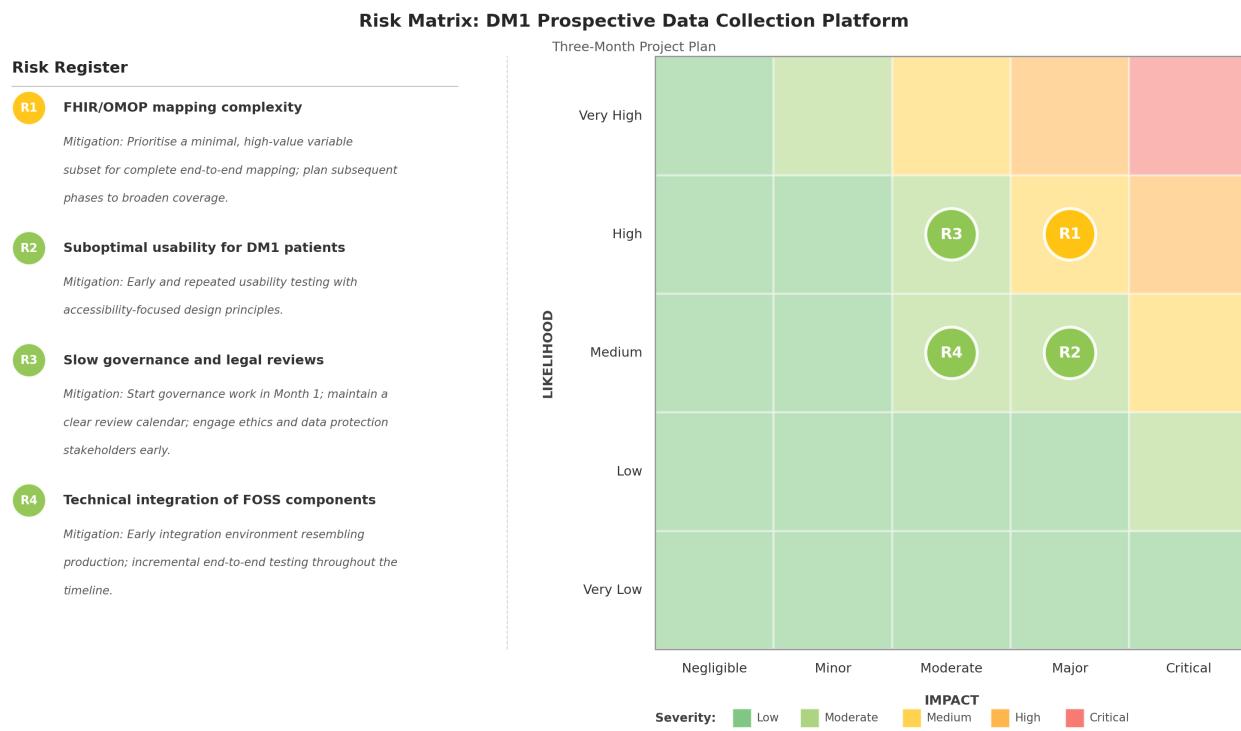
*All artefacts are available at full resolution in the project repository: <https://github.com/stradichenko/task-ref-2026-14>*



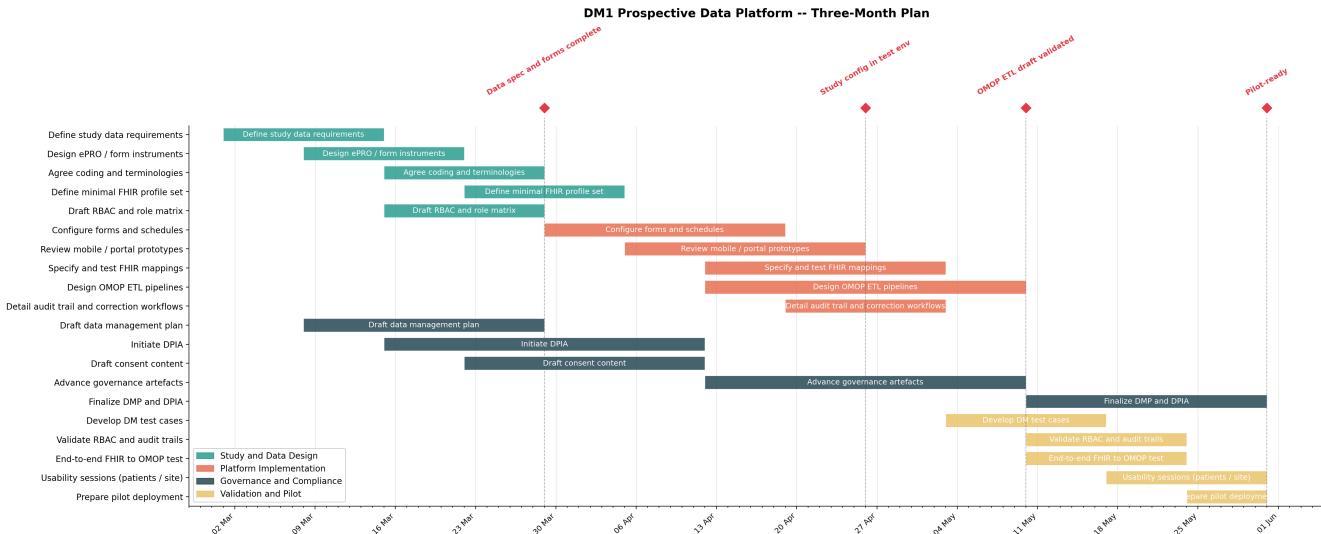
**Figure 1:** System Data Flow Diagram. Seven-layer architecture from patient mobile app and clinician portal through API services, Identity and Access Management (Keycloak), operational database, de-identification pipelines, OMOP CDM warehouse, to observability and audit logging.



**Figure 2:** Platform Architecture Map. Zoned view of all system components-Client, API & Identity, Operational Data, Processing & ETL, Research & Analytics, and External & Interoperability-with Identity & Access Management and Observability as cross-cutting concerns. Data-flow sequence numbers indicate the order of interactions.



**Figure 3:** Risk Likelihood–Impact Matrix. Four identified project risks (R1–R4) plotted by likelihood and impact severity. Colour coding indicates residual risk level after mitigation.



**Figure 4:** Project Gantt Chart. Three-month timeline showing four overlapping workstreams: Foundation & Design (Month 1), Configuration & Implementation (Month 2), Validation & Pilot (Month 3), and cross-cutting Governance. Key milestones are marked.

### Role-Based Access Control Permission Matrix -- DM1 Data Collection Platform

Permission	Patient	Caregiver	Clinical Researcher	Data Manager	Data Engineer	Auditor	System Admin
<strong>DATA CAPTURE</strong>							
Create and submit own entries	G	S	-	-	-	-	-
Correct own entries (within time window)	G	S	-	-	-	-	-
View own submissions and trends	G	S	-	-	-	-	-
<strong>CLINICAL REVIEW</strong>							
View participant data (own site)	-	-	S	-	-	-	-
Annotate and classify entries	-	-	S	-	-	-	-
Flag serious adverse events	-	-	S	R	-	-	-
Monitor adherence dashboards	-	-	S	G	-	-	-
<strong>QUERIES</strong>							
Create data queries	-	-	S	G	-	-	-
Respond to queries	G	S	S	G	-	-	-
Manage queries study-wide	-	-	-	G	-	-	-
<strong>STUDY CONFIGURATION</strong>							
Configure forms and instruments	-	-	-	G	-	-	-
Configure edit checks and validation	-	-	-	G	-	-	-
Configure visit schedules	-	-	-	G	-	-	-
Version and deploy configurations	-	-	-	G	-	R	-
<strong>DATA QUALITY AND LOCKS</strong>							
Run data quality reports	-	-	-	G	-	-	-
Lock and unlock data at milestones	-	-	-	G	-	-	-
View data quality dashboards	-	-	S	G	-	R	-
<strong>DATA PIPELINES AND EXPORTS</strong>							
Configure ETL pipelines	-	-	-	-	G	-	-
Run ETL jobs	-	-	-	-	G	-	-
Configure and run data exports	-	-	-	-	G	-	-
Manage external system integrations	-	-	-	-	G	-	-
Edit clinical values in production	-	-	-	-	-	-	-
<strong>OMOP AND RESEARCH ACCESS</strong>							
Access OMOP research datasets	-	-	S	R	G	-	-
Run cohort queries (Atlas)	-	-	S	R	G	-	-
Configure OMOP access policies	-	-	-	G	G	-	-
<strong>AUDIT AND COMPLIANCE</strong>							
View audit trail	-	-	-	S	-	G	R
Export audit trail segments	-	-	-	-	-	G	-
View system configuration snapshots	-	-	-	R	-	G	G
Filter and review security events	-	-	-	-	-	G	G
<strong>CONSENT MANAGEMENT</strong>							
Provide or withdraw own consent	G	S	-	-	-	-	-
Manage consent forms and versions	-	-	-	G	-	R	-
View consent status per participant	-	-	S	G	-	R	-
<strong>IDENTITY AND ACCESS</strong>							
Manage user accounts	-	-	-	-	-	-	G
Assign and revoke roles	-	-	-	-	-	-	G
View role assignments	-	-	-	R	-	R	G
<strong>SYSTEM ADMINISTRATION</strong>							
System and infrastructure configuration	-	-	-	-	-	-	G
View technical logs	-	-	-	-	G	-	G
Monitor system health and performance	-	-	-	-	G	-	G

[Legend: G = Granted, S = Scoped (site/own/proxy), R = Read-only, - = Denied]

**Table 1:** Role-Based Access Control (RBAC) Permission Matrix. Seven roles (Patient, Caregiver, Clinical Researcher, Data Manager, Data Engineer, Auditor, System Admin) mapped against 38 permissions across 11 categories.

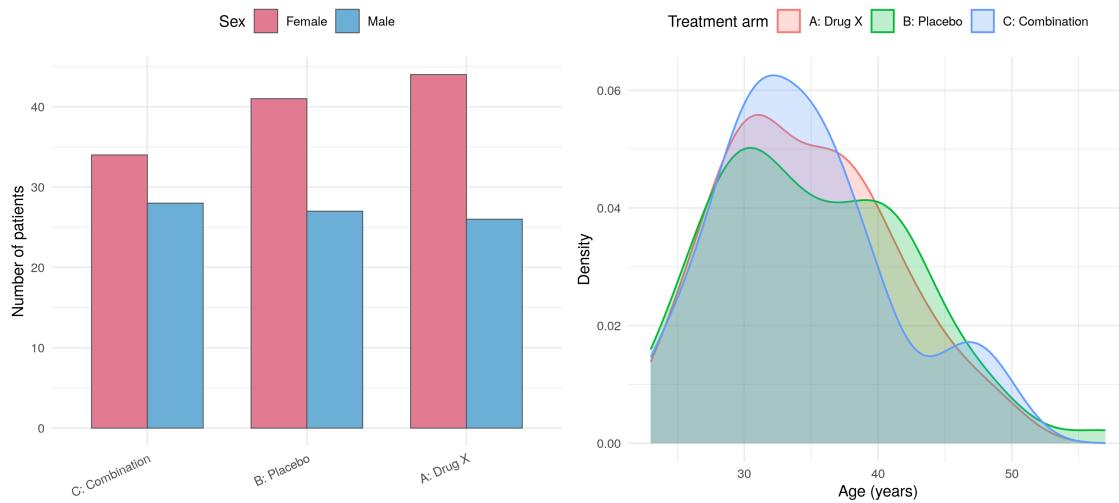
RACI Matrix: DM1 Prospective Data Collection Platform								
Activity	CDM	Clinical Investigators	Data Engineering	Development / Technical	Legal / DPO	Biostatistics	Study Leadership	DevOps / SysAdmin
<b>Month 1: Foundation and Detailed Design</b>								
Study data specification	R A	C	C	I	I	C	I	-
Instrument and schedule design	R A	C	I	C	I	C	I	-
Standards, terminologies, and coding	R A	I	C	C	-	C	I	-
Minimal FHIR profile set	R	I	C	R A	-	-	I	-
Role and permission matrix	R A	I	C	C	C	-	I	C
Initial governance documentation	R	I	I	C	R A	-	C	I
<b>Month 2: Configuration, Implementation Support, and Governance</b>								
Configuration of forms and schedules	R A	C	I	C	-	-	I	-
Review of application prototypes	R	C	I	R A	-	-	I	-
FHIR mapping specification and testing	R	I	C	R A	-	-	I	-
OMOP ETL design	C	I	R A	C	-	C	I	-
Audit trail and data correction workflows	R A	I	I	R	C	-	I	C
DPIA and governance refinement	R	I	I	C	R A	-	C	I
<b>Month 3: Validation, User Testing, and Pilot Readiness</b>								
Data management testing	R A	I	C	C	-	-	I	-
Audit trail and RBAC verification	R A	-	I	C	C	-	I	C
End-to-end FHIR to OMOP validation	R	I	R A	C	-	C	I	-
Usability sessions	R A	C	I	C	-	-	C	-
Finalisation of CDM and governance docs	R A	I	I	I	C	I	C	I
Pilot preparation	R	C	C	C	I	I	R A	C

R = Responsible   
 A = Accountable   
 C = Consulted   
 I = Informed

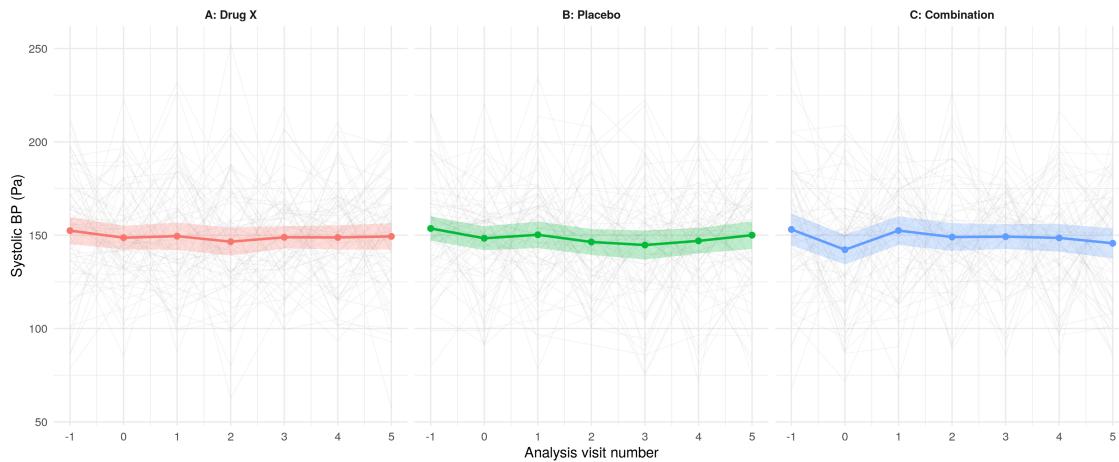
**Table 2:** Responsible–Accountable–Consulted–Informed (RACI) Responsibility Matrix. Task allocation across eight roles–Clinical Data Manager, Clinical Investigators, Data Engineering, Development/Technical, Legal/DPO, Biostatistics, Study Leadership, and DevOps/SysAdmin–for all major deliverables.

## Exploratory Statistical Analysis - Selected Figures

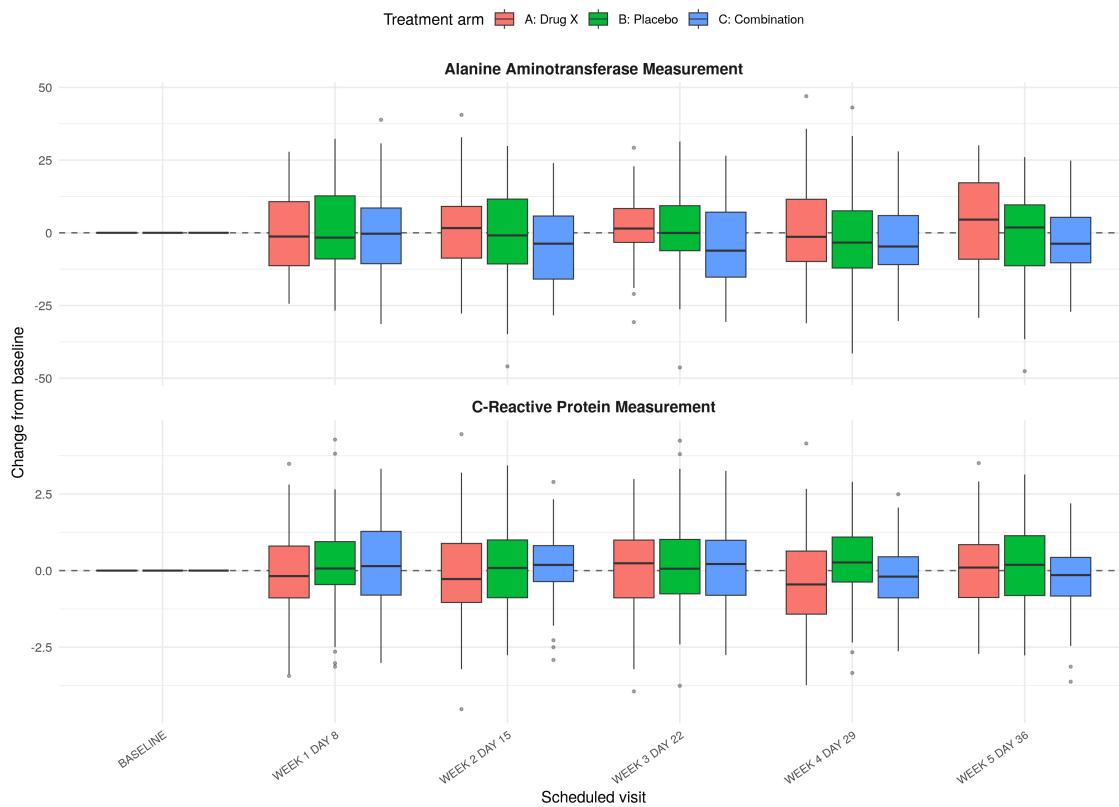
The figures below are excerpts from the full interactive exploratory analysis report, available at [stradichenko.github.io - Exploratory Analysis](https://stradichenko.github.io - Exploratory Analysis).



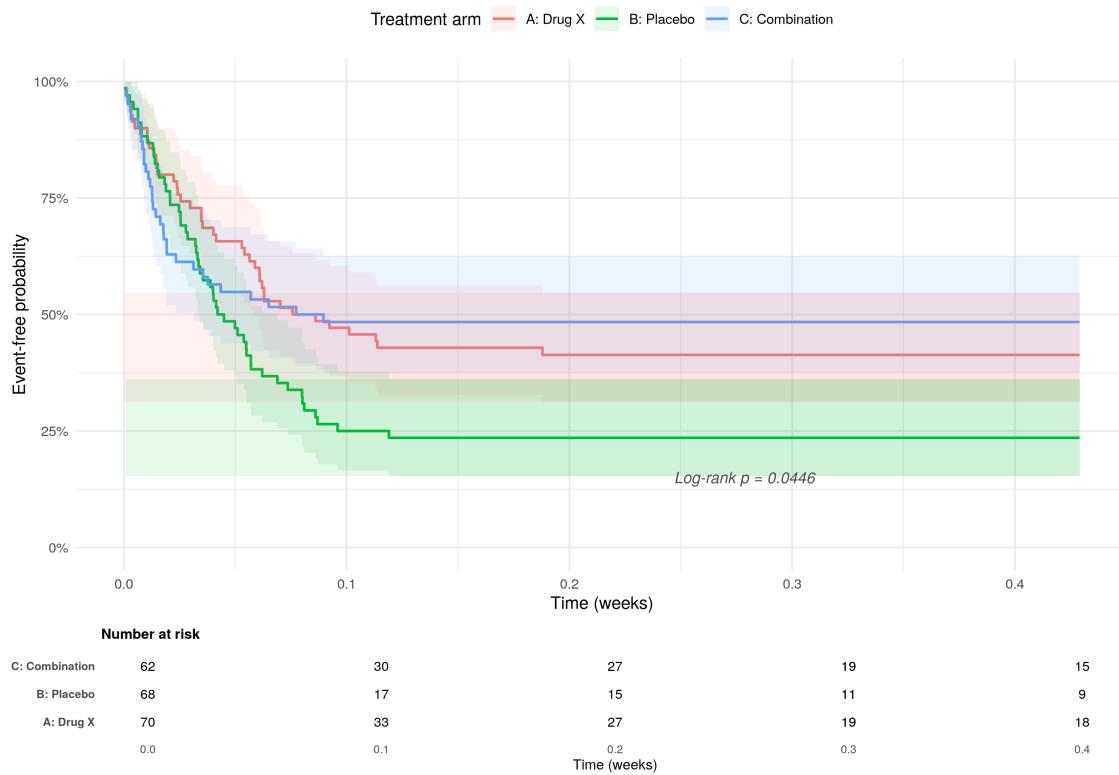
**Figure 5:** Demographic summary of the synthetic CDISC cohort. Distribution of age, sex, and race across treatment arms.



**Figure 6:** Longitudinal systolic blood pressure trajectories. Individual patient trajectories with LOESS smoothing by treatment arm, illustrating temporal trends and between-arm divergence.



**Figure 7:** Change from baseline in laboratory parameters. Box plots showing the distribution of change-from-baseline values for key laboratory markers by treatment arm and visit.



**Figure 8:** Kaplan-Meier survival curves for time to first adverse event. Estimated event-free probability by treatment arm with 95% confidence intervals and number-at-risk table.