

Annex — Supporting Figures and Tables

Clinical Data Management for DM1 — IGTP

Gary Espitia

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

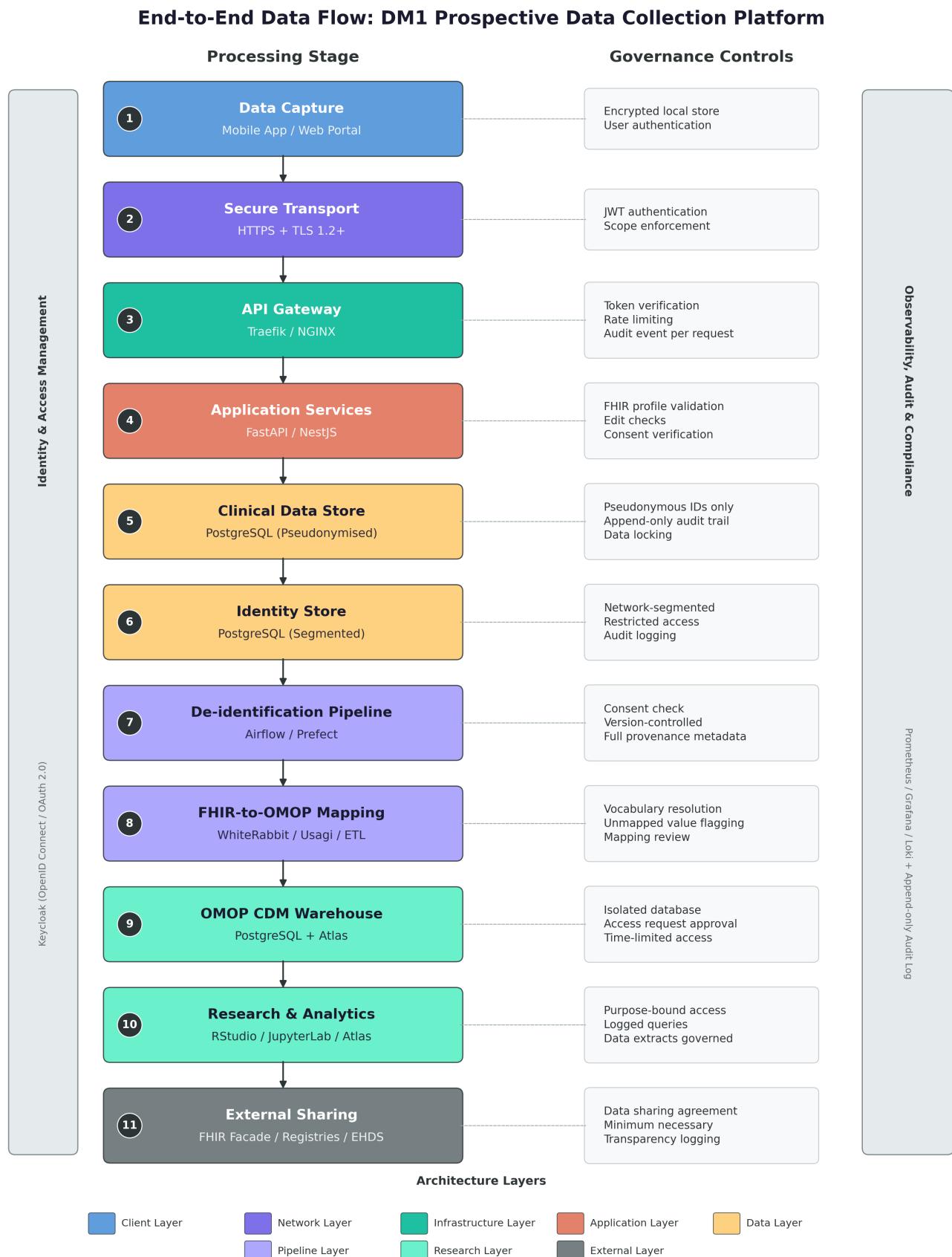


Figure 1: System Data Flow Diagram. Seven-layer architecture from patient mobile app and clinician portal through API services, Identity and Access Management (Keycloak), operational database, de-identification pipelines, OMOP CDM warehouse, to observability and audit logging.

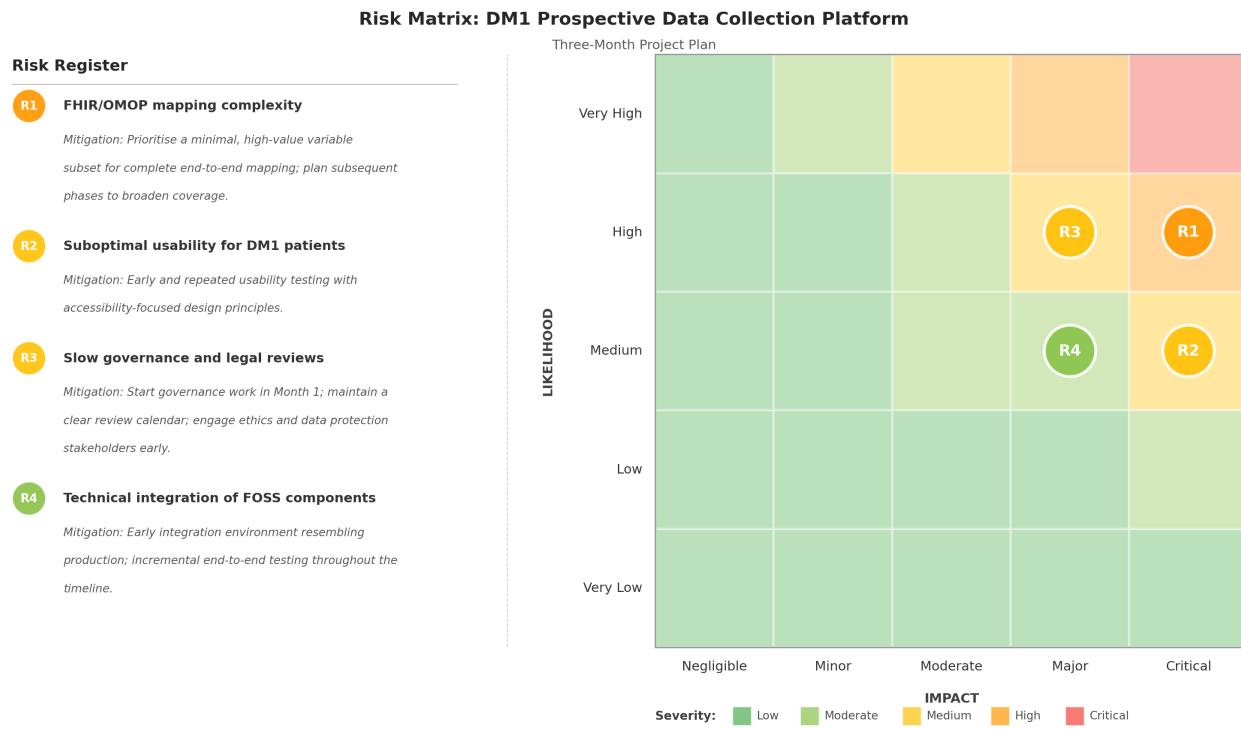


Figure 2: Risk Likelihood–Impact Matrix. Four identified project risks (R1–R4) plotted by likelihood and impact severity. Colour coding indicates residual risk level after mitigation.

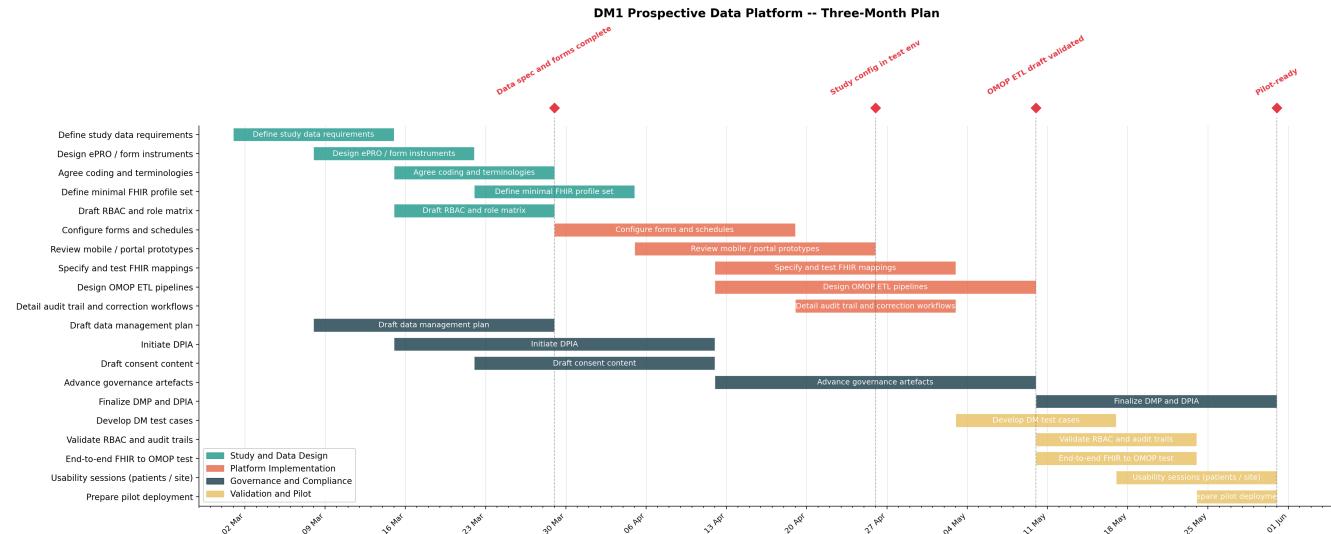


Figure 3: Project Gantt Chart. Three-month timeline showing four overlapping workstreams: Foundation & Design (Month 1), Configuration & Implementation (Month 2), Validation & Pilot (Month 3), and cross-cutting Governance. Key milestones are marked.

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

Permission	Patient	Caregiver	Clinical Researcher	Data Manager	Data Engineer	Auditor	System Admin
DATA CAPTURE							
Create and submit own entries	G	S	-	-	-	-	-
Correct own entries (within time window)	G	S	-	-	-	-	-
View own submissions and trends	G	S	-	-	-	-	-
CLINICAL REVIEW							
View participant data (own site)	-	-	S	-	-	-	-
Annotate and classify entries	-	-	S	-	-	-	-
Flag serious adverse events	-	-	S	R	-	-	-
Monitor adherence dashboards	-	-	S	G	-	-	-
QUERIES							
Create data queries	-	-	S	G	-	-	-
Respond to queries	G	S	S	G	-	-	-
Manage queries study-wide	-	-	-	G	-	-	-
STUDY CONFIGURATION							
Configure forms and instruments	-	-	-	G	-	-	-
Configure edit checks and validation	-	-	-	G	-	-	-
Configure visit schedules	-	-	-	G	-	-	-
Version and deploy configurations	-	-	-	G	-	R	-
DATA QUALITY AND LOCKS							
Run data quality reports	-	-	-	G	-	-	-
Lock and unlock data at milestones	-	-	-	G	-	-	-
View data quality dashboards	-	-	S	G	-	R	-
DATA PIPELINES AND EXPORTS							
Configure ETL pipelines	-	-	-	-	G	-	-
Run ETL jobs	-	-	-	-	G	-	-
Configure and run data exports	-	-	-	-	G	-	-
Manage external system integrations	-	-	-	-	G	-	-
Edit clinical values in production	-	-	-	-	-	-	-
OMOP AND RESEARCH ACCESS							
Access OMOP research datasets	-	-	S	R	G	-	-
Run cohort queries (Atlas)	-	-	S	R	G	-	-
Configure OMOP access policies	-	-	-	G	G	-	-
AUDIT AND COMPLIANCE							
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
CONSENT MANAGEMENT							
Provide or withdraw own consent	G	S	-	-	-	-	-
Manage consent forms and versions	-	-	-	G	-	R	-
View consent status per participant	-	-	S	G	-	R	-
IDENTITY AND ACCESS							
Manage user accounts	-	-	-	-	-	-	G
Assign and revoke roles	-	-	-	-	-	-	G
View role assignments	-	-	-	R	-	R	G
SYSTEM ADMINISTRATION							
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 (System Administrator, Data Manager, Investigator, Site Coordinator, Data Engineer, Analyst/Researcher, External Auditor) mapped against 37 permissions across 11 categories.

RACI Matrix: DM1 Prospective Data Collection Platform								
Three-Month Project Plan -- Responsibility Assignment								
Activity	CDM	Clinical Investigators	Data Engineering	Development / Technical	Legal / DPO	Biostatistics	Study Leadership	DevOps / SysAdmin
	R	A	C	C	I	I	C	I
Month 1: Foundation and Detailed Design								
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
Initial governance documentation	R		I	I	C	R	A	C
								I
Month 2: Configuration, Implementation Support, and Governance								
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	-	I
Audit trail and data correction workflows	R	A	I	I	R	C	-	I
DPIA and governance refinement	R		I	I	C	R	A	C
								I
Month 3: Validation, User Testing, and Pilot Readiness								
Data management testing	R	A	I	C	C	-	-	I
Audit trail and RBAC verification	R	A	-	I	C	C	-	I
End-to-end FHIR to OMOP validation	R		I	R	A	C	-	I
Usability sessions	R	A	C	I	C	-	-	C
Finalisation of CDM and governance docs	R	A	I	I	I	C	I	C
Pilot preparation	R		C	C	C	I	I	R
								C

 = Responsible  = Accountable  = Consulted  = Informed

Table 2: Responsible–Accountable–Consulted–Informed (RACI) Responsibility Matrix. Task allocation across Clinical Data Manager, Development/Technical, Data Engineering, Legal/DPO, and Study Leadership roles 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](#).

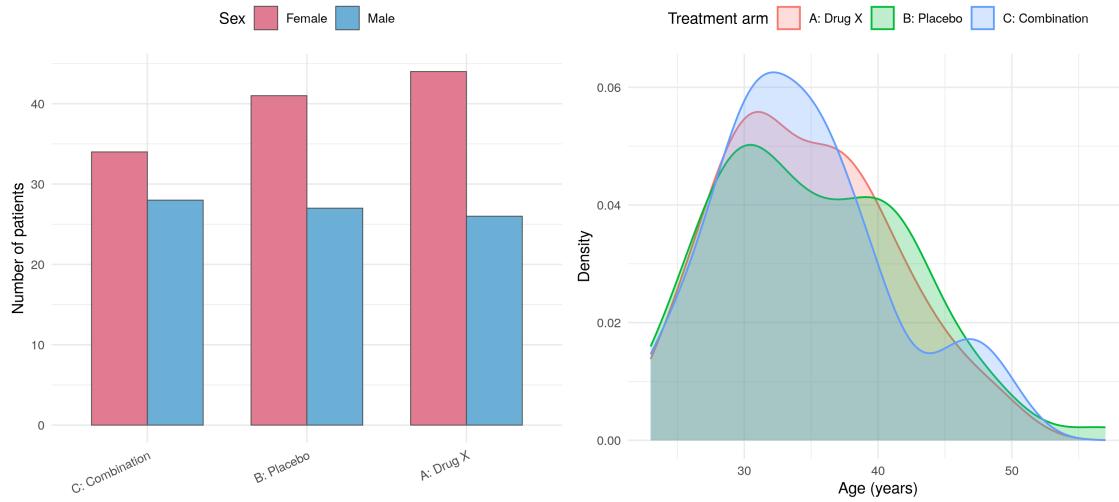


Figure 4: Demographic summary of the synthetic CDISC cohort. Distribution of age, sex, and race across treatment arms.

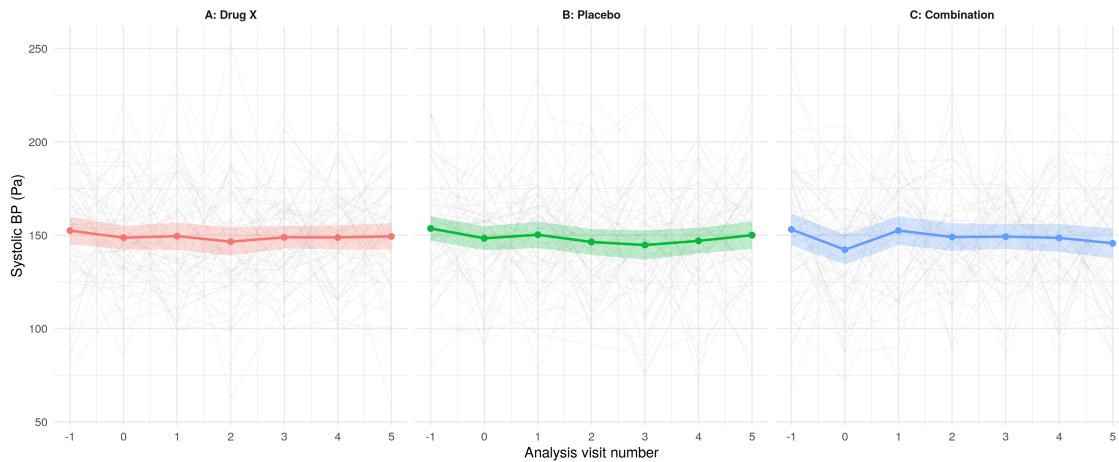


Figure 5: Longitudinal systolic blood pressure trajectories. Individual patient trajectories with LOESS smoothing by treatment arm, illustrating temporal trends and between-arm divergence.

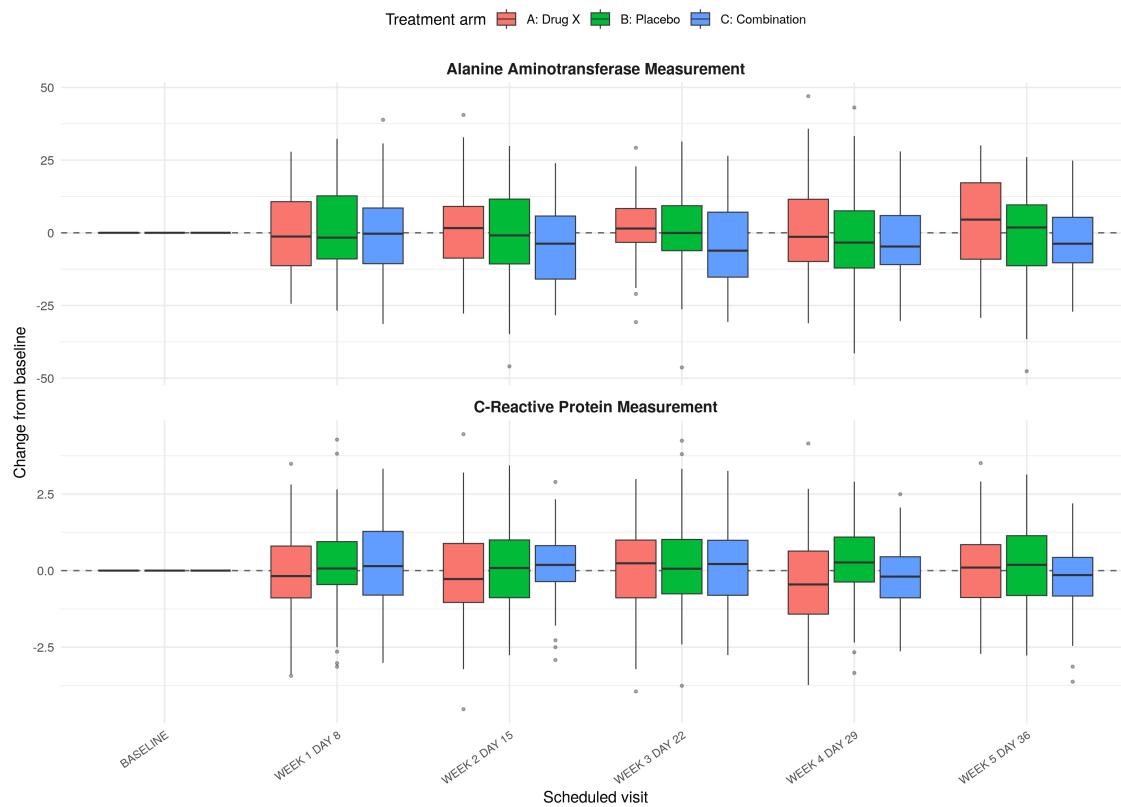


Figure 6: Change from baseline in laboratory parameters. Box plots showing the distribution of change-from-baseline values for key laboratory markers by treatment arm and visit.

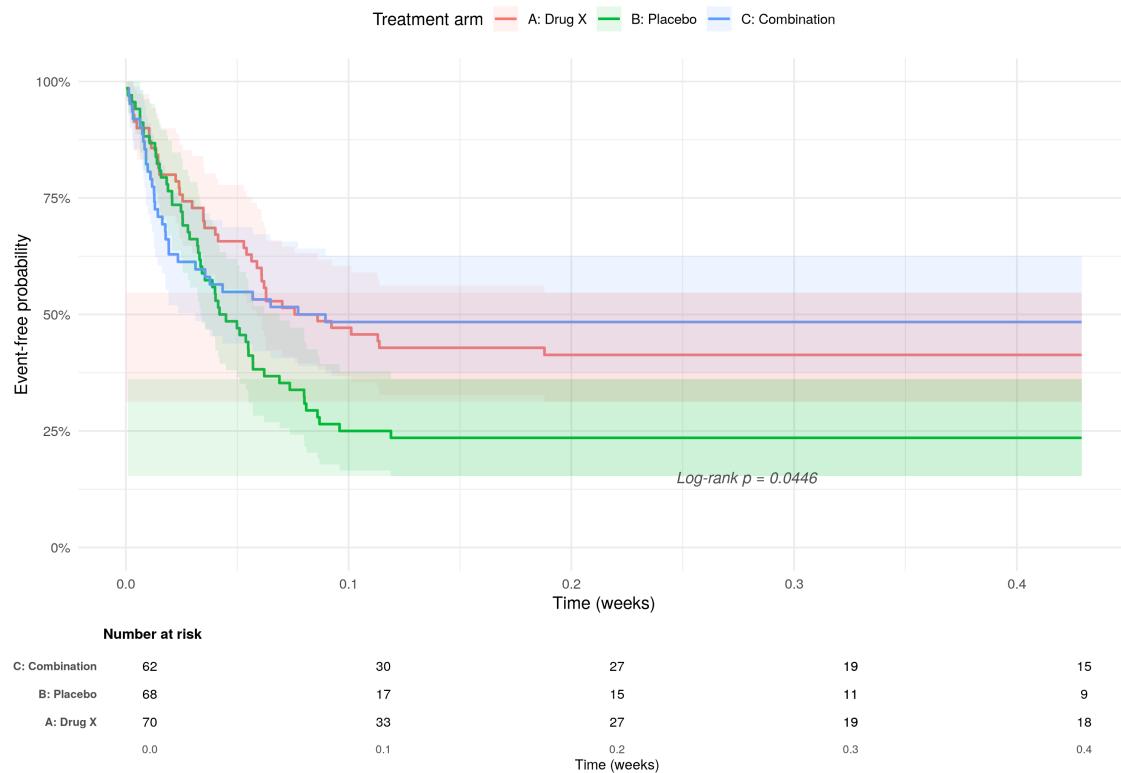


Figure 7: Kaplan-Meier survival curves for time to first adverse event. Estimated event-free probability by treatment arm with 95% confidence intervals and number-at-risk table.