Annex — Supporting Figures and Tables

Clinical Data Management for DM1 — IGTP

Gary Espitia

February 2026

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

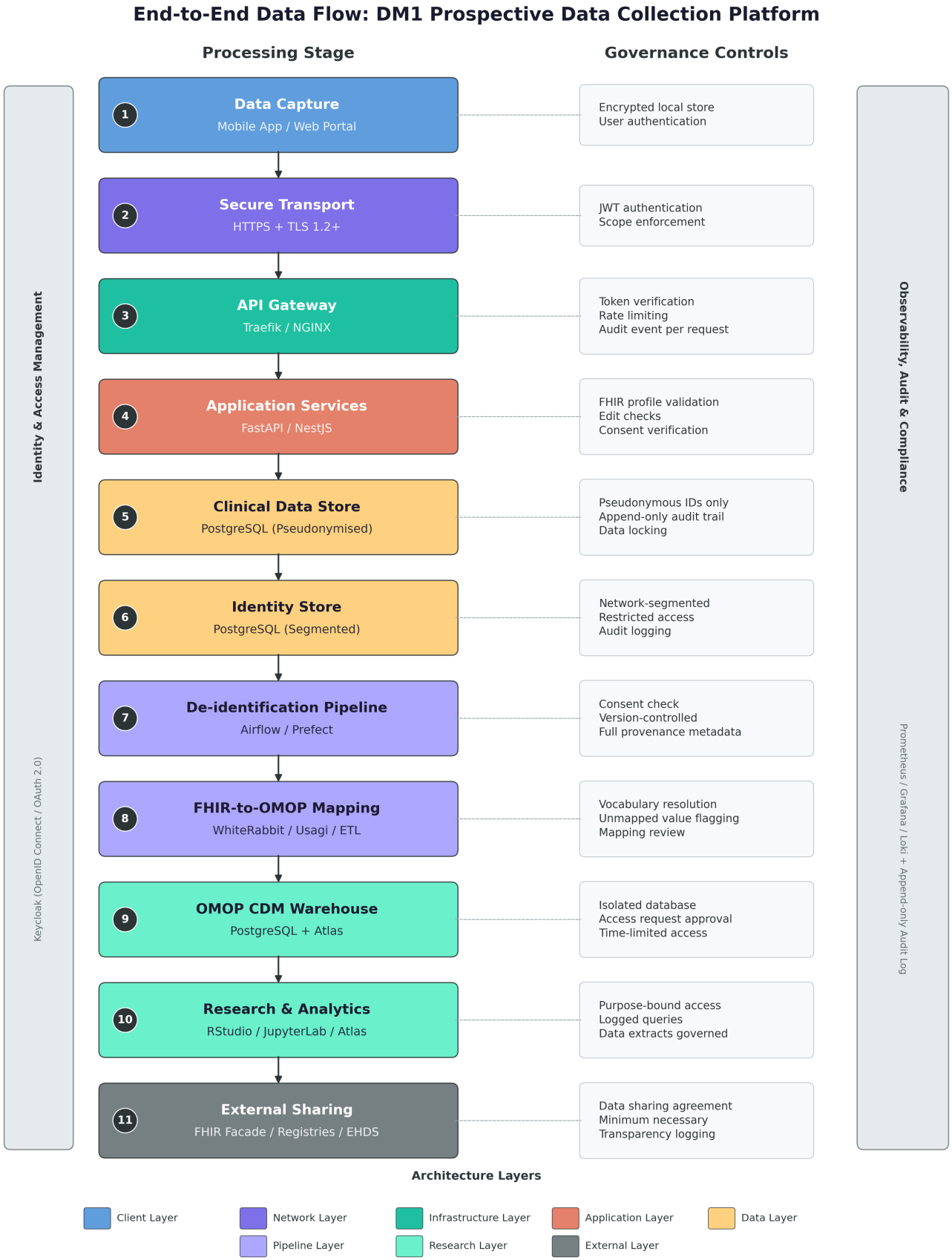

Figure 1: System Data Flow Diagram. Seven-layer architecture from patient mobile app and clinician portal through API services, Identity and Access Management (Keycloak), operational database, de-identification pipelines, OMOP CDM warehouse, to observability and audit logging.

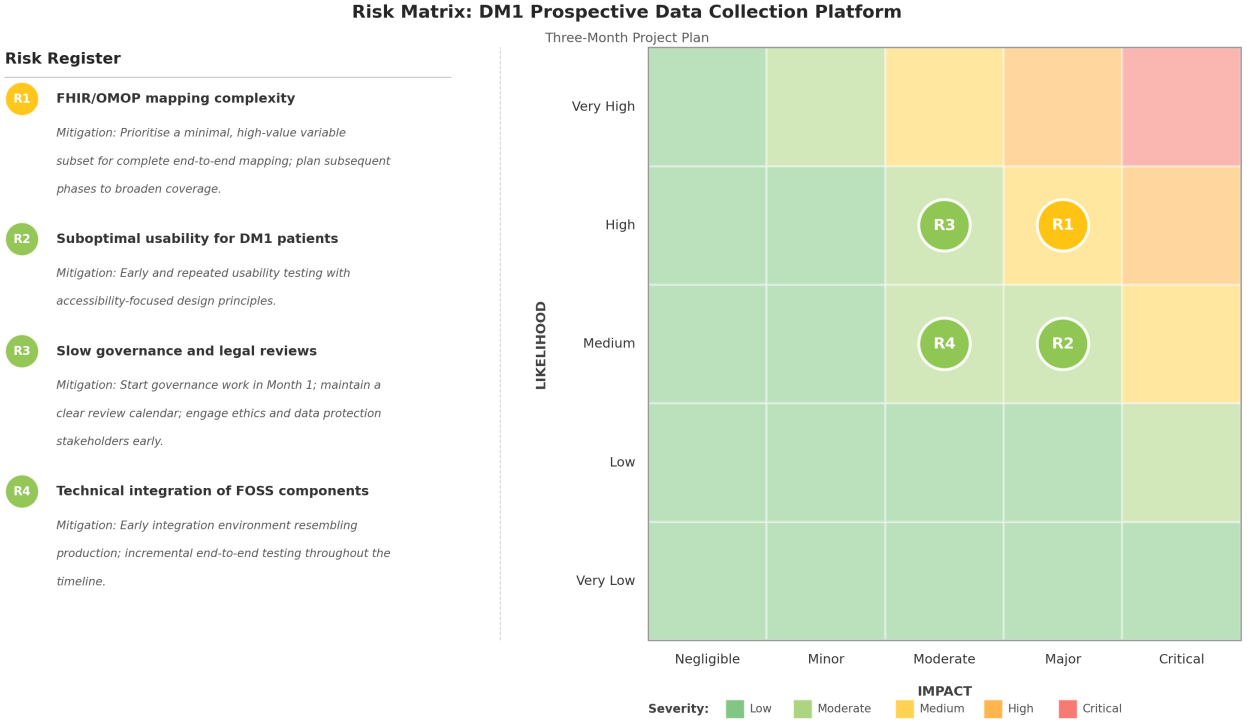

Figure 2: Risk Likelihood–Impact Matrix. Four identified project risks (R1–R4) plotted by likelihood and impact severity. Colour coding indicates residual risk level after mitigation.

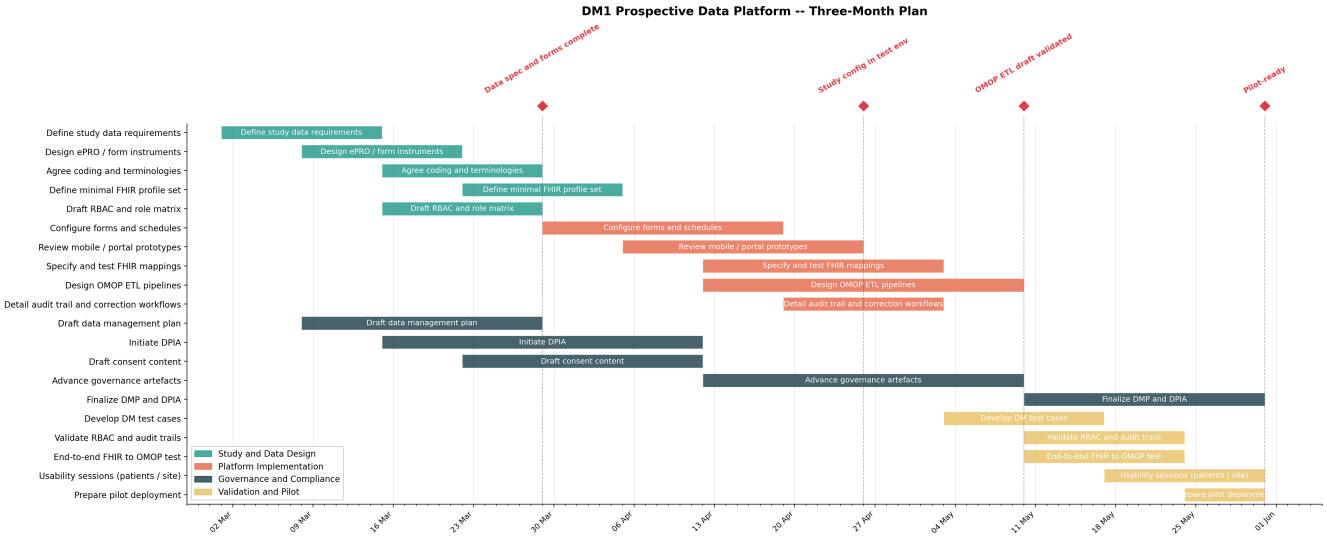

Figure 3: Project Gantt Chart. Three-month timeline showing four overlapping workstreams: Foundation & Design (Month 1), Configuration & Implementation (Month 2), Validation & Pilot (Month 3), and cross-cutting Governance. Key milestones are marked.

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

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

Three-Month Project Plan -- Responsibility Assignment

Activity	CDM	Clinical Investigators	Data Engineering	Development / Technical	Legal / DPO	Biostatistics	Study Leadership	DevOps / SysAdmin
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	C
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	-	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
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	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**.

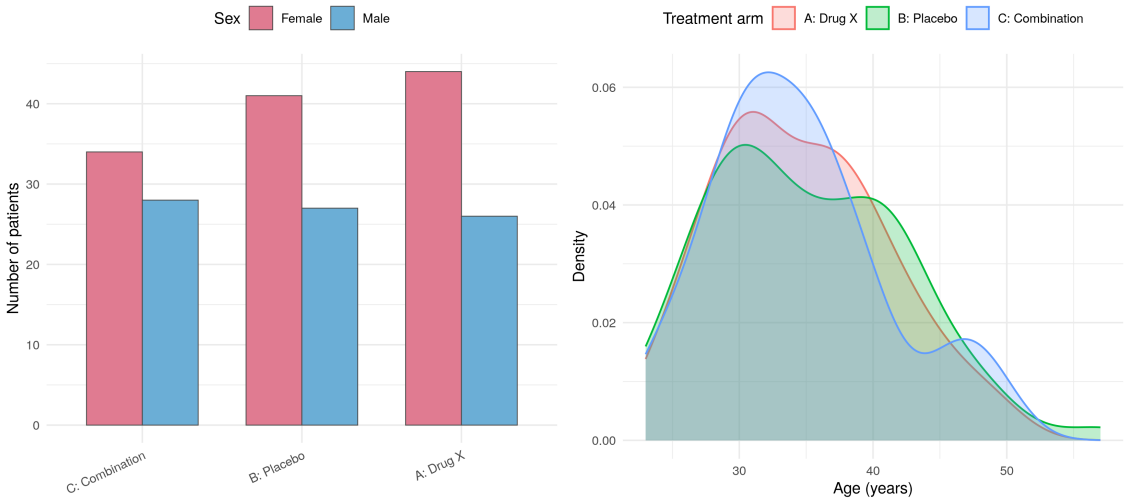

Figure 4: Demographic summary of the synthetic CDISC cohort. Distribution of age, sex, and race across treatment arms.

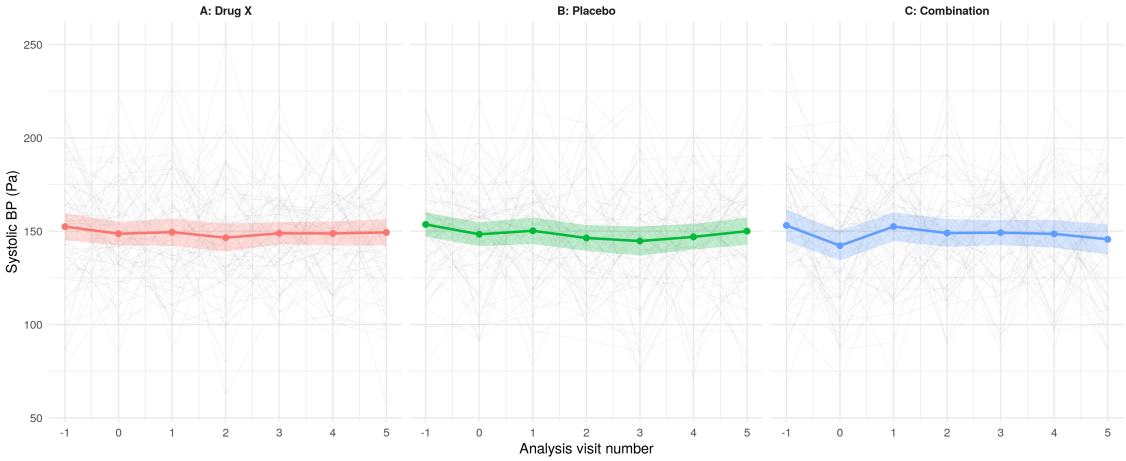

Figure 5: Longitudinal systolic blood pressure trajectories. Individual patient trajectories with LOESS smoothing by treatment arm, illustrating temporal trends and between-arm divergence.

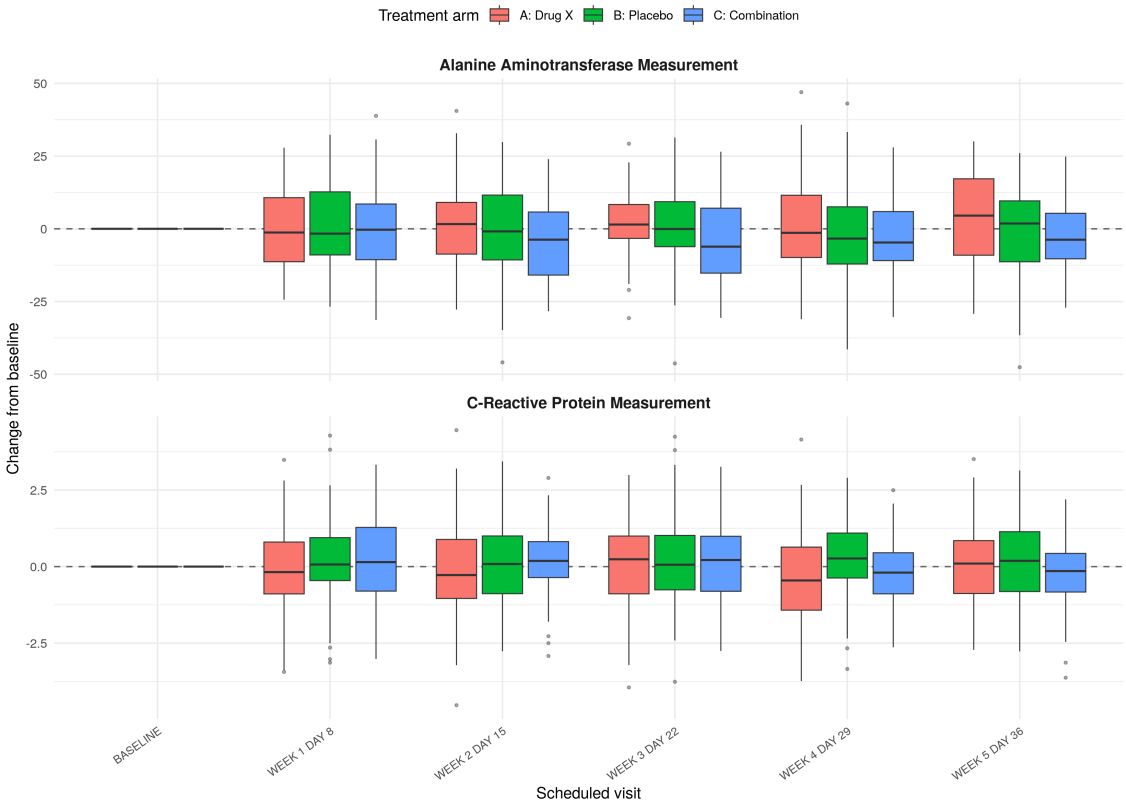

Figure 6: Change from baseline in laboratory parameters. Box plots showing the distribution of change-from-baseline values for key laboratory markers by treatment arm and visit.

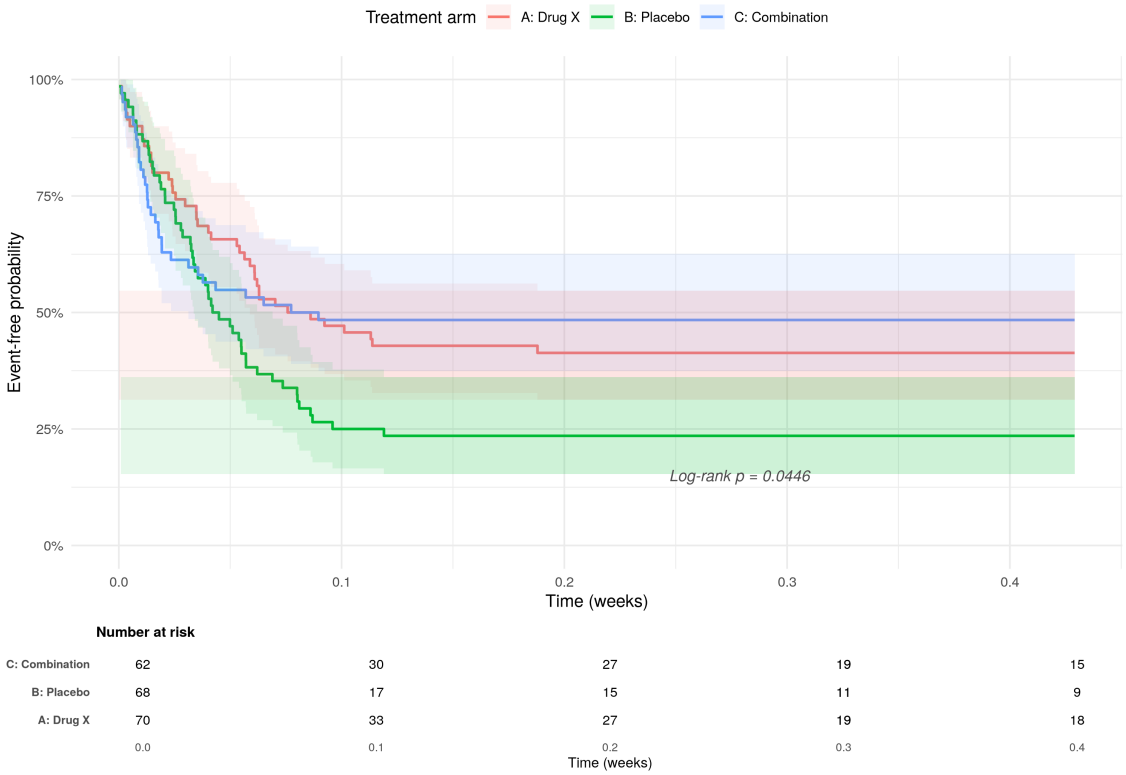

Figure 7: Kaplan–Meier survival curves for time to first adverse event. Estimated event-free probability by treatment arm with 95% confidence intervals and number-at-risk table.