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Leveraging Data Visualization from Clinical Trial Registries for Enhanced Insights

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ABSTRACT

Analyzing clinical trial registry data is one of the critical and crucial steps in pharmaceutical research and drug development for informed decision-making. We present a visualization platform that transforms data (from clinicaltrials.gov) into accessible and actionable insights for multi-disciplinary teams. This approach will summarize trials by therapeutic area, study design, phase, clinical endpoints, enrolment, and participant demographics. With Advanced AI and machine learning algorithms the infographic approach of clinicaltrials.gov can be utilized to organize similar trials based on curated inclusion and exclusion criteria, enabling systematic reviews and robust comparative analyses. Granular adverse event data are also aggregated by disease condition and treatment, highlighting key safety signals. The idea of this infographic approach has the capability to perform an automated meta-analysis and network meta-analysis to further facilitate comprehensive evidence synthesis, referencing relevant PubMed publications. This approach enhances transparency, expedites hypothesis generation, and strengthens risk assessment, ultimately supporting data-driven strategies in clinical and translational research.

Keywords: ClinicalTrials.gov, Evidence synthesis, Meta-analysis, Network meta-analysis, Visual analytics, Pharmacovigilance

INTRODUCTION

Systematic reviews and network meta-analyses (NMA) are foundational to evidence-based medicine, informing regulatory decisions, clinical guidelines, payer evaluations, and portfolio strategy [1,3,11]. Traditionally, systematic reviews rely on meticulous manual processes to scope questions, search literature, screen studies, extract data, and conduct syntheses in accordance with reporting standards such as PRISMA [1]. These steps ensure rigour and transparency but are time-consuming and strain capacity when evidence landscapes evolve rapidly.

Clinical trial registries, especially ClinicalTrials.gov, have expanded substantially in scale, diversity, and complexity [12,13]. Registry records include structured fields (e.g., phase, design, enrolment) and extensive free-text content (e.g., outcomes, eligibility criteria), often with variable completeness and heterogeneity [14,15]. Although registries improve transparency, their utility for early feasibility assessment and rapid evidence reconnaissance is limited by data quality issues, inconsistent terminologies, and the effort required to harmonise endpoints and interventions.

This paper outlines a development framework for an AI-assisted evidence synthesis tool designed to accelerate early trial discovery, feasibility assessment, and exploratory evidence analysis prior to formal meta-analysis or NMA. The framework intentionally supports, rather than replaces, established review methodologies. It integrates a dual acquisition strategy for ClinicalTrials.gov data, robust data engineering to produce structured intermediate datasets, transformer-based embeddings to identify semantically similar trials, and visual analytics to evaluate evidence connectivity, comparability, and safety profiles. Downstream automated synthesis components are conceptualised to operate under human governance, ensuring methodological integrity and alignment with best practices.

By emphasising human-in-the-loop design, provenance, and explainability, the framework seeks to reduce time-to-insight and improve decision readiness for multidisciplinary teams across clinical development, medical affairs, pharmacovigilance, and health economics.

BACKGROUND AND RATIONALE

Two trends motivate the framework. First, the volume of registered trials and updates per record (e.g., protocol changes, new outcomes, posted results) has increased, challenging manual monitoring and curation [12]. Second, modern AI/NLP methods can extract and organise meaning from free text at scale, enabling semantic trial grouping

beyond keyword matching [5-7,28-31]. Together, these trends create an opportunity to use AI as a reconnaissance layer for evidence landscapes, while retaining human oversight for eligibility adjudication, bias assessment, and synthesis.

From the synthesis perspective, early feasibility questions - Is there a connected network of trials? Are endpoints comparable? Are populations sufficiently similar? - often determine whether formal meta-analysis or NMA is viable and worth pursuing. Rapid answers to these questions can redirect efforts, highlight gaps, and focus curation on the most promising evidence clusters. The proposed tool operationalises this pre-synthesis stage through data engineering, similarity modelling, and visual analytics.

DATA SOURCES AND ACQUISITION STRATEGY

ClinicalTrials.gov is the primary data source. Two complementary acquisition strategies balance timeliness and scale:

- **Direct API-based queries:** The ClinicalTrials.gov API supports near–real-time retrieval of trial metadata, enabling targeted queries by condition, intervention, phase, status, start date, and geographic filters [12]. This pathway is suited to continuous portfolio monitoring and question-driven exploration (e.g., “Phase 3 trials in metastatic NSCLC with PD-1 inhibitors, recruiting since 2021”).
- **Bulk data ingestion:** Registry dumps allow comprehensive historical coverage and construction of a local analytical warehouse for longitudinal analyses (e.g., trends in endpoints over a decade) [12,13]. Bulk ingestion supports reproducibility and cohort reconstruction, and it enables computationally intensive tasks (e.g., embedding and clustering of entire therapeutic areas).

DATA ENGINEERING AND INTERMEDIATE DATASETS

Raw registry data are nested, heterogeneous, and variably structured. To support scalable analytics, the framework transforms raw data into analysis-ready intermediate datasets that mirror the SDTM-to-Adamu separation of operational inputs and analysis outputs [17,18]. Four core datasets are proposed:

- **Studies:** Trial-level attributes, including sponsor, condition (mapped to MeSH), therapeutic area, phase, design (randomised/non-randomised; parallel/crossover), interventions per arm, enrolment, recruitment status, timelines, locations, and free-text summaries. Eligibility criteria are stored both as raw text and parsed features (e.g., age ranges, biomarker requirements, comorbidity exclusions) using NLP pipelines.
- **Interventions:** Normalised intervention representations capturing generic/brand names, classes (e.g., ATC), mechanisms of action, dosage forms and schedules, and arm mappings [19-21]. Synonym resolution and combination therapy parsing reduce ambiguity; mapping tables maintain links to raw nomenclature for traceability.
- **Outcomes:** Structured endpoint definitions consolidating primary, secondary, exploratory outcomes into standard constructs (e.g., OS, PFS, ORR, safety incidence, biomarker change) with units, timepoints, populations, and analyses described [22–24]. When posted or derivable, effect sizes (hazard ratios, risk ratios, mean differences) and uncertainty measures (CIs, SEs) are extracted.
- **Adverse events:** Granular per-arm AE data mapped to preferred terms and system organ classes, with severity grades when available (CTCAE), denominators, and reporting windows [25–27]. Aggregations at condition and treatment-class levels enable cross-trial safety comparisons and preliminary signal detection.

Standardisation steps include terminology mapping (MeSH, RxNorm, ATC), unit harmonisation (e.g., ng/mL vs µg/L), and schema validation. Outlier detection and plausibility checks (e.g., enrolment exceeding target populations, inconsistent dates) flag records for curation. Intermediate datasets record transformation provenance and parameter settings to enable reproducible analyses [17,18].

AI-ASSISTED TRIAL SIMILARITY IDENTIFICATION (PROPOSED)

To scale trial grouping beyond manual screening, the framework employs transformer-based biomedical text embeddings to capture semantic relationships within titles, conditions, interventions, eligibility criteria, and outcome descriptions [5-7,28-31]. Several design choices improve clinical fidelity:

- **Embedding Strategy:** Domain-adapted models (e.g., BioBERT, PubMedBERT, SciBERT) encode free-text fields, while structured features (phase, design, endpoint categories, intervention classes) are concatenated or fused via learned weights to form multi-view vectors. Feature scaling and calibration ensure that trial design features contribute appropriately compared to text semantics.
- **Clustering and Retrieval:** Density-based algorithms (DBSCAN/HDBSCAN) group trials into cohorts without requiring predefined labels, supporting discovery of clinically meaningful strata (e.g., biomarker-positive subgroups, adjuvant vs metastatic settings) [32,33].
- **Human-in-the-loop Governance:** Clusters are decision-support artefacts, not inclusion engines. Reviewers can inspect feature-level contributions to similarity (e.g., eligibility overlap vs endpoint similarity), accept or adjust clusters, and annotate misclassifications to update rules (e.g., separating maintenance from first-line therapy) [36,37]. Rule-based overlays incorporate clinician guidance (lines of therapy, disease stage, prior treatment exposures) to refine clusters.
- **Explainability and Safeguards:** Embedding contributions are displayed with local explanations (e.g., SHAP-like feature attributions) to support trust. Thresholds for minimum comparability (e.g., endpoint type match, population overlap) ensure that clusters do not mix incompatible evidence.

This component accelerates reconnaissance by surfacing related trials and highlighting where evidence is fragmented or disconnected, guiding curation efforts before formal synthesis.

VISUAL ANALYTICS FOR EVIDENCE FEASIBILITY ASSESSMENT

Interactive visualisations enable rapid, transparent assessment of whether evidence is sufficient and connected for meta-analysis or NMA:

- **Clinical Trial Insights (overall landscape):** Dashboard summarizing the global trial corpus with a recruitment-status bar chart highlighting the mix of completed, ongoing, and inactive studies. Donut charts profile results reporting among completed trials, allocation schemes (randomized vs non-randomized), and masking levels. The view communicates dataset maturity, reporting completeness, and potential risk of bias features.

- **Interventions Analysis:** Side-by-side donut charts show the proportion of study types (interventional, observational, expanded access) and the intervention mix across categories such as drugs, procedures, devices, biologics, and behavioural interventions. A horizontal bar chart lists the most often frequent experimental drugs, illustrating the therapy classes that dominate the evidence base.

- **Top Comparators (Active vs Placebo):** Horizontal bar chart ranking common comparators, with colour coding distinguishing active comparators from placebo/control. The plot reveals comparator preferences across trials and visually indicates the anchor arms most likely to connect treatment networks for indirect comparisons.

- **Conditions based on MeSH term and Top Reported Condition Names:** Two stacked horizontal bar charts. The upper chart groups trials by broad MeSH condition categories, showing the thematic spread of research areas. The lower chart breaks out the most frequent named conditions, offering a more granular view of indications that drive trial volume.

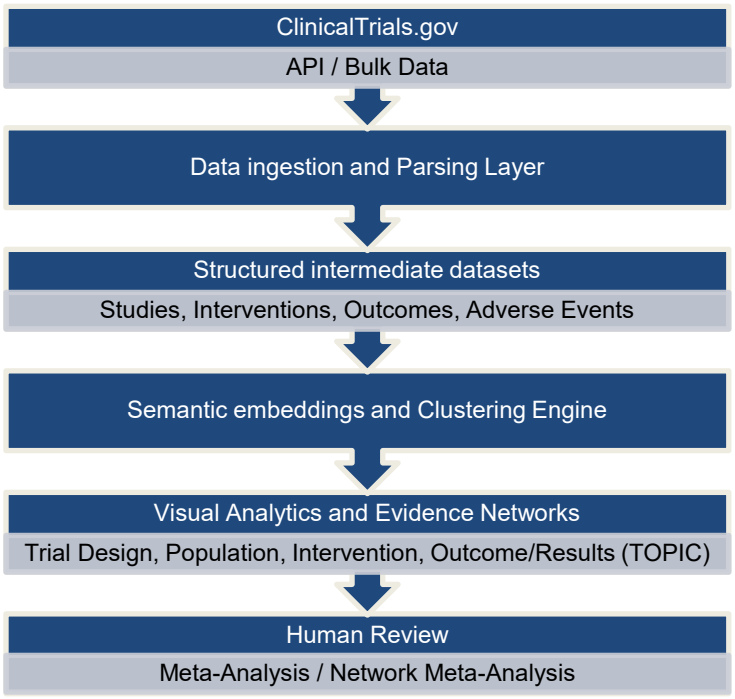
- **Evidence Maturity and Provenance:** Compact panel combining donuts for results reporting, allocation, and masking with bar charts for clinical trial phase distribution and sponsor class. Together, these visuals characterize the maturity of evidence, typical design features, and sponsor provenance, helping anticipate heterogeneity and potential reporting or bias considerations.

PROPOSED SYSTEM ARCHITECTURE (CONCEPTUAL)

The architecture supports modularity, scalability, and auditability:

- **Ingestion and Parsing:** Scheduled API harvests and bulk imports populate the warehouse; parsers normalise schema and log transformations [12-14].
- **Intermediate datasets:** SDTM-like operational tables and ADaM-like analysis tables are maintained with version control and validation reports [17,18].
- **Embeddings and Clustering:** Compute services generate embeddings, perform clustering, and build similarity indexes; outputs include explanations and comparability scores [5-7,28-35].
- **Visual Analytics:** Dashboards render distributions, networks, and safety views with interactive filters and export functions; provenance metadata are displayed per panel [16,38].
- **Human review / Intervention:** Analysts validate clusters, define inclusion/exclusion rules for synthesis cohorts, and initiate meta-analysis/NMA workflows where feasible [1-3,11].

Figure 1 Conceptual System Architecture



AUTOMATED META-ANALYSIS AND NETWORK META-ANALYSIS (PLANNED)

Automated synthesis modules are conceptualised as downstream capabilities activated under human oversight:

- **Effect size extraction and conversion:** Outcomes are parsed to compute hazard ratios, risk ratios, odds ratios, mean differences, and their variances using reported Confidence intervals, p-values, or established conversion methods (e.g., deriving SD from medians/IQRs where justified) [23-25,45].
- **Pairwise meta-analysis:** Random-effects models (Restricted Maximum Likelihood) quantify pooled effects and heterogeneity (I^2, τ^2), with sensitivity analyses for small studies and influential trials [2,23,24,44,46].
- **Network meta-analysis:** Treatment networks constructed from connected trials undergo consistency checks (design-by-treatment interaction, node-splitting) and transitivity assessments [3,11,42,47]. Ranking metrics are presented with uncertainty; incoherent substructures are flagged.
- **Bias and reporting checks:** Modules surface potential publication/reporting biases using funnel plots and selection models, caveating registry-only datasets where structured results are sparse [49]. Risk-of-bias indicators (randomisation, blinding, attrition) are drawn from registry fields or linked publications when available.
- **Traceability:** Each pooled estimate links to underlying trials, versions, and extraction parameters. Outputs include forest plots, league tables, and network diagrams with annotations.

Critically, automated synthesis is only executed after reviewers confirm endpoint comparability, population similarity, and network connectivity, aligning with PRISMA and Cochrane guidance [1,2,11].

PRACTICAL CHALLENGES AND LESSONS LEARNED

Development surfaced challenges that reinforce the human-in-the-loop approach:

- **Inconsistent intervention naming:** Brand/generic names, combinations, and dosing variants complicate mapping; ontology alignment (RxNorm, ATC) and curated synonym tables are necessary, with exception handling for novel modalities [19-21,48].

- **Heterogeneous outcomes:** Endpoint definitions, timepoints, and units vary; harmonisation requires careful mapping (e.g., RECIST criteria, event definitions) and sometimes conversion rules with explicit uncertainty [22-24,45].

- **Sparse and uneven results reporting:** Many registry records lack full statistics; reliance on linked publications increases traceability but adds curation burden [12-14,49]. The visual layer should flag insufficient data to prevent premature synthesis.

- **Disconnected evidence networks:** Lack of common comparators can preclude valid NMA; network diagnostics identify gaps and potential bridging trials, guiding search strategies or signalling that synthesis is not yet feasible [42,47].

- **Eligibility parsing complexity:** Nuanced criteria and ambiguous phrasing challenge NLP; embeddings help cluster but do not guarantee comparability. Reviewer annotations and rules improve precision over time [28-31,36].

- **Representativeness and fairness:** Demographic and geographic imbalances affect generalisability; dashboards should expose these patterns and encourage subgroup and sensitivity analyses [40,41,50].

Lessons highlight the importance of modularity, provenance, transparent uncertainty communication, and interfaces for reviewer annotation and correction, which progressively enhance data quality and clustering fidelity [18,36,37].

USE CASES AND DECISION IMPACT

The framework supports several cross-functional applications:

- **Portfolio strategy and competitive intelligence:** Rapidly map crowded spaces, identify unmet needs, and detect differentiation opportunities by comparing endpoints, populations, geographies, and safety profiles across trials [12,16]. Treatment networks reveal where new comparators can increase evidence connectivity.

- **Protocol optimisation:** Align inclusion/exclusion criteria and endpoints with successful precedents while avoiding overly restrictive criteria that hinder enrolment. Visual eligibility flows and demographic summaries inform feasibility [14,41].

- **Early go/no-go decisions:** Preliminary efficacy signals and safety profiles, contextualised by comparability and heterogeneity, help teams prioritise programmes before investing in full systematic reviews and statistical syntheses [2,3,11].

- **Medical affairs and HEOR:** Transparent summaries and preliminary comparisons support evidence narratives, payer dialogues, and health technology assessments, with clear caveats where registry data are incomplete [49,50].

- **Pharmacovigilance reconnaissance:** Cross-trial AE aggregation by condition and treatment class surfaces recurring signals and informs risk management planning, with severity stratification and uncertainty bands [25-27].

CONCLUSION AND FUTURE DEVELOPMENT

This paper presents a development framework for an AI-assisted evidence synthesis tool that combines structured data engineering, semantic similarity methods, and visual analytics to reduce time-to-insight and improve feasibility assessment for meta-analysis and Network Meta-Analysis (NMA) [1-3,11]. The approach emphasises human oversight, methodological rigour, and transparency, positioning AI as an accelerant to established review workflows rather than a replacement.

Future work will include formal validation studies, integration with additional registries (e.g., EU CTR, ISRCTN) and publication databases, expansion of ontology coverage (e.g., mechanisms, biomarkers), and tighter alignment with PRISMA and Cochrane processes [1,2,51]. Enhancements to manual curation tools, reviewer annotation workflows, and fairness assessments across demographics will strengthen reliability. As capabilities mature, gated automated synthesis modules will be enabled under reviewer governance to ensure robust, reproducible evidence generation [2,3,11,42,47].

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