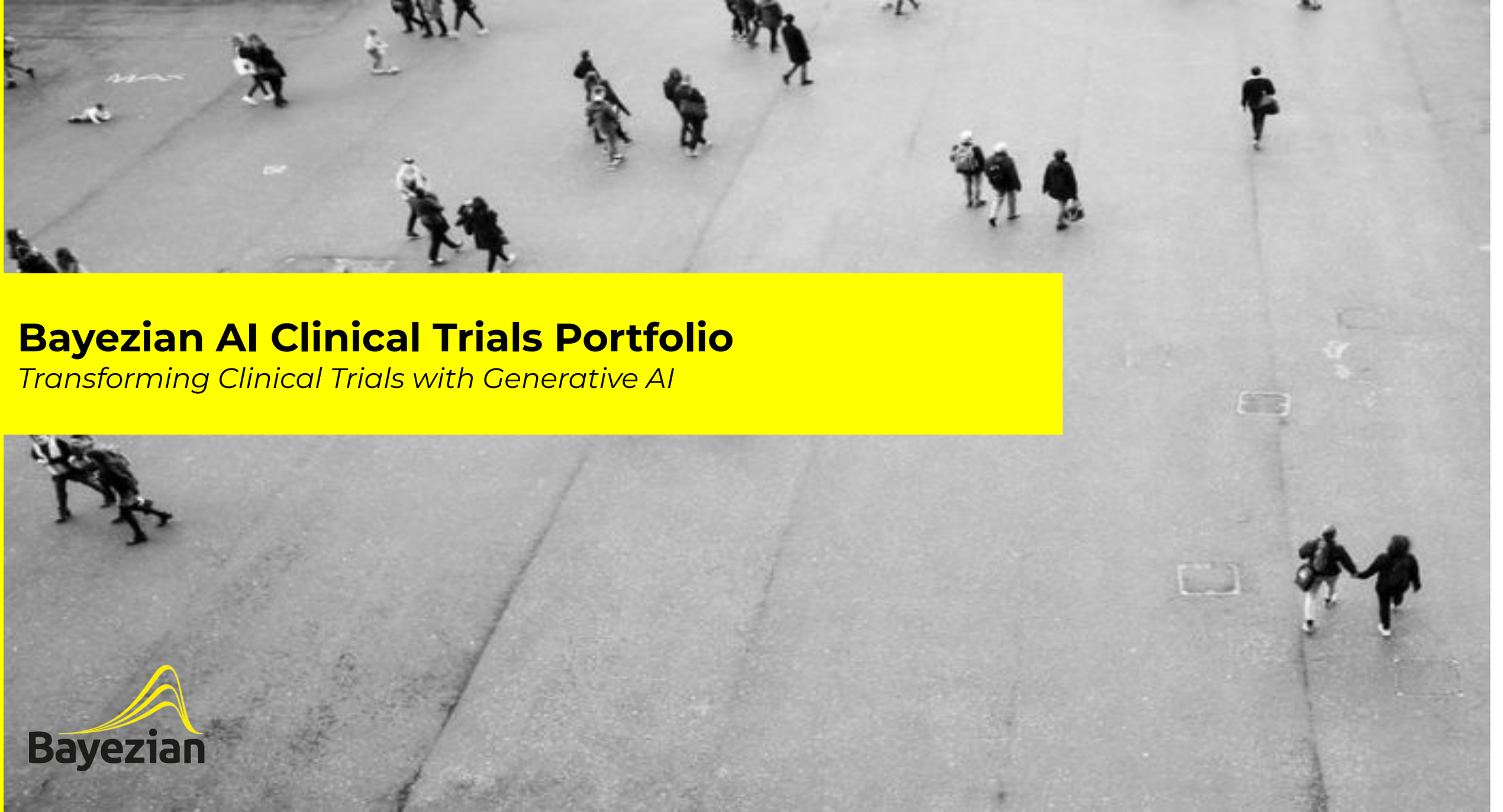

Bayezian AI Clinical Trials Portfolio

Transforming Clinical Trials with Generative AI

Bayezian

Pre-Trial Planning and Feasibility

Bayezian

01	Feasibility Assessment: Feasibility assessment is the cornerstone of successful trial planning.	• **Application:** Evaluates historical trial outcomes, site readiness, and patient demographics to assess logistical and operational feasibility. • **Why It's Important:** Avoids trial delays by proactively identifying risks and optimizing site and investigator selection.
02	Cost Estimation: Budgeting is a critical step in trial planning, requiring precise calculations to allocate resources effectively while accounting for contingencies.	• **Application:** Generates real-time budget models, factoring in historical data, vendor quotes, and contingency planning. • **Why It's Important:** Prevents budget overruns and accelerates financial approvals with detailed, transparent forecasts.
03	Risk Modeling: Identifying potential risks early is essential to avoid costly delays and disruptions during clinical trials.	• **Application:** Predicts potential risks (e.g., recruitment delays, logistical bottlenecks) and recommends mitigation strategies. • **Why It's Important:** Minimizes disruptions by addressing challenges before they occur, ensuring smoother trial execution.
04	Resource Allocation Optimisation: Efficient allocation of resources, such as staff, equipment, and budget, is key to maintaining trial timelines and quality.	• **Application:** Optimises resource distribution across sites based on patient availability and investigator performance. • **Why It's Important:** Improves efficiency and ensures trials meet enrollment targets by maximizing the use of available resources.
05	Protocol Feasibility Checks: Trial protocols must be practical and achievable, balancing scientific rigor with logistical realities to ensure smooth execution.	• **Application:** Reviews protocol complexity and predicts feasibility issues related to enrollment, timelines, and logistics. • **Why It's Important:** Ensures that trial protocols are realistic and achievable, reducing the likelihood of costly amendments.

Regulatory and Ethical Approvals

Bayezian

01	Study Protocol Development: Study protocols serve as the blueprint for clinical trials, detailing objectives, endpoints, and methodologies.	• **Application:** Automates the creation of detailed and compliant study protocols, tailored to therapeutic areas and trial objectives. • **Why It's Important:** Reduces errors, accelerates regulatory approval, and minimizes costly amendments that can delay trial timelines.
02	Informed Consent Simplification: Informed consent documents ensure participants fully understand the trial's purpose, risks, and benefits.	• **Application:** AI rewrites complex informed consent documents into clear, participant-friendly language. • **Why It's Important:** Enhances participant understanding, reduces dropout rates, and ensures ethical compliance.
03	Investigator's Brochure (IB): Provides critical information about the investigational product, including preclinical and clinical data, to investigators and regulatory authorities.	• **Application:** Summarises preclinical and clinical data into a concise brochure format. • **Why It's Important:** Simplifies stakeholder communication, ensures consistent documentation, and reduces time for manual compilation.
04	Case Report Forms Creation: CRFs are standardised forms used to collect trial data in a structured manner.	• **Application:** Customises CRF templates by aligning fields with protocol objectives, regulatory guidelines, and therapeutic area requirements. • **Why It's Important:** Ensures that all required data points are included and structured properly, minimising ambiguity for site staff.
05	Regulatory Submission Preparation: Regulatory submissions are crucial for obtaining approvals to initiate or continue clinical trials.	• **Application:** AI automates formatting, cross-referencing, and compliance checks for submission packages. • **Why It's Important:** Reduces administrative workload, improves submission accuracy, and ensures faster regulatory review cycles.

Trial Setup

Bayezian

01	Site Selection and Preparation: Selecting the right trial sites is critical for ensuring smooth operations, timely recruitment, and high-quality data collection.	• **Application:** Identifies high-performing sites based on historical performance, geographic accessibility, and patient demographics. • **Why It's Important:** Optimises trial outcomes by ensuring the best locations are chosen, reducing variability.
02	Participant Recruitment Strategy: Recruitment is one of the biggest challenges in clinical trials, requiring targeted strategies to engage diverse and eligible participants.	• **Application: C**rafts personalised recruitment strategies using social media data, EHRs, and population analytics. • **Why It's Important:** Reduces recruitment timelines, increases participant diversity, ensures that enrollment goals are met efficiently.
03	Investigator and Staff Training: Proper training for investigators and site staff is essential for ensuring compliance with protocols and minimising errors during the trial.	• **Application:** Generates protocol-specific training content tailored to the needs of site staff. • **Why It's Important:** Improves protocol adherence, reduces deviations during trial execution, and enhances overall trial quality.
04	Recruitment Risk Prediction: Predicting and addressing recruitment challenges early is vital for keeping trials on schedule and avoiding costly delays.	• **Application:** Predicts enrollment challenges and suggests proactive solutions (e.g., site expansion, targeted outreach). • **Why It's Important:** Keeps trials on track by mitigating recruitment delays and ensuring participant enrollment stays on schedule.

Clinical Trial Execution

Bayezian

01	Safety Monitoring and Adverse Event Reporting: Ensuring participant safety during clinical trials is paramount, requiring continuous monitoring and prompt reporting.	• **Application:** Tracks real-time safety data, flags potential adverse events, and generates regulatory-compliant reports. • **Why It's Important:** Enhances patient safety, ensures rapid responses to emerging risks, and meets regulatory requirements efficiently.
02	Participant Retention Management: Retaining participants throughout a trial is essential to ensure reliable data and minimize disruptions to trial timelines.	• **Application:** Identifies dropout risks and recommends personalized retention strategies (e.g., reminders, incentives). • **Why It's Important:** Maintains trial momentum, reduces participant attrition, and ensures the integrity of trial results.
03	Protocol Compliance Monitoring: Adherence to trial protocols by sites and participants is critical to ensuring trial validity and data reliability.	• **Application:** Monitor site activities and participant behavior to ensure adherence to trial protocols. • **Why It's Important:** Prevents deviations that could compromise trial outcomes and reduces the risk of regulatory non-compliance.
04	Real-Time Data Capture and Validation: Accurate and timely data collection is the backbone of successful clinical trials, supporting reliable decision-making.	• **Application:** Automates data collection, ensures accuracy, and resolves inconsistencies on the go. • **Why It's Important:** Improves data quality, minimises manual errors, and accelerates downstream analysis and reporting.
05	Intervention Adherence Tracking: Monitoring participants' compliance with interventions is vital to ensure the reliability of trial outcomes and scientific validity.	• **Application:** Track participant compliance with interventions (e.g., drug intake, visit schedules) in real time. • **Why It's Important:** Ensures consistent protocol execution, reliable trial outcomes, and actionable insights into intervention efficacy.

Data Analysis and Reporting

Bayezian

01	Creating SDTM Datasets: SDTM datasets are a regulatory requirement for submitting standardised clinical trial data to agencies like the FDA and EMA.	• **Application:** Automates the mapping and creation of SDTM datasets from raw clinical trial data, aligning fields with CDISC standards. • **Why It's Important:** Saves significant time and ensures compliance with global submission standards, reducing errors in regulatory datasets.
02	Creating ADaM Datasets: ADaM datasets are critical for statistical analysis and reporting, providing a structured foundation for study analysis aligned with the SAP.	• **Application:** Interprets ADaM specifications and other documents, such as the SAP to generates executable R/Python code for creating the ADaM datasets, ready for statistical analysis. • **Why It's Important**: Automates the coding process, saving time and minimising human error, ensures alignment with the SAP
03	Safety Data Analysis: Safety data analysis is essential for understanding participant well-being and ensuring compliance with safety regulations across all trial sites.	• **Application:** Analyse safety data to identify patterns, trends, and outliers across sites. • **Why It's Important:** Enhances safety monitoring, supports data-driven risk assessments, and ensures trial compliance with safety standards.
04	Clinical Study Report Creation: CSRs summarise trial results and are essential for regulatory review, requiring precise and comprehensive documentation.	• **Application:** Drafts CSRs, summarising trial findings into regulatory-compliant documents. • **Why It's Important:** Reduces report generation time, ensures submission-readiness, and improves overall document quality.

Bayezian Research Hub: AI-Powered Research Assistant for Biological Publications

Bayezian

Enhancing Medical Communications: Bayezian Research Hub

Bayezian

Built on **GPT-4o-mini**

Curated inputs from **PubMed** and **ClinicalTrials.gov** ensure relevance and accuracy.

Key Features

Research Article Drafting: Generates structured drafts with citations, tailored to your study focus.

Study Protocol Builder: Templates for RCTs, cohorts, and adaptive trials (ICH-GCP compliant).

Statistical Analysis Plan (SAP): Aligns statistical methods (ANOVA, regression) with study endpoints.

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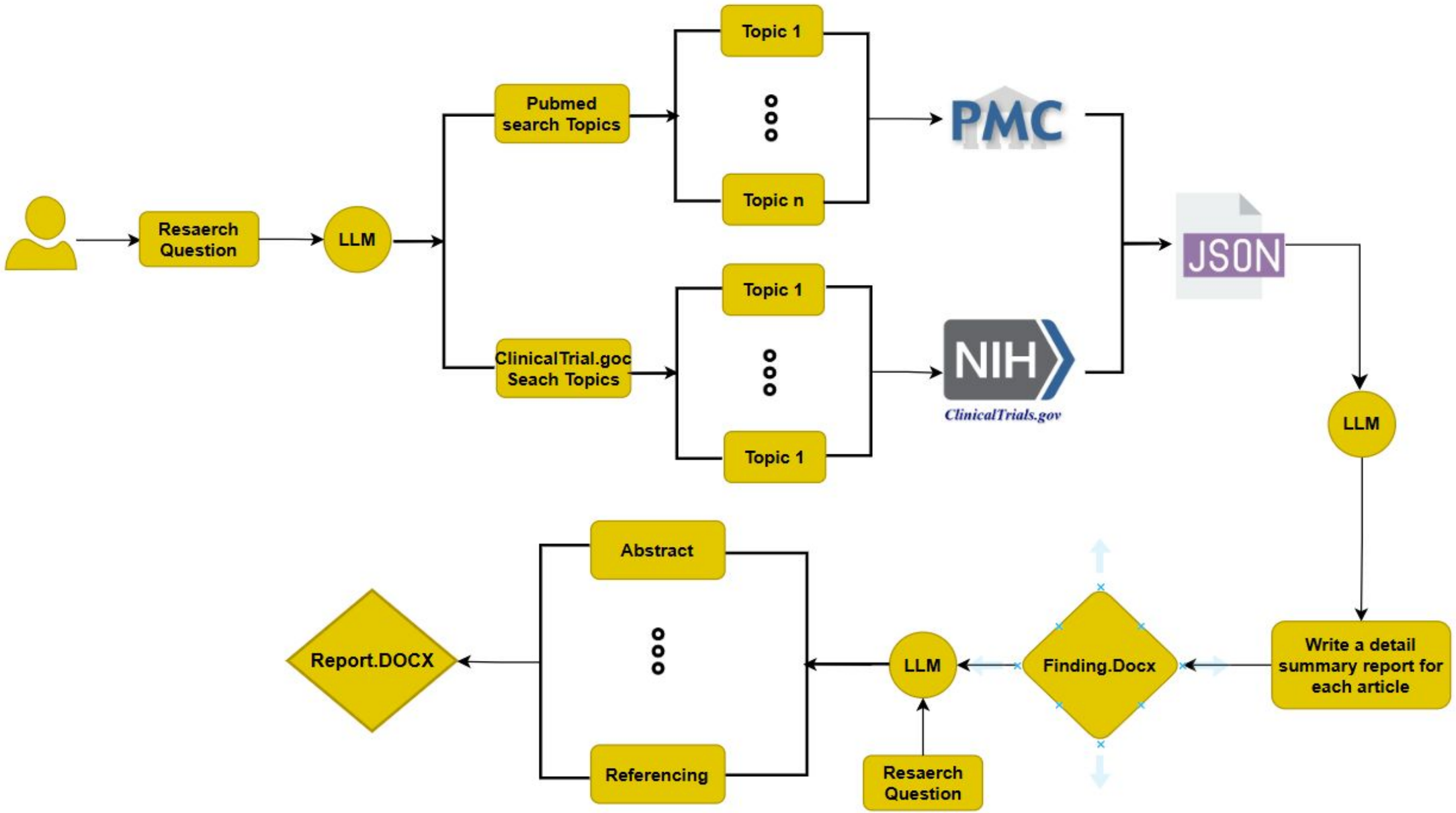
Enhancing Medical Communications: Bayezian Research Hub



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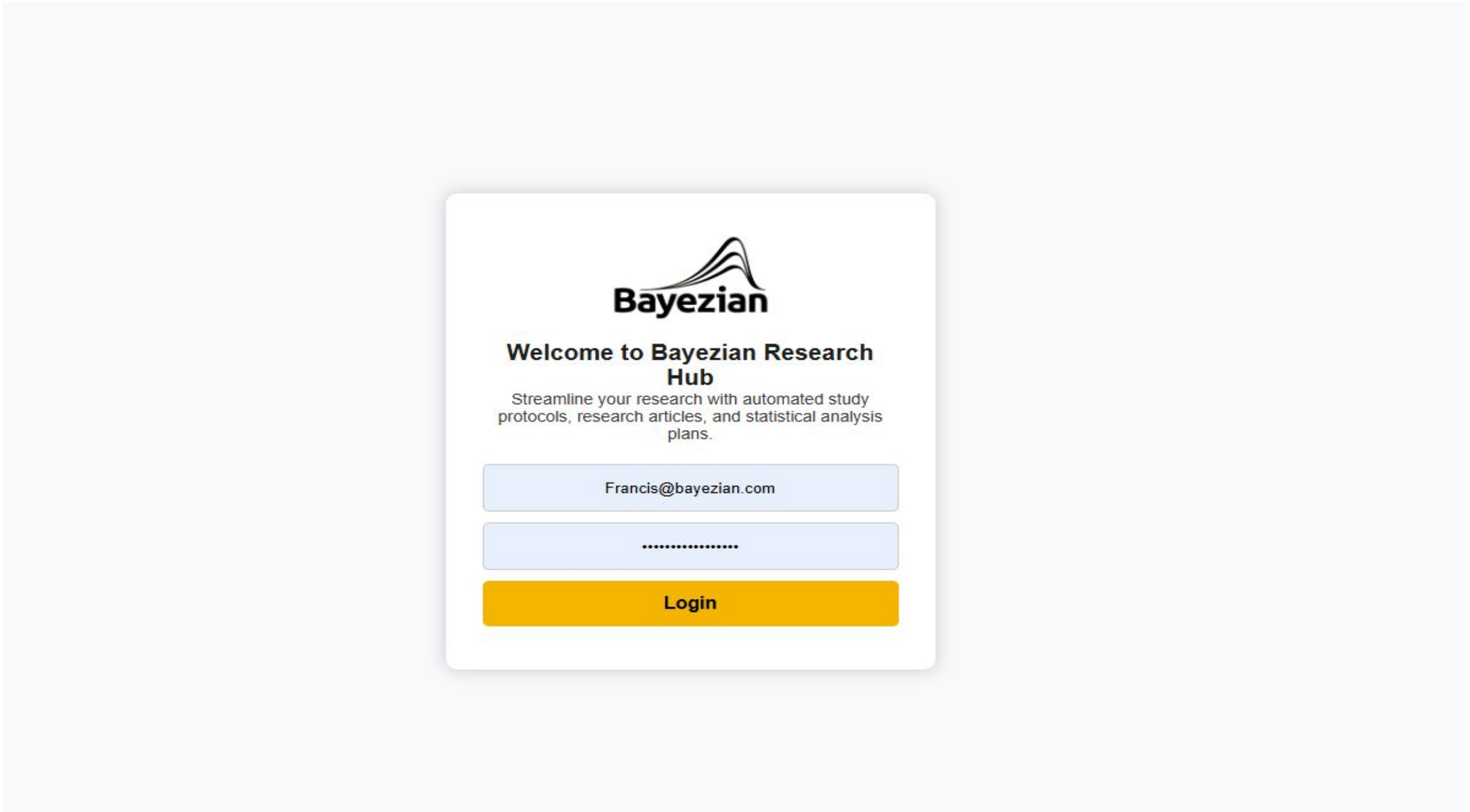

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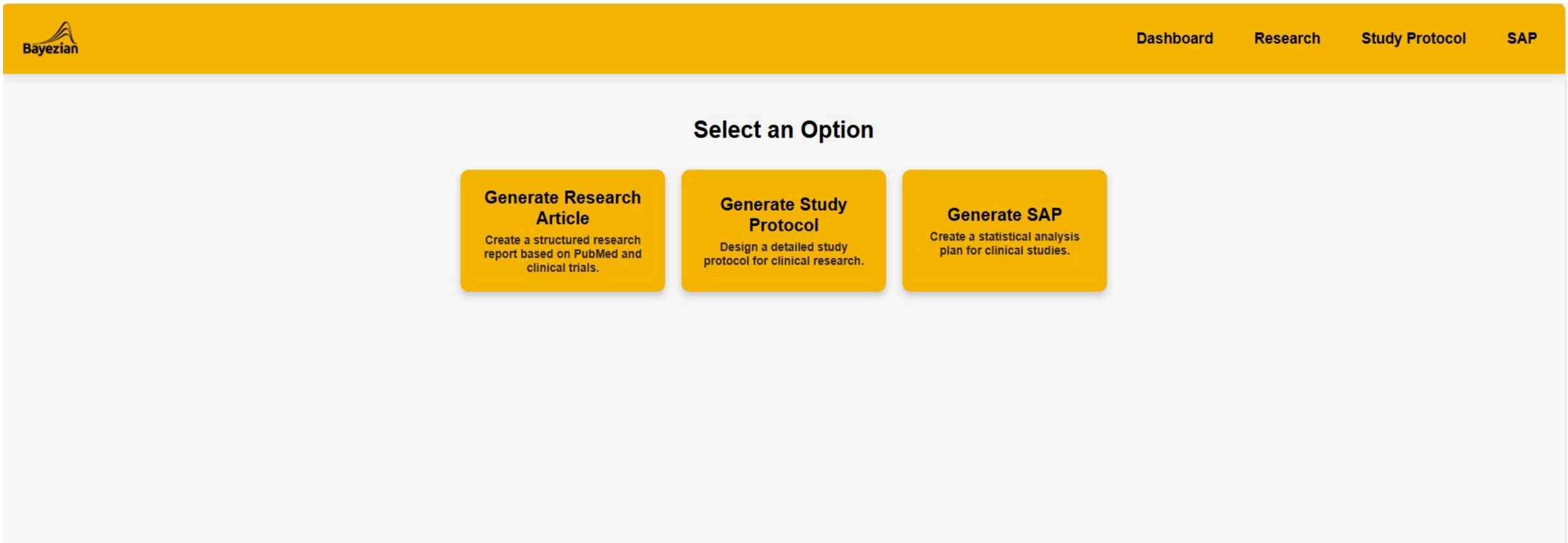

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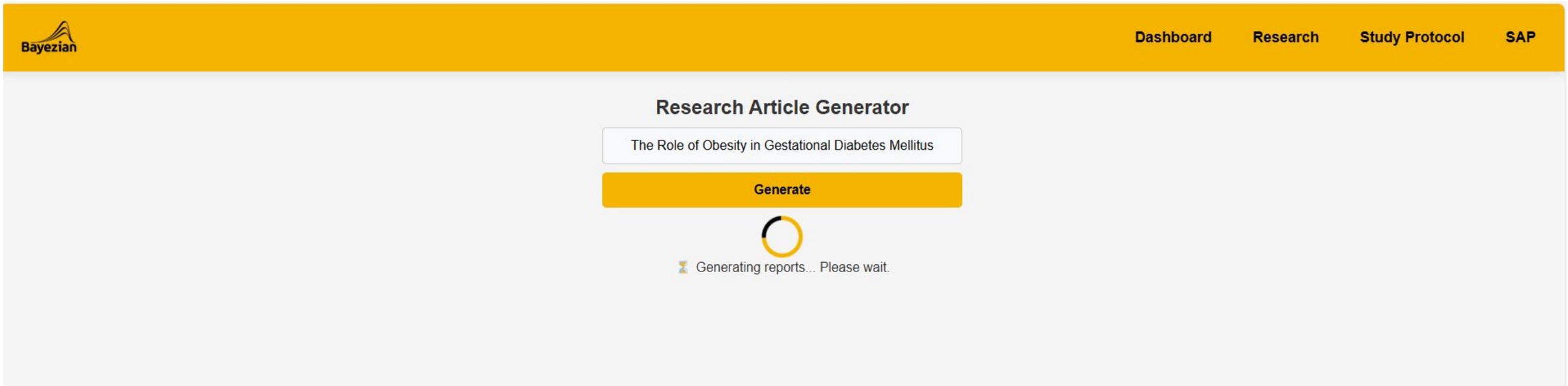

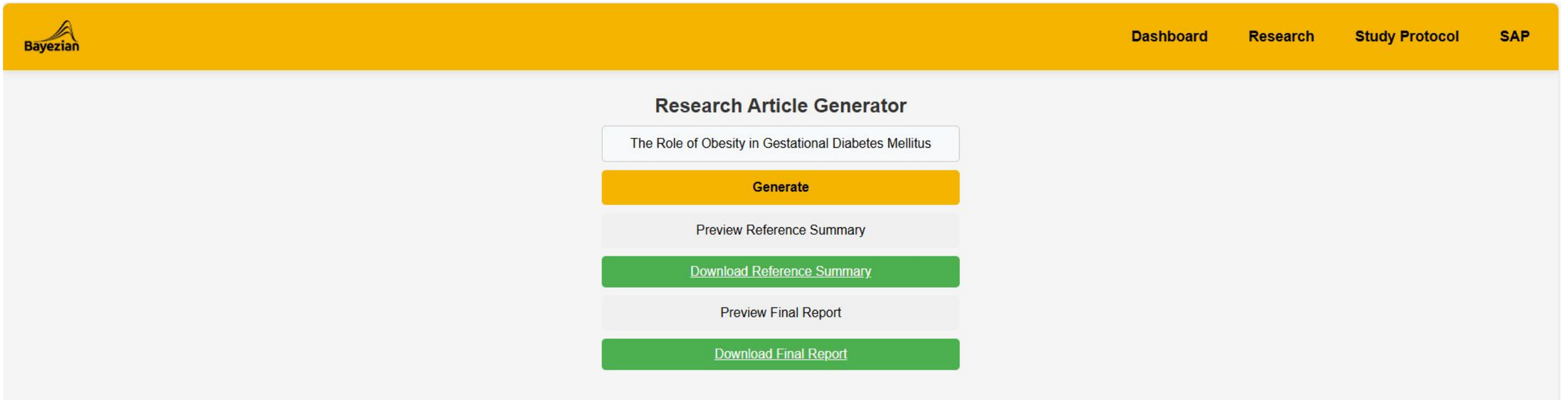

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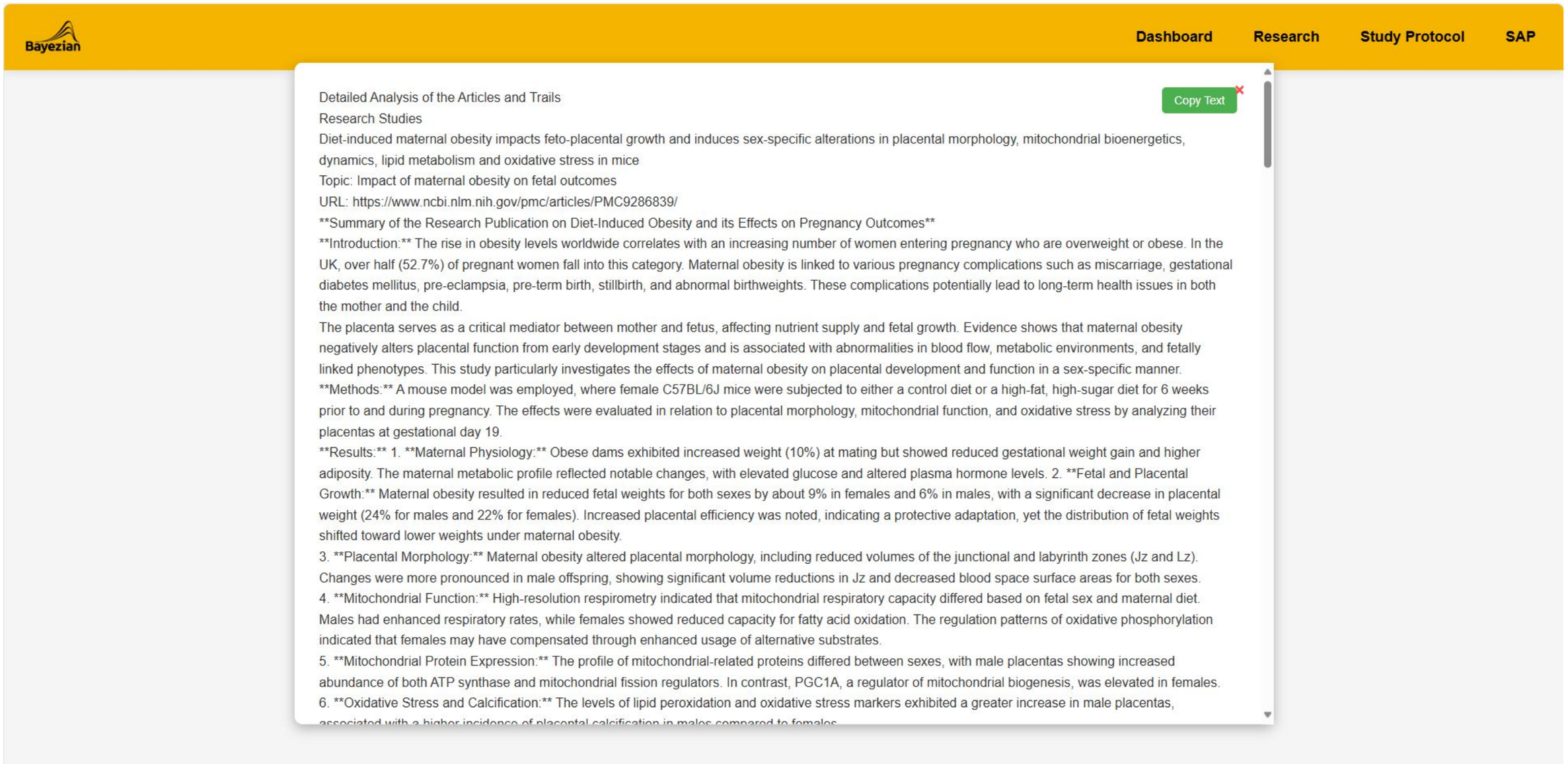

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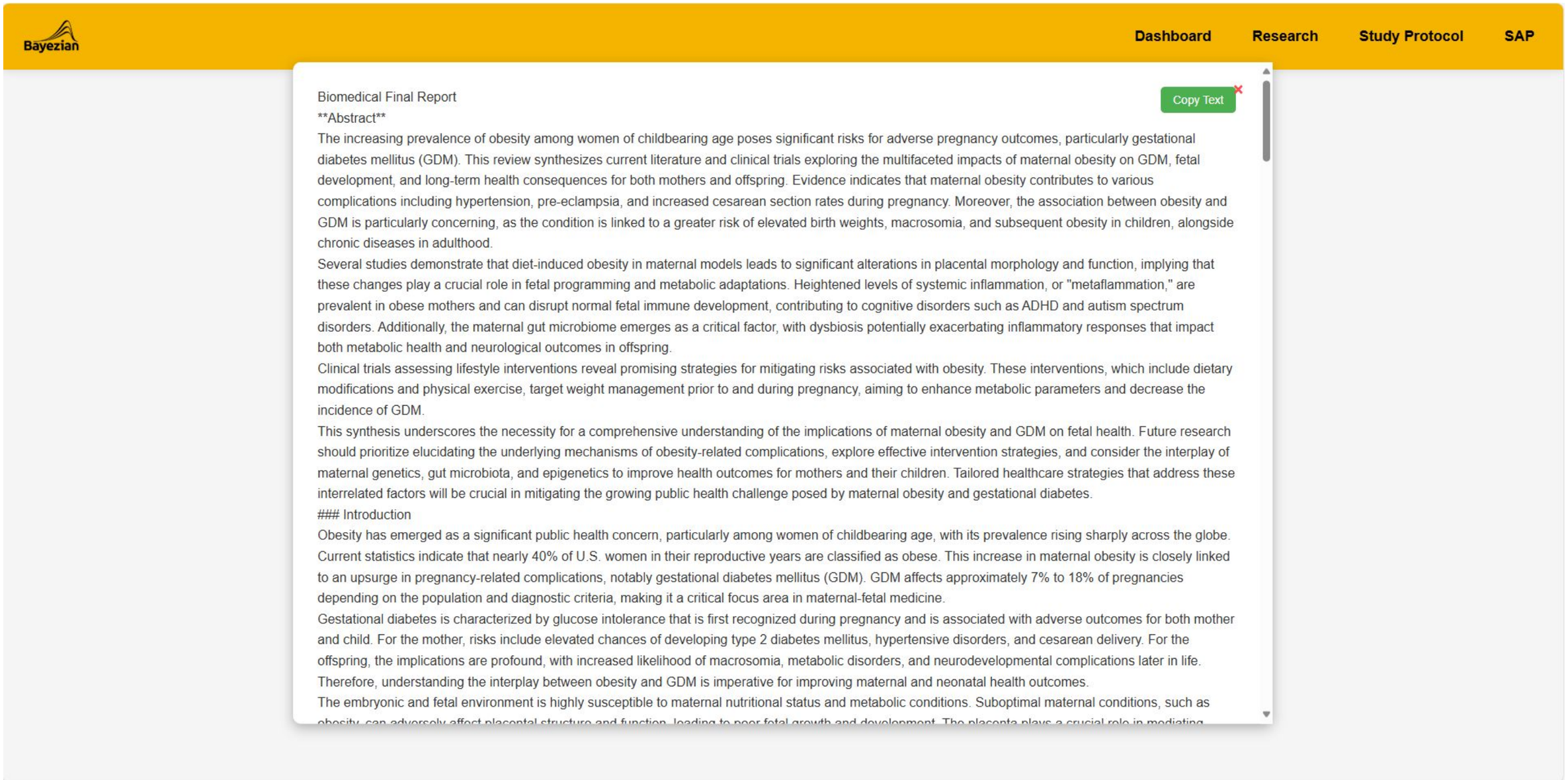

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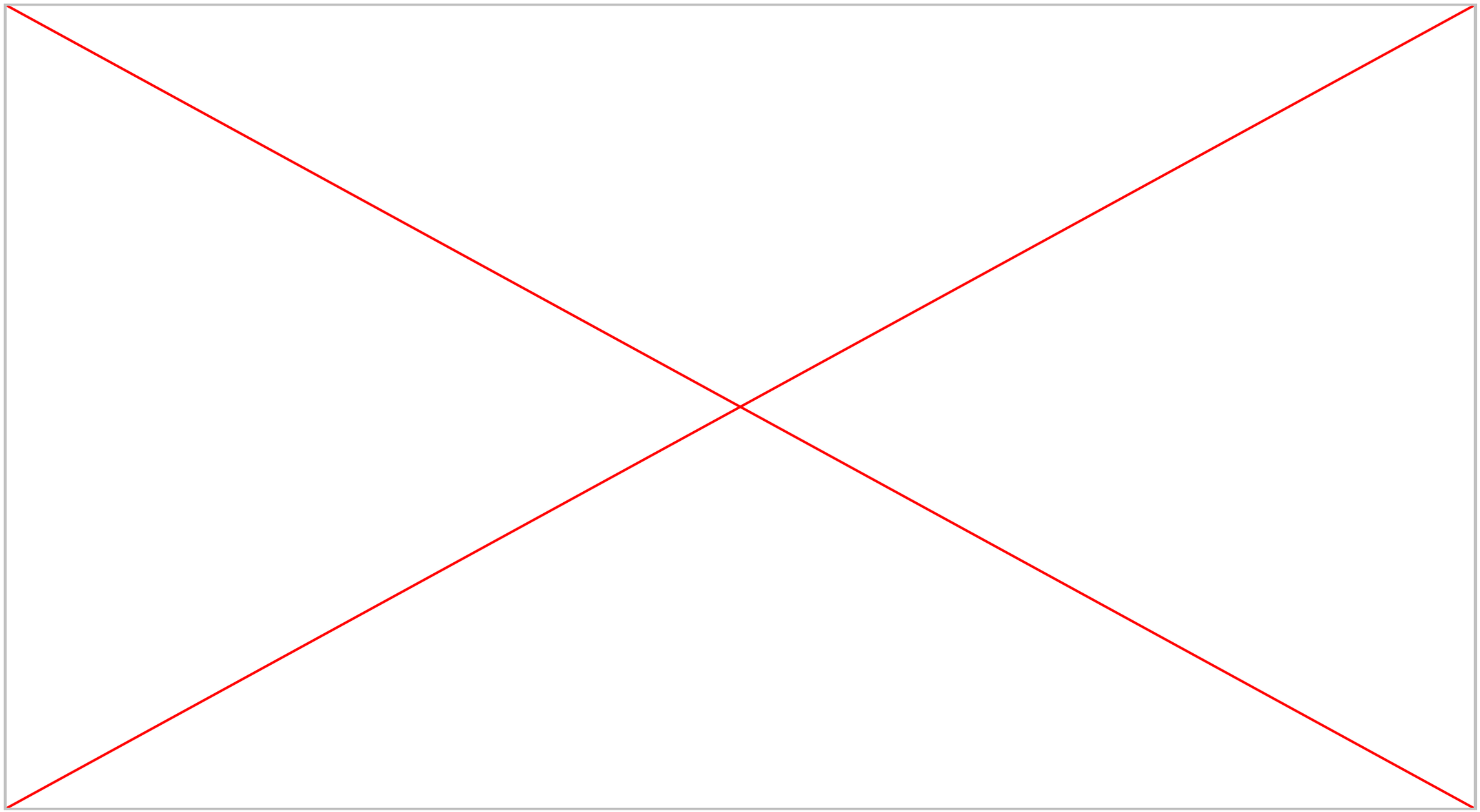

Thank You

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