



GPT-Powered Data Insights: Advancing Clinical Data Analytics with Large Language Models (LLMs)

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Formation Bio

Agenda

- Intro to AI in Analytics
- GPT-Powered Workflows
 1. Data Cleaning & Transformation
 2. Data Modeling & Analysis
 3. QC & Validation of AI-Generated Outputs
- Key Takeaways & Future Directions

AI-Powered Clinical Data Geneticists

Why LLMs in Clinical Data Analytics?

Much like geneticists decode DNA to understand biological functions, LLMs can decode clinical data to extract meaningful insights while overcoming challenges such as:

- **Data Growth & Complexity:** exponential growth of data (structured & unstructured)
- **Data Quality:** cleaning and standardizing data for analysis is slow and prone to error
- **Regulatory Requirements:** FDA & EMA require structured, traceable, and validated data reporting

💡 *Manual processes are no longer scalable.*



Transforming Clinical Data Analytics with LLMs

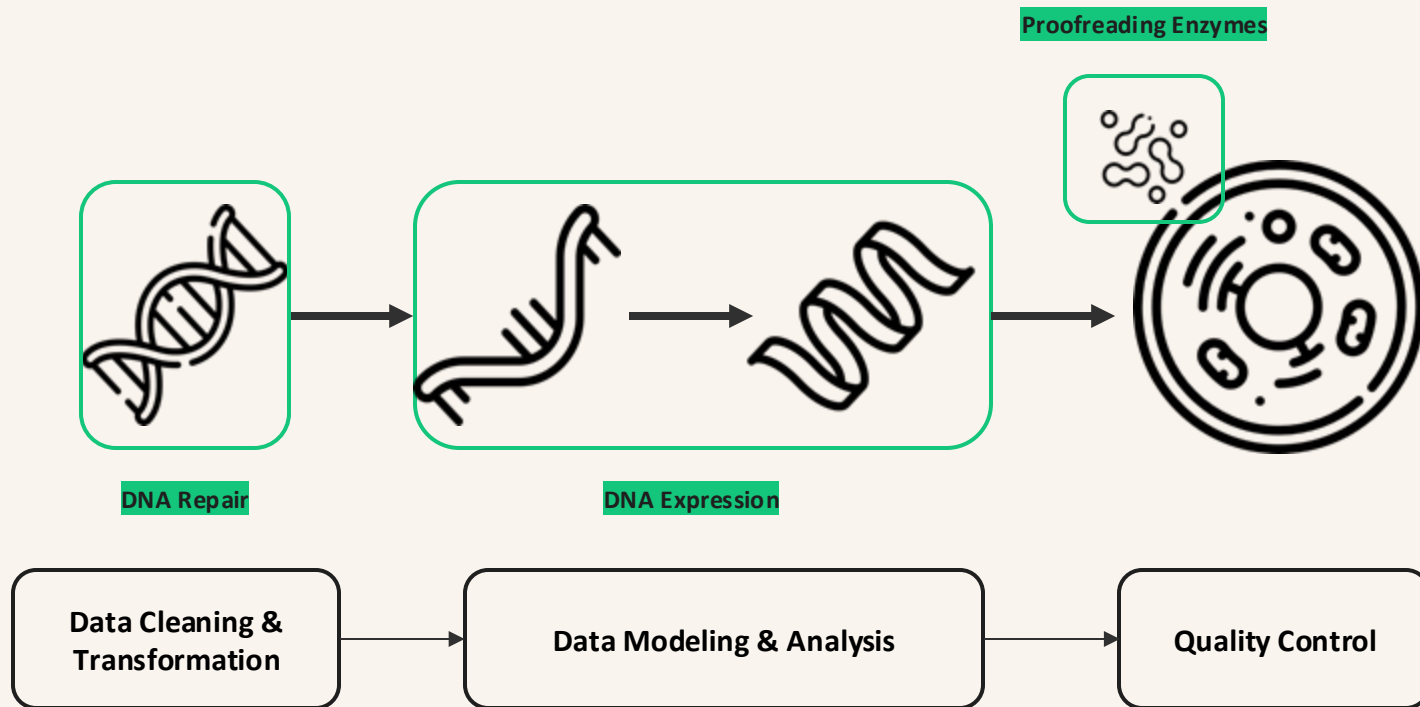
- ✅ **Natural Language Understanding (NLU):** AI can put data into context to interpret study protocols, medical narratives, and investigator comments.
- ✅ **Pattern Recognition in Structured Data:** GPT models can flag inconsistencies in case report forms (CRFs) and clinical datasets.
- ✅ **Automated Report Generation:** AI can summarize safety trends, efficacy endpoints, and statistical analysis results.



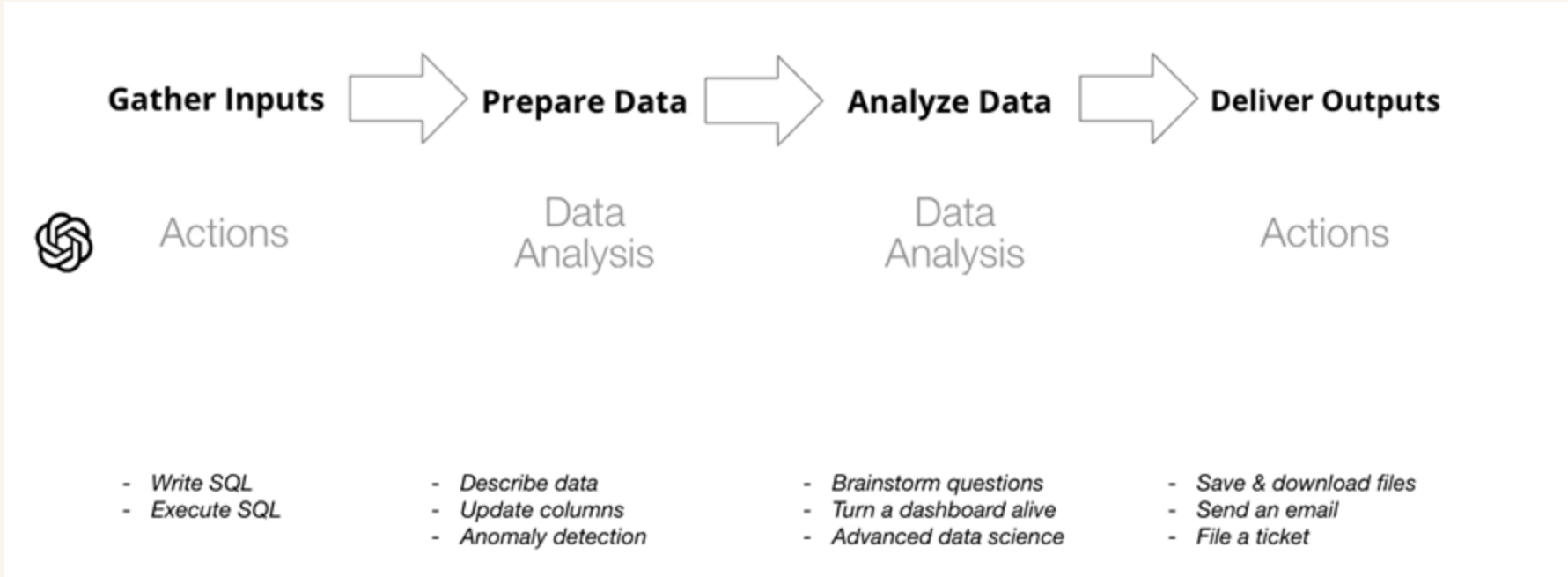
 *Example: A recent study demonstrated that GPT-4 outperformed traditional rule-based NLP methods in summarizing unstructured EHR data and extracting clinical phenotypes*



GPT-Powered Workflows



Data Analysis Process



Data analysis is an iterative process where you continually explore questions, data, and results. There are opportunities for AI to support you throughout this process!

ChatGPT's "Data Analyst" Custom GPT

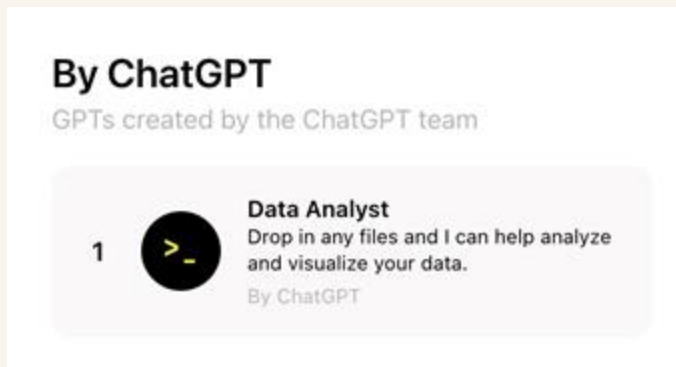
Collaborate with ChatGPT's AI Data Analyst Custom GPT to get from data to insights faster.

Capabilities:

- Chat with your data
- Get proactive insights and suggestions
- Create customizable, presentation-ready charts

Why ChatGPT is recommended for data analysis:

- Automates repetitive analyses
- Advanced data exploration and insights
- Enterprise-grade data privacy and security
- No training the LLM based on your data, ever



Note: Reference your company's data governance guidelines before uploading data.

Case Study: Using AI to Analyze the Osteoarthritis Initiative (OAI) Public Database

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The natural history of end-stage knee osteoarthritis: Data from the osteoarthritis initiative*

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ABSTRACT

Objective: We aimed to describe the natural history leading to end-stage knee osteoarthritis (eKOA), focusing on knee symptoms, radiographic severity, and the presence of limited mobility or instability.

Methods: We performed knee-based analyses of Osteoarthritis Initiative data from 7691 knees (4165 participants). We used a validated definition of eKOA that relied on meeting one of two criteria: (1) severe radiographic knee osteoarthritis (Kellgren-Lawrence [KL] grade=4) with moderate-to-intense pain (Likert WOMAC pain+function>13/80) or (2) KL grade<4 with intense or severe pain (WOMAC pain+function>22) and limited mobility (flexion contracture>5°) or instability (based on a varus and valgus stress test). We also introduced an alternate definition of eKOA that relied on meeting one of two criteria that omitted physical exam findings(3)



The Osteoarthritis Initiative

The Osteoarthritis Initiative (OAI) is a multi-center, ten-year observational study of men and women, sponsored by the National Institutes of Health (part of the Department of Health and Human Services). The goals of the OAI are to provide resources to enable a better understanding of prevention and treatment of knee osteoarthritis, one of the most common causes of disability in adults.

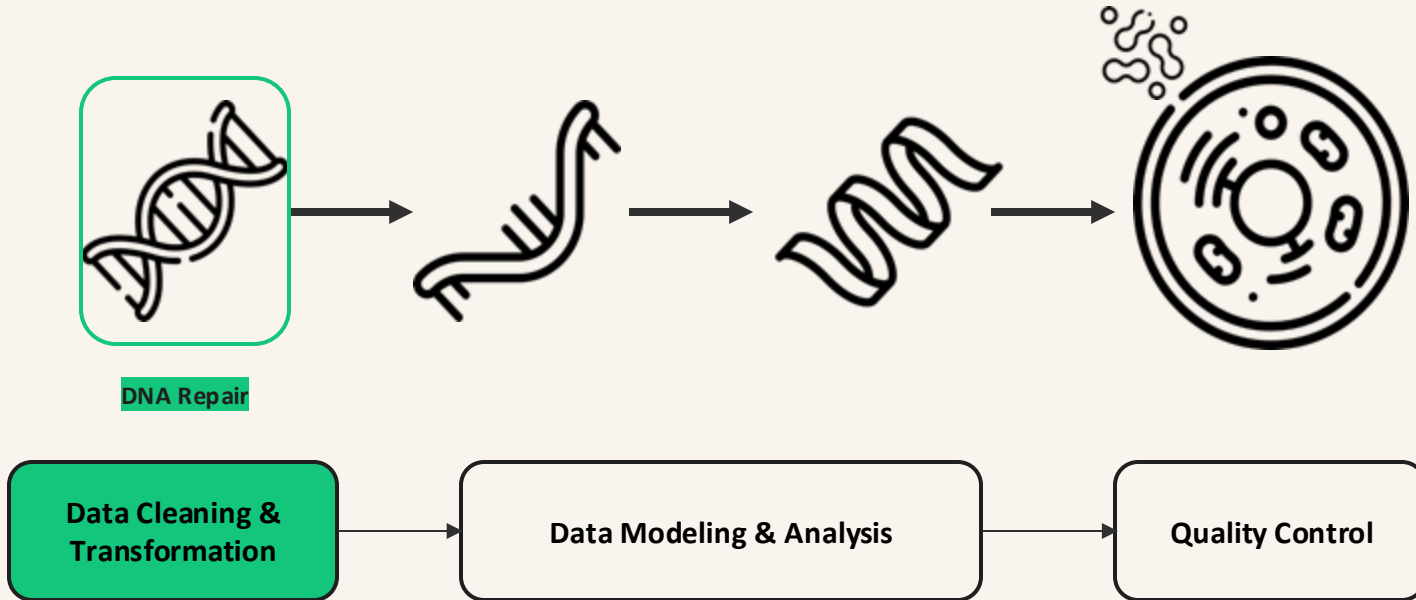
 Data Dictionary

 Full Downloads

 Images



1. Data Cleaning & Transformation



Prompts to assess data quality and add columns



Variable Guide: by Data Collection Form

Enrollment Visit p 1

Variable Name: V00COHORT

Label: EV.Subcohort assignment (calc)

SAS Dataset: Enrollees

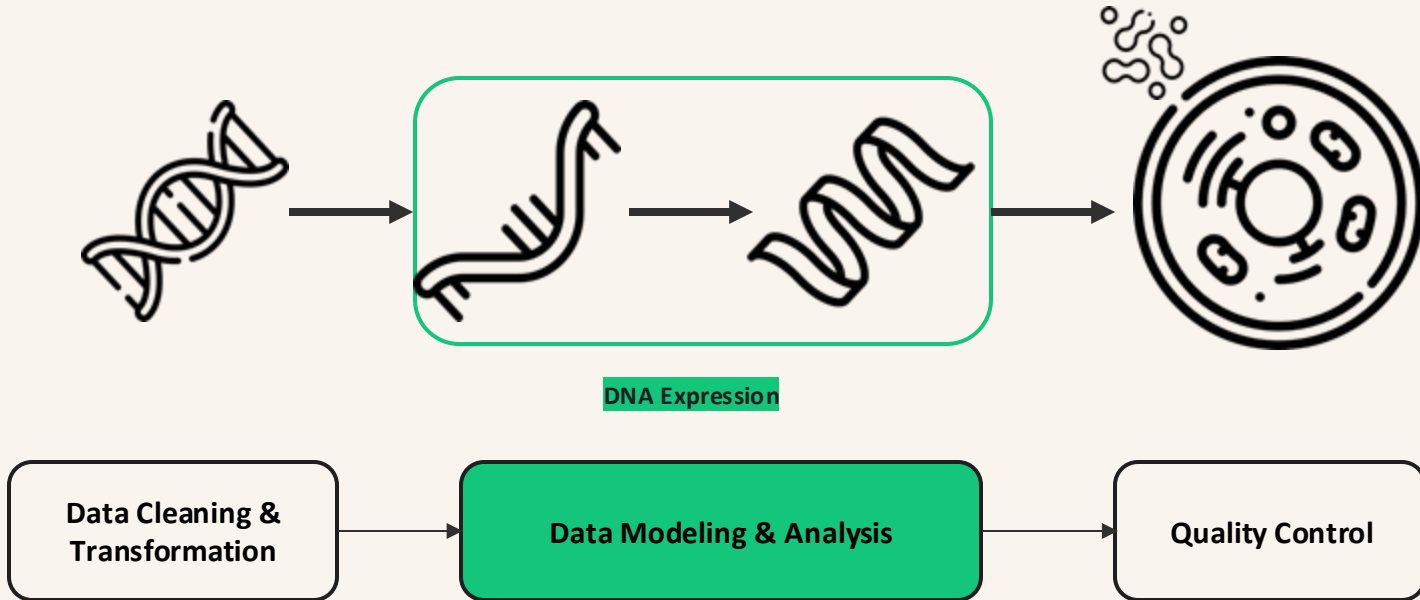
Release Comments: Notes available: see individual SAS dataset documentation for details

Category	SubCategory
Knee pain/OA status	Knee pain/OA status
Study eligibility	Other

	Value	N	%	Cumulative N	Cumulative %
1: Progression	1,390	26.98		1,390	26.98
2: Incidence	3,284	66.47		4,674	93.46
3: Non-exposed control group	122	2.54		4,796	100.00

- **Data cleaning:** What are some anomaly checks to run in this dataset?
- **Data transformation:** Add a column after “V00COHORT” to the enrollees dataset labeled V00COHORT_Verbatim” and in that column for each subject’s ID, enter the text “Progression” if “V00COHORT” is a 1, “Incidence” if “V00COHORT” is a 2, and “Control” if “V00COHORT” is a 3.

2. Data Modeling & Analysis

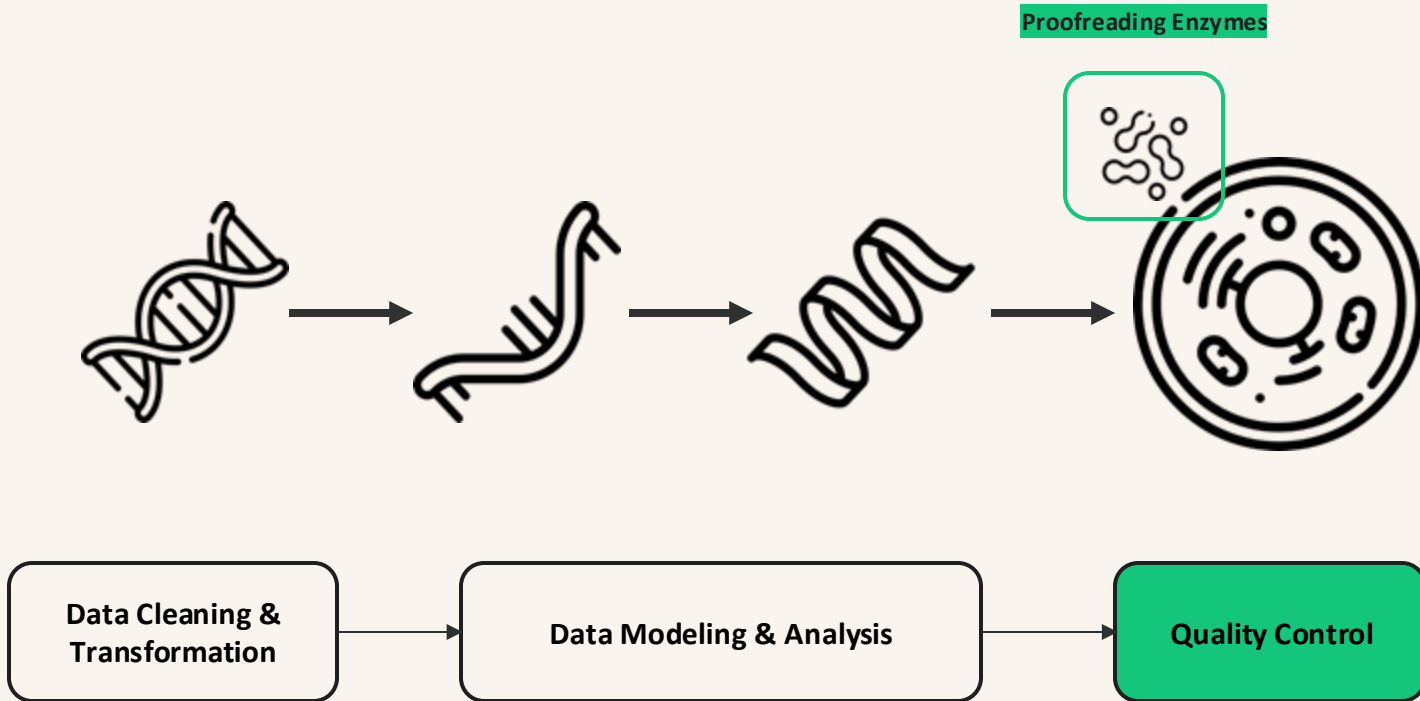


Prompts to analyze and interact with data

- **Data summarization:** Will perform upon upload and then specify further, such as asking how many subjects in the “outcomes 99” table had a knee replacement
- **Data viz:** Create a bar chart to show the breakdown of race and ethnicity for each cohort.
- **Data interactivity:** Generate R code for a Shiny app that allows you to explore data.

Custom Population Key Metrics							
Population	N	1-yr	2-yr	3-yr	4-yr	5-yr	Crude Risk
Custom	4796	99.5%	98.6%	97.7%	96.4%	95.2%	1.1%

3. QC & Validation of AI-Generated Outputs



Quality Control

Regardless of the classification of data, critical thinking is required to evaluate risk based on the data, information, and decisions being made for each use case, including the ability to quality control (QC) outputs because AI can be inconsistent, factually incorrect, and hallucinate.

Tips to check quality of AI analyses:

- Logical checks
- Ask for sources
- Output verification (i.e. human-in-the-loop)
- Awareness of bias in the data



Key Takeaways

- 1 **LLMs enhance data processing** by automating cleaning, transformation, and modeling, improving efficiency of data insights.
- 2 **AI-powered analytics facilitate data quality and exploration**, making complex clinical trial data more interpretable and actionable.
- 3 **Shiny apps with LLM integration** allow for real-time interaction with clinical datasets.
- 4 **Validation & QC remain critical**—AI-generated insights must be rigorously verified to ensure accuracy and compliance.

Future Directions



Advancements in Multi-Modal AI

- Next-gen models (e.g., GPT-5, Med-PaLM 2) will integrate **text, images, and structured data**, enabling deeper insights from multi-source clinical datasets.



Regulatory Landscape Evolution

- As AI adoption grows, **regulatory bodies (FDA, EMA, MHRA)** will refine guidance on AI-driven analytics, emphasizing transparency and validation.



Ethical & Interpretability Challenges

- While AI augments clinical decision-making, **explainability remains a challenge**—future AI models must improve interpretability and trustworthiness.



Questions?