Data Analytics & Ai Project

Enovis Global Surgical and Clinical Affairs Team

PoC:
Luca Dozza
Data Analytics Manager
luca.dozza@enovis.com
M +(39) 335 1947884

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This document is intended to provide the consultant with the idea behind the project and the essential project and vendor requirements, along with a selection of potential use cases to support the definition of a possible solution.

Executive Summary

In today's highly competitive market, the ability to quickly analyze and accurately interpret data is essential for making informed-strategic decisions that drive business success.

This Data Analytics project is designed to explore large and small Enovis datasets, integrating clinical, safety and market volume data from multiple internal sources to uncover meaningful insights and trends.

It combines statistical and computational methods to create an advanced environment able to manage, merge, analyze, query and visualize data, no matter what format table, text or pdf are the data and regardless the skill of the user on data analysis.

This enables faster and more effective decision-making across multiple departments, supporting stakeholders such as managers, colleagues, and the sales force.

Automation, predictive modelling, and artificial intelligence accelerate analyses, enhance job quality, and improve employee satisfaction by replacing repetitive manual tasks with high-level conceptual work.

The service involves collaboration between GSCA, IT, DPO, and Marketing teams, and once implemented, it could serve as a scalable model across the company.

Why we need data analytics?

The Glogal Surgical Clinical Affair (GSCA) team operates at the intersection of scientific and product innovation, market demands, and patient needs.

An effective data analytics support can:

1. **Enhance Decision-Making:** By providing *accurate, timely, and actionable insights*, the GSCA team can draw and follow a more specific and appropriate strategy that align with both clinical and business goals.

2. **Improve Efficiency:** *Predictive models,* advanced analytics and artificial Intelligence *minimize the time and resources* spent on data analysis.

3. **Improve Oversight:** by the *routine access to clinical data coming from country registries, clinical trials, literature and spontaneous surveys* the GSCA team can improve the oversight and the actualization of the Clinical Strategy by monitoring the patient outcomes and satisfaction.

Objectives and scopes:

1. To implement the **GSCA Data Warehouse,** that integrates multiple data sources into a unified repository.

2. To combine **statistical and computational methods** in an advanced environment able to manage, merge, analyze, query and visualize data, no matter what format table, text or pdf are the data and regardless the skill of the user on data analysis

3. To develop an analytics framework able to generate

   - ad hoc reports,
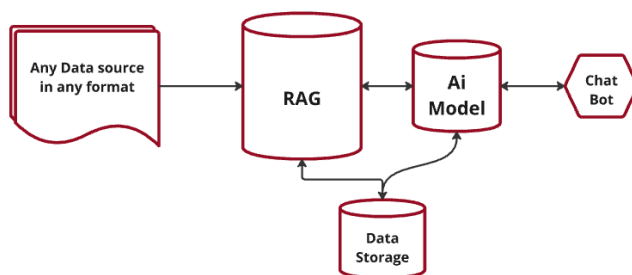   - interactive dashboards,
   - in-depth analyses

   powered by data-driven methodologies and Ai agents.

GSCA Data Warehouse Model

The **GSCA Data Warehouse Model** will be developed using a **Retrieval-Augmented Generation (RAG) combined with an AI assistant (LLM)** approach. Within this architecture, the RAG component will collect information from our data sources and reorganize it by creating embeddings that are stored and indexed within the RAG model.

The **AI assistant** will then interact with the RAG layer to retrieve the relevant information and provide accurate answers to user queries expressed in natural language.

This design ensures that responses are firmly grounded in the available data, thereby reducing the risk of inaccurate or fabricated outputs. Furthermore, if the model cannot provide a reliable answer, it will explicitly return *"I do not know"* instead of offering a speculative response, thus preventing users from being misled by uncertain information.

Data Sources

Source	Description	Format	Location	Type of Access	Update Frequency
Sale volumes data	Sales data form Lima, Mathys Legacy are updated on daily base and released on the DataWare House. The DWH can be Queried using Business Object producing a CSV file.	Structured (CSV File) or Unstructured (PDF file)	DWH (queried by Business Object Tool)	(Up to Now) Manual Extraction	Daily based
Sale volumes forecast data	TBD				
Clinical Study data (EDC, CSR, raw data)	Data are collected and extracted directly from the clinical study database. The application are calle Electornic data captures (EDC) or Case report forms (CRF)	Structured	WebApp	API or Manual Extraction depending on the system in use	Real time access
	Clinical study report	Unstructured (PDF or Word Document)	Sharepoint	Direct access	None
	Sharepoint Folder. This is an example on how data are clinical study document are stored in our sharepoint folder.	Unstructured (PDF or Word Document) and structured (Excel)	Sharepoint	Direct access	Not Appllicable
	RAW data from Investigator Initiated studies. In this case the output is customized by the Hospital and it is not possibile to anticipate a specific structure. Usually it is an Excel Spreadsheet.	Structured	Sharepoint	Direct access	It depends on the clinical protocol
Registries	Clinical data are collected by individual countries in registry databases to monitor product performance and safety. The outputs generated from registries differ from those produced in periodic reports, both in structure and scope.	Mainly Unstructured PDF files, but we have examples of registry that are providing raw data.	Saharepoint	Direct access	At least once per year, but it depends from several factors.
Literature	Scientific papers are archived to support oversight of product performance and safety, and to facilitate internal knowledge sharing across the company.	PDF	Sharepoint		
		In depends	Direct access to Pubmed or Editor	API connection	
		PDF	Article Galaxy	Direct access	
Surveys	A clinical survey is a structured method of collecting health-related data from individuals or groups, typically outside the framework of a formal clinical trial protocol. These surveys are designed to gather insights on patient experiences, treatment outcomes, safety signals, or healthcare practices, and may support observational research, post-market surveillance, or internal decision-making.	Structured		API or Manual Extraction	Real time access
Monday.com	Monday.com data refers to structured information collected and visualized through boards, dashboards, and automations within the platform, enabling internal team management and performance tracking. These data points include task progress, completion rates, workload distribution, collaboration metrics, and resource utilization. By aligning these metrics with business goals, teams can monitor efficiency, identify bottlenecks, and make data-driven decisions to improve productivity and accountability.	Structured	Our Monday.com Serrver	API connection	Real time access

List of Project Requirements

- **Regulatory Compliance:** The project must comply with applicable US and European regulations on data protection and artificial intelligence, including the EU AI Act (Regulation EU 2024/1689), GDPR, Directive 2011/24/EU on cross-border healthcare, and national laws governing clinical data usage and AI systems. Specific attention should be given to transparency, human oversight, and risk mitigation for high-risk AI applications in clinical settings.

- **GCP and 21 CFR Part 11 Compliance:** All data handling, storage, and processing activities must adhere to Good Clinical Practice (GCP) standards and FDA 21 CFR Part 11 requirements for electronic records and electronic signatures, ensuring data integrity, traceability, and auditability in clinical research environments.

- **MDR, ISO 14155 and MEDDEV 2.12/2 Compliance:** The proposed solution should operate within the framework of internationally recognized standards and regulations applicable to clinical data systems and medical device products, including Regulation (EU) 2017/745 (MDR), ISO 14155 for clinical investigations involving human subjects, and MEDDEV 2.12/2 for post-market clinical follow-up. These standards ensure ethical conduct, scientific validity, and regulatory readiness across the solution's lifecycle.

- **SaaS Distribution Requirement:** The proposed solution should be delivered as a Software as a Service (SaaS) model. This ensures centralized maintenance, scalability, secure access across geographies, and reduced infrastructure burden for the organization. The vendor should guarantee service availability, data protection, and compliance with relevant cloud security standards.

- **User Access and Management:** The vendor should clarify how the solution will manage user access and authentication, if the system can support multiple user roles with differentiated permissions (e.g., administrator, analyst, viewer), and ensure secure login mechanisms (e.g., username/password, multi-factor authentication).

- **System Validation and Auditability:** The solution implementation should include a formal validation phase in accordance with recognized industry standards. This includes documented test protocols, traceability matrices, and audit trails to ensure system reliability, reproducibility, and regulatory compliance. The system must support periodic revalidation and be prepared for external audits by regulatory authorities.

- **Cybersecurity and Data Protection:** The system must implement robust cybersecurity measures across all components, including encryption at rest and in transit, role-based access control, and continuous monitoring. It must comply with organizational security policies and relevant data protection regulations (e.g., GDPR, NIS2 Directive), ensuring resilience against unauthorized access, data breaches, and cyber threats.

- **Operating System Compatibility:** The proposed solution should be fully compatible with all major operating systems, including Windows and macOS. No limitations should be imposed based on the user's device or platform. The system must ensure consistent performance, accessibility, and security regardless of the operating environment, supporting both desktop and mobile access where applicable.

- **Storage System Access:** The solution should be enabling secure access to the organization's storage system (e.g., SharePoint) to locate, retrieve, and save specific documents as required by operational workflows.

- **Document Output Storage:** The system should be able to support storing output documents (e.g., task results, generated reports) within the designated storage environment to ensure traceability and future accessibility.

- **Document Presence Verification:** The solution should be capable of scanning the storage system to verify the presence or absence of specific documents or folders (e.g., checking a TMF folder for a required file), supporting compliance and audit readiness.

- **Information Extraction and Organization:** The system should be able to extract, structure, and organize relevant information from documents and emails upon request, facilitating efficient data retrieval and decision-making.

- **Natural Language Interaction:** The solution should be able to support interaction with end users via natural language, providing real-time clinical insights and information to cross-functional teams (e.g., Marketing, Regulatory, Sales) that collaborate with the GSCA Clinical Team.

- **Multi-format Data Interpretation:** The system should be able to interpret and compare data organized in various formats (e.g., CSV, PDF, DOC, TXT, JSON) and execute predefined actions based on structured instructions.

- **API Connectivity:** The solution should be able to connect to external data sources via API (e.g., Clininfo EDC, Monday.com), enabling seamless data integration and interoperability.

- **Task Execution Automation:** The system should be capable of executing predefined and programmed tasks (e.g., consistency checks on ClinInfo EDC), supporting automation and data quality assurance.

- **Trend and Correlation Detection:** The solution should be able to identify positive or negative trends and correlations within clinical and safety datasets (e.g., detecting underperforming products acting as outliers), enabling proactive risk management.

- **Automated Report Generation:** The system should be able to generate automated reports tailored to the GSCA Team's needs, supporting strategic planning and operational transparency.

- **Programming Language Support:** The solution should be able to provide input and support for programming languages commonly used in data analytics (e.g., R, Python, SQL, GraphQL), enabling advanced customization and analysis.

- **Statistical Analysis Capability:** The system should be able to perform statistical analysis on datasets provided by the user or extracted via API, supporting evidence-based decision-making.

- **Data Cleaning Support:** The solution should be able to assist in Data Management activities, including identifying data entry errors and inconsistencies to ensure dataset integrity.

- **Literature Scanning:** The system should be able to perform literature scans via API (e.g., using R scripts) or through internal databases, supporting research and clinical documentation.

- **PDF Literature Comprehension:** The solution should be able to comprehend PDF-based literature and provide ad hoc selections based on specific user-defined purposes.

- **Legal Document Support:** The system should be able to assist in contract evaluation, oversight, and review, supporting legal compliance and operational governance.

- **Collaborative Knowledge Sharing:** The solution should be able to support collaborative thinking and internal knowledge sharing based on historical experiences and organizational context.

- **Reminder Assistance:** The system should be able to assist in sending reminders for specific operational or clinical purposes, enhancing task follow-up and accountability.

- **Clinical Document Drafting:** The solution should be capable of drafting clinical documents or presentations based on specific guidelines or objectives, supporting regulatory and scientific communication.

- **Meeting Participation and Note-taking:** The AI agent should be able to attend virtual meetings, take notes, and generate meeting minutes, supporting documentation and follow-up actions.

- **Onboarding and Training Support:** The system should be able to provide tutorial support for onboarding and training activities, facilitating user adoption and operational readiness.

- **Sentiment Analysis and Communication Advice:** The solution should be able to perform sentiment analysis and provide stakeholder communication advice, supporting engagement strategies and relationship management.

List of Vendor Requirements

The chosen vendor will be qualified according to the company's internal standard procedure. This list represents the essential requirements and expectations as defined by the commissioning project management team.

1. Company Profile & Experience

- Demonstrated experience in Ai and data analytics projects.

- A signed declaration confirming the absence of ongoing legal disputes, especially related to intellectual property.

2. Project Delivery & Timeline

- Clear definition of project phases: Proof of Concept (PoC), full implementation, validation, and feedback integration.

- Estimated delivery timeline for each phase, with milestones and deliverables.

- Flexibility to adapt scope based on pilot outcomes and evolving use cases.

3. Maintenance & Support

- Provision of ongoing maintenance and technical support, either included or clearly priced.

- Service Level Agreements (SLAs) covering system uptime, bug resolution, and response times.

- Training and onboarding support for internal teams to ensure smooth adoption.

4. Cost Structure & Licensing

- Transparent cost breakdown for Proof of Concept (PoC), development, licensing, and hardware provisioning.

- Options for annual licensing versus perpetual license purchase.

- Clarification on whether cloud infrastructure is included or must be managed separately.

- If cloud infrastructure is provided by the vendor, the related cost must be clearly stated as an optional item. The client will evaluate whether to include this service or manage infrastructure independently.

- Specification of maintenance and support costs.

- Cost implications for updating the solution in case of new AI model releases.

5. Compliance & Legal

- Full compliance with GDPR and FDA regulations for data handling and AI-generated outputs.

- Readiness to sign Non-Disclosure Agreements (NDAs) and participate in legal review processes.

- Documentation of data privacy policies, cybersecurity certifications, and regulatory alignment.

6. System Validation and Auditability

- The vendor must conduct a formal validation of the solution in accordance with recognized industry standards. This includes providing:

  - Documented test protocols and validation reports.

  - A traceability matrix linking requirements to test cases.

  - A description of procedures for periodic revalidation and readiness for external audits by regulatory authorities.

7.Cybersecurity and Data Protection

- The vendor must provide:

- A Valid cybersecurity certification

- Evidence of compliance with applicable data protection regulations (e.g., GDPR).

- A statement disclosing whether any data breaches have occurred in the past 3 years. If applicable, the vendor must describe the internal procedures in place for breach detection, response, and mitigation.

8.Scalability & Future Integration

- Modular architecture that supports future expansion, including integration of additional data sources and newly released AI models.

9. Company Life Expectation

- The vendor must demonstrate long-term viability and a clear commitment to ongoing support, innovation, and product evolution.

List of Use Cases: (Priority for implementation)

- **Clinical Strategy team**

  - Manage, interpret and organize large volumes of data from many data sources at different timepoints (for example Registry data). **(A)**
  - Identify trends, correlations, and outliers within the Clinical and safety data. **(A)**
  - Incorporate scenario analysis to simulate different strategic approaches. **(B)**
  - Generate automated reports tailored to the Clinical Strategy Team's needs. **(A)**
  - Provide inputs on how to present and analyze data (Pbi, Tableau, Python, R, Excel, PPT, etc.) **(A)**
  - Provide inputs on programming (R, Python, SQL, GraphQL, etc.) **(A)**
  - By means of a chatbot-like solution, collect registry requests and the relative required predefined information **(C)**

- **Scientific Communication & Investigator Initiated Studies (IIS)**

  - Extracting and organizing info from documents and emails **(B)**
  - Supporting IIS data management on Data Cleaning and Edit checks **(A)**
  - Preparing clinical data and visuals for e.g. presentations and tenders **(A)**
  - Enabling fast access to key clinical data **(A)**
  - Provide clinical insight or updates to stakeholders by mean of a chatbot-like solution in natural language. **(A)**
  - Literature searching tool for the team and the stakeholders looking for a specific bibliography reference **(B)**
  - Congress overview: Perform an automatic online search for PIs and check whether they have presented anything at conferences. **(C)**

- **Clinical Operation Services (COS)**

  - Ai tool that can support on stratifying/analysing of data from clinical study data. **(A)**
  - Ai tool that can support on interdisciplinary work between CIS & COS (data entries, data analysis, etc.) **(B)**
  - Data Cleaning support finding Data Entry error and run consistency checks on CRF Data base
  - Tracking reports on different topic, not limited to Enrollment status **(B)**
  - During clinical protocol drafting provide advice on Endpoint definition **(B)**
  - Literature searching tool starting from a specific question. **(B)**
  - Generate new and recurrent reports from a specific requirement **(A)**
  - Define completeness of a specific Sharepoint folder **(A)**
  - Support on contract evaluation **(B)**
  - Advise on internal methodological approached based on Know-how acquired in previous similar tasks. (How we have done last year?) **(B)**

- **Company Initiated Studies (CIS)**

    - Sending reminders, organizing milestones and visits **(A)**
    - Support on evaluation Monitoring visit timing **(A)**
    - Tracking study progress and upcoming actions **(C)**
    - Missing data and consistency checks evalutating data entry **(B)**
    - Preparing clinical data and visuals for e.g. presentations **(A)**
    - Draft presentations following specific requirements and inputs **(B)**
    - Clinical Protocol Drafting (Text Modules) **(B)**
    - IRB Administration: filling out forms based on templates found on internet/in legislation **(B)**
    - Check eTMF for completeness **(C)**
    - Run auto searches of PIs to see which other studies they are participating in (clinicaltrials.gov, drks, who, etc.) **(C)**
    - Study newsletters **(B)**

- **Others use cases not specifically related to a team.**

    - Ai tool that can interact with Marketing/Sales in natural language providing required clinical information or reference in real time **(B)**
    - Ai Tool available as chat on Teams for supporting on clinical data or keeping minutes during daily meetings **(C)**
    - Tutorial support step by step for following complex or not-daily used procedures **(C)**
    - Tutorial approach on On Boarding program on SOPs or guidelines **(C)**
    - Searching tool for any data on any resource **(A)**
    - Co-Thinking and advice based on available knowledge. **(B)**
    - Checking procedures with the relevant appropriate GCP or legal regulation **(C)**

Priority Definition:

(A) High Priority: Tasks that cannot be automated without AI implementation. These should be considered first for initial deployment or PoC feasibility assessment.
(B) Medium Priority: Tasks that can be performed manually or through other automation methods, but would significantly benefit from AI integration.
(C) Low Priority: Tasks that may accelerate workflows but have limited impact on overall efficiency or time savings.

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Potential Prompt Examples

ID	Prompt	Solution	Area
1	In the S-11 study, please provide the number of patients enrolled in each of the study arms, target and actual, per site and cumulative.	Connect to the S-11 eCRF and extract the number of patient actually enrolled and who underwent surgery.	Data Management
2	Help me understand biomechanical properties between SMR Stemless Reverse and SMR Stemmed Product.	This case seems to require to have access to the technical documents, that are actually available, but the question can be summarized in the difference between Stemmed and Stemless products. The answer can be found on internet.	Information on Product
3	For the S-11 study, could you create a step-by step guide for site staff on accurate eCRF data entry?	Based on CRF, draft a data entry guiding document.	Data Management
4	For the S-11 study, generate a list of potential protocol deviations that might occur.	Based on CRF, list a potential Protocol deviation tat might occur.	Study Management
5	Generate a checklist for eCRF data review before database lock.	based on eCRF and clinical research methodology draft a checklist document for Entry and consistency checks befor proceed to database lock.	Data Management
6	please list all registries that contains data of Delta PF and the date of registry report generation.	Connect to the Registry Sharepoint folder and search for documents on Delta PF. Report the results together with the Report date	Study Management
7	please list me how many total procedures are availble in each registry for Delta PF.	Connect to the folder with all available registries. Select the ones related to Delta PF product and extract the total number of procedures for Delta PF. Present the results in a summary table	Data Interpretation
8	please give me number of patients at risk at 5 years and the corresponding revision rate for Delta PF.	Analyze registry data for Delta PF, find the number of patients at risk at 5 years, and determine the corresponding revision rate. Present the findings clearly	Data Interpretation
9	Please provide the latest interim report of study xy.	Search internal databases and project folders for the most recent interim report of study xy, and provide either the document or a summary of the main results.	Study Management
10	please list me how many pts had 2y follow up.	Extract from study data(eCRF) the number of patients who completed the 2-year follow-up and present the result.	Statistical Analysis
11	how many pts have safety results and how many pts have PROMS and which PROMs.	Analyze study data to identify: the number of patients with safety results, the number of patients with PROMs, and specify which types of PROMs were collected	Data Management
12	Based on the existing change order, can you give me an estimate of the CRO costs from now until the end of the study or a budget estimate for next year?	Analyze the current change order and financial data to estimate CRO costs for the remainder of the study or to generate a budget forecast for the next year	Study Management

ID	Prompt	Solution	Area
13	Analyze the study export file: evaluate the difference in KSS scores, the study's primary endpoint, from pre-op to 5-year follow-up. Compare study result with the literature.	Extract KSS scores from the study export file, calculate the change from pre-op to 5-year follow-up, and compare these results with published literature. Specific Literature can be requested to the user, if needed.	Statistical Analysis
14	Could you please provide the total amount paid to the study sites over the entire duration of the study?	Aggregate payment records for all study sites and calculate the total amount paid throughout the study period.	Study Management
15	Could you please calculate the cost we should pay to the site based on data available in eCRF (end year calculations)?	Review eCRF data and the study center contract, and apply the relevant payment formulas to determine the site costs for end-of-year calculations.	Study Management
16	Review XX ClinInfo/MEMdoc data extraction and provide descriptive statistics on PROMs/clinical scores	Analyze the extracted data from ClinInfo/MEMdoc and generate descriptive statistics for PROMs and clinical scores.	Statistical Analysis
17	considering enrolment exports, could you project enrolment trend in the next months/years?	Connect to the specific Study eCRF and Use historical enrolment data to model and forecast future enrolment trends over the coming months and years.	Data Management
18	Based on the documents archived in sharepoint, could you fill in the ISF index with documents name in the note section?	Review archived documents in SharePoint and populate the ISF index, listing document names in the notes section.	Study Management
19	Regarding the S-52 study, could you provide a table and related graphs showing the values of "stem positioning" (neutral, varus, valgus) compared to the values of "subsidence"?	Extract data on stem positioning and subsidence from the S-52 study, create a comparative table, and generate related graphs.	Statistical Analysis
20	[valid for any study] Could you please provide a trend of the PROMs [eg. VAS, HHS] and clinical evaluation [eg.CMS] at the study-defined time-points?	Analyze study data to plot trends of PROMs and clinical evaluation scores at each defined time-point.	Statistical Analysis
21	recent publications on enovis products (replacing the manual search on pubmed/journal websites)	Search internal and external databases for recent publications on Enovis products and compile a summary of findings.	Scientific Knowledge
22	For the S-52 study could you please provide the current results of CS in terms of mean and median?	Calculate and report the mean and median CS values from the current S-52 study data	Statistical Analysis
23	Could you please share an overview of the clinical strategy for PRIMA and PRIMA TT Glenoid?	Summarize the clinical strategy for PRIMA and PRIMA TT Glenoid based on available documentation and strategic plans.	Strategy Insight
24	For the S-08 study please make a description of the tables for the CIR	Review the S-08 study CIR tables and provide a descriptive summary of their content and structure.	Study Management
25	Please review Export of intraoperative data collected into ClinInfo eCRF and calculate how many fields are empty so data is not available	Analyze the intraoperative data export from ClinInfo eCRF and count the number of empty fields indicating missing data.	Data Management

ID	Prompt	Solution	Area
26	Could you please provide me the number of cases for the uncemented version of the twinsys hip stem from all available registries, including the respective survival rate (including confidence intervalls) at 5 years follow up in a table?	Extract case numbers and survival rates (with confidence intervals) for the uncemented twinsys hip stem from all registries and present the results in a table.	Data Interpretation
27	Could you provide me an overview of the available data of the ceramic Delta liners from registires?	Compile and summarize registry data related to ceramic Delta liners, highlighting key findings and trends.	Data Interpretation
28	Regarding the eTMF, could you provide automatic reminder notifications for expired documents that need to be updated.	Set up automated notifications for document expired and require updating.	Study Management
29	Review ClinInfo export and calculate numbers of patients implanted with SMR Cementless Finned Short Stem vs other Stems and numbers of follow-up visits done at each study timepoint for each stem type	ClinInfo export data to compare patient counts for SMR Cementless Finned Short Stem versus other stems, and summarize follow-up visits by stem type and timepoint.	Data Management
30	Review ClinInfo export data and analyze study outcomes and PROMs to identify possible outliers	Examine study outcomes and PROMs in the ClinInfo export to detect and report potential outliers.	Data Management
31	Review clinical study protocol and identify which data are more critical from data management point of view to ensure data quality and integrity	Based on Clinical Research methodology, Assess the clinical study protocol to determine which data elements are most critical for maintaining data quality and integrity.	Data Management
32	Review radiographic data collected and identify patients for which radiolucent lines are not progressive during Follow-up visits	Analyze radiographic data to find patients whose radiolucent lines remain stable across follow-up visits.	Data Management
33	Review study data and analyze study outcomes (HHS) to ensure primary endpoint of study is met	Evaluate study data, focusing on HHS outcomes, to confirm achievement of the primary study endpoint.	Data Management
34	Review AEs collected and identify only events for which study device is involved	Filter adverse events to include only those directly involving the study device.	Data Management
35	Regarding the data retention, which are the ISO 14155 requirements?	Summarize the ISO 14155 requirements for data retention, referencing the relevant regulatory guidelines.	Regulatory Insight
36	Compare radiographic data and PROMs outcome to identify patients with good radiographic data but negative PROMs and viceversa	Cross-analyze radiographic and PROMs data to identify patients with discordant outcomes (good radiographic results but poor PROMs, and vice versa).	Data Management
37	Review eCRF of this new clinical study and identify possible automatic checks to implement directly into eCRF to ensure data quality	Assess the eCRF and propose automated data quality checks for direct implementation.	Data Management
38	Review data export and for each study site calculate total numbers of: patient enrolled, patient complete study,	Analyze data export to compute totals for each study site: enrolled, completed, withdrawn, lost-to-follow-up, deaths, and revisions.	Data Management

ID	Prompt	Solution	Area
	withdrawn, lost-to-Follow-up, death, revisions		
39	Review intraoperative data and calculate number of different type of shoulder stem and all other components (e.g. glenoid type, glenosphere type, liner etc..) of shoulder implant by study site	Summarize intraoperative data to report counts of shoulder stem types and other implant components by study site.	Data Management
40	Review AEs and categorize them by MEdra coding	Classify adverse events using MedDRA coding and provide a categorized summary.	Data Management
41	Prepare an overview of clinical data available on a specific product/class of products (for example "stemless shoulder arthroplasty"). Data should be used to prepare state-of-the-art for meetings and reports.	Compile and synthesize clinical data on the specified product/class to create a state-of-the-art overview for meetings and reporting.	Statistical Analysis
42	Based the last 3 years UK Registri releases on SMR Glenoid, Compare Revision Rates and highlight if there are significant changes in Revision Rates of Demographic data over time.	Connect to the correct UK Registry folder, select the correct years and extract the relevant data. Compare revision rates and demographic data overtime. Present the results by mean of tables and text description.	Statistical Analysis