1. Persona: Product Manager (The "Product Guardian")

Objective: Oversee product lifecycle health, safety signals, and clinical success to prevent recalls and maintain market leadership.

Core Use Cases

- **Safety Risk Monitoring:** Identifying early-warning signals in adverse events (AEs).
- **Clinical Performance Tracking:** Monitoring revision rates vs. industry benchmarks.
- **Regulatory Compliance:** Tracking document completeness for MDR/FDA.

Strategic AI Prompts

1. **Safety Correlation:** "Analyze the S-33 study and identify if there is any statistical correlation between glenosphere size and the incidence of scapular notching across all study sites."
2. **Benchmark Analysis:** "Compare the 2-year survivorship of the SMR Reverse HP (98.1%) against the bottom 25% of reverse shoulder systems in the UK National Joint Registry."
3. **Recall Risk Assessment:** "Review the last 12 months of device deficiency reports for the Delta Revision Cup. Is there a rising trend in specific mechanical failures that warrants a proactive field safety notice?"
4. **Demographic Impact:** "Identify if revision rates for the Mueller Cemented Cup are significantly higher in patients with a BMI over 35, and recommend if instructions for use (IFU) should be updated."
5. **Regulatory Gap Analysis:** "Check the SharePoint folder for the SMR system and list all required 'Clinical Evaluation Reports' (CER) that are missing or will expire within the next 6 months."
6. **Site-Specific Performance:** "Identify which clinical study sites have a revision rate that is >2 standard deviations away from the study mean, and list the common surgeons at those sites."
7. **Data Synthesis:** "Summarize all intraoperative complications reported in the H-31 study and categorize them by 'Device-Related' vs. 'Procedure-Related'."

---

2. Persona: Sales (The "Competitive Closer")

Objective: Use real-world evidence and clinical data to defend market share and convert competitor surgeons.

Core Use Cases

- **Competitive Battle Cards:** Instant evidence-based rebuttals.
- **Economic Value Modeling:** Proving cost-savings via clinical superiority.
- **HCP Relationship Management:** Identifying brand champions through data.

Strategic AI Prompts

1. **The Rebuttal:** "Draft a rebuttal for a surgeon currently using Zimmer Biomet's Comprehensive system, specifically highlighting the SMR's 88.5% success rate versus the 76.3% found in our control group."
2. **Outcome Visualizer:** "Extract the Harris Hip Score (HHS) improvements for the Mueller Cup (from 43.9 to 92.9) and generate a summary showing mobility gains for sedentary patients."
3. **Competitor Weakness:** "Search recent literature for known complications of 'Competitive Product X' and cross-reference them with our study H-34 to show how the Delta Cup avoids those issues."
4. **Procurement Pitch:** "Calculate the predicted 5-year revision cost savings for a hospital if they switch from a competitor cup with a 94% survival rate to our Mueller Cup's observed 100% survival."
5. **Technical Deep-Dive:** "Provide a simple explanation of the 'Vitamin E' infusion benefits in our liners compared to standard UHMWPE for a surgeon who is concerned about long-term wear."
6. **Champion Identification:** "Based on recent registry data, identify surgeons in the Northeast region who are publishing high-success rates using Enovis shoulder implants."
7. **Sales Scripting:** "Generate a 30-second elevator pitch for the SMR Stemless system based on the anatomical restoration data found in our internal white papers."

---

3. Persona: Marketing (The "Brand Storyteller")

Objective: Translate complex clinical data into compelling market claims and "State-of-the-Art" content.

Core Use Cases

- **State-of-the-Art (SOTA) Reporting:** Automated synthesis of market trends.
- **Claim Validation:** Ensuring all marketing copy is clinically supported.
- **Patient Education:** Simplifying clinical outcomes for patient-facing content.

Strategic AI Prompts

1. **SOTA Generation:** "Generate a comprehensive 'State-of-the-Art' report for stemless shoulder arthroplasty using internal CSRs and the last 3 years of PubMed publications."

2. **Claim Validator:** "Check if the claim 'Industry-leading safety for reverse shoulders' is supported by the AE rates in study S-33 compared to three major competitors."
3. **Patient Success Narrative:** "Identify 'super-responder' patients in the H-31 study (those with >50 point HHS improvement) and draft a de-identified patient success story for our website."
4. **Visual Data Extraction:** "Create a table comparing the Oxford Shoulder Score (OSS) responder rates (89.8%) from our latest study against the industry average for reverse shoulder procedures."
5. **Congress Intelligence:** "Scan competitor abstracts from the latest AAOS meeting and identify the top three themes being used to market competitive hip revision cups."
6. **Channel Optimization:** "Draft a series of LinkedIn posts targeting orthopedic surgeons that highlight the 0% device-related adverse events in our Mueller Cup study."
7. **Brand Perception:** "Analyze the language used in recent Clinical Investigation Reports to identify the most frequently used positive adjectives to describe the DELTA Revision system."

---

4. Persona: Clinical Operations (The "Compliance & Financial Lead")

Objective: Manage the execution, data integrity, and complex financials of global clinical studies.

Core Use Cases

- **Financial Tracking:** Monitoring CRO costs, site payments, and budget forecasts.
- **Study Oversight:** Enrollment tracking and protocol deviation monitoring.
- **GCP Compliance:** Ensuring eTMF and ISF completeness.

Strategic AI Prompts

1. **Financial Forecast:** "Analyze the current CRO change orders for Study S-11 and provide a budget estimate for the remaining 24 months of the 5-year follow-up period."
2. **Automated Site Payments:** "Calculate the total site payments due for Q4 by cross-referencing completed eCRF visits in Study H-31 with the per-patient fee schedule in the site contracts."
3. **Site Risk Alert:** "Identify study sites that have an enrollment rate <50% of their target but have consumed >80% of their allocated budget."
4. **MedDRA Coding Check:** "Scan the 'Other' category in our AE reports and suggest the correct MedDRA coding for entries that mention 'persistent joint discomfort'."
5. **Document Audit:** "Review the electronic Trial Master File (eTMF) for the SMR study and flag any sites where the Principal Investigator's medical license has expired."

6. **Missing Data Analysis:** "Identify sites with a >20% rate of 'Lost to Follow-up' and analyze if there is a correlation between patient age and study withdrawal."
7. **Protocol Compliance:** "Search for all reported protocol deviations related to 'post-operative imaging window' and identify which sites require additional training."

---

5. Persona: Strategy (The "Visionary")

Objective: Refine the product portfolio, monitor user sentiment, and identify long-term market opportunities.

Core Use Cases

- **Portfolio Health & Sentiment:** Analyzing the "Voice of the Customer" from registries and surveys.
- **Product Refinement Strategy:** Identifying gaps in current designs based on clinical feedback.
- **Macro-Trend Analysis:** Monitoring the impact of regulatory changes and market shifts.

Strategic AI Prompts

1. **Sentiment Gap Analysis:** "Analyze surgeon feedback from Investigator-Initiated Studies (IIS) and identify the top 3 requested refinements for the next generation of glenoid baseplates."
2. **Portfolio Sustainability:** "Compare 10-year survivorship trends of our cemented vs. uncemented portfolios. Should we shift R&D focus based on the aging demographic trends in the EU?"
3. **Voice of Customer (VoC):** "Perform a sentiment analysis on the last 100 internal surveys regarding SMR instrumentation. Is the feedback on 'ease of use' improving or declining compared to 2022?"
4. **Competitive Threat Assessment:** "Evaluate the risk of new 'robotics-assisted' shoulder systems on our current manual SMR portfolio based on clinical success trends in registry data."
5. **Refinement Opportunity:** "Examine the 13% fracture rate in Study H-34 (Delta Cup). Based on patient bone-density data, should we develop a 'reinforced' version for high-risk osteoporotic patients?"
6. **Global Market Entry:** "Simulate the clinical evidence requirements needed to launch our hip portfolio in the Japanese market based on recent PMDA regulatory shifts."
7. **Interdisciplinary Advice:** "Based on all clinical and sales data, recommend whether Enovis should pursue a 'value-segment' hip product or continue focusing on 'premium-tech' revisions."

6. Persona: Quality Head

Mission: To ensure zero-defect manufacturing, proactive risk mitigation, and a state of "perpetual audit readiness." This persona owns the feedback loop between real-world complaints and internal process improvements.

Core Modules

- **Complaints Management Hub:** An AI-driven triage center that categorizes incoming reports, detects trending failure modes, and automates Medical Device Reporting (MDR/Vigilance) decisions.
- **CAPA & Vigilance Dashboard:** Real-time tracking of Corrective and Preventive Actions (CAPAs), linking them directly to the clinical or manufacturing data that triggered them.
- **Risk Management File (RMF) Live Link:** A module that automatically flags when a "Real-World" complaint or adverse event exceeds the predicted "Risk Occurrence" levels defined in the product's technical file.
- **Post-Market Surveillance (PMS) Analytics:** Correlating complaint data with sales volumes to calculate "Complaints Per Million" (CPM) and identify geographic or batch-specific quality clusters.

Medium to Difficult Prompts

1. **Trend Detection vs. Sales Volume:** "Analyze the complaint rate for the SMR Reverse HP over the last 18 months. Normalize the data against sales volume (CPM) and identify if the 5% increase in 'liner wear' reports is statistically significant or a byproduct of market growth."
2. **Root Cause Cross-Analysis:** "Cross-reference recent complaints regarding 'baseplate loosening' with manufacturing lot numbers and clean-room environmental logs. Is there a correlation between these events and the batch produced in Q3 2024 at the Milan facility?"
3. **CAPA Effectiveness Check:** "Review the effectiveness of CAPA-2023-004 (designed to address glenosphere locking screw issues). Compare the incident rate in products manufactured *before* the fix versus those manufactured *after* the implementation."
4. **Vigilance Reporting Logic:** "A surgeon reported a 'suspected' material failure on a Mueller Cup during a revision surgery. Based on FDA 21 CFR 803 and EU MDR Article 87, determine if this event meets the 'Serious Deterioration of Health' threshold and draft the initial Vigilance report."
5. **Risk File Update:** "Scan all post-market data for the DELTA Revision Cup. Identify any 'new' hazardous situations reported by surgeons that are not currently listed in the existing Risk Management File (RMF) for this device class."

6. **Silent Quality Signal Search:** "Perform a sentiment analysis on the last 100 entries in the 'Service & Repair' logs. Are there recurring technician comments regarding 'instrument stiffness' that have not yet been escalated to a formal complaint?"
7. **Supplier Quality Audit Preparation:** "Generate a 'Quality Scorecard' for our primary UHMWPE supplier by aggregating all material-related complaints, incoming inspection failures, and clinical study deviations from the last 24 months."