Janssen
(a Johnson & Johnson Company)

Software Strategy for
Clinical Data Management &
Statistical Computing Environment

ENTERPRISE ARCHITECTURE
BRIEF CASE STUDY for ACHIEVE INTELLIGENCE
Version 01
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Note: certain people and product names have been redacted to preserve confidentiality.

Contents

Introduction to Janssen

Janssen is a major Enterprise within the global pharmaceutical sector. As a Johnson & Johnson company it also has much interoperability with the larger group as a whole. Within Janssen, three services organisations are collectively responsible for delivering quality data and analyses to support the submission of drug and biologic applications to regulatory authorities.

iDAR
Responsible for collection, statistical analysis and reporting of clinical data.

EBIS
Provide system, application and process support to the iDAR team.

IT
Providing information technology support across Janssen, with relationship managers accountable to business units such as EBIS.

Purpose of engagement

At the time of engagement, the main application for data management and statistical computing had a number of significant failings, and in the view of some key leaders in the group was no longer fit for purpose. This legacy platform represented a substantial investment. Janssen therefore required a quantifiable, fact-based and independent process to steer strategic decision making for future investment in their core platform for data management (acquisition, curation and provisioning) and quantitative analytics.

Approach

Janssen leadership engaged Achieve Intelligence to provide Enterprise Architecture services: to define the current state of Janssen's Business, Data, Applications and Technology domains; to formally identify the problems; to uncover the overall vision; and to provide an effective roadmap for the transformational journey away from the current state towards an agreed vision state.

Using TOGAF® 9.1 methodology, Achieve Intelligence performed stakeholder identification, defined architecture principles, held business scenario workshops, collated the vision outline, performed a gap analysis, drafted a solution concept diagram, assessed the business readiness for embarking on a transformation project, and detailed an implementation plan with costs to perform said transformation.

Finally, this was collated in an Executive Summary report for review by the senior leadership team.

Stakeholder Identification

Using a collaborative and democratic survey, Achieve Intelligence were able to interview the nominated stakeholders, identify additional stakeholders, and facilitate an assessment of all stakeholders invested in this area. Using this analysis, the stakeholders were segmented into four groups based on their interest, power and influence: an Operational team, a Steering Committee, the Consulting Experts and a Milestone Updates group.

This enabled effective communication throughout the exercise and allowed the intense activity to be focussed on those stakeholders identified as the core operational team.
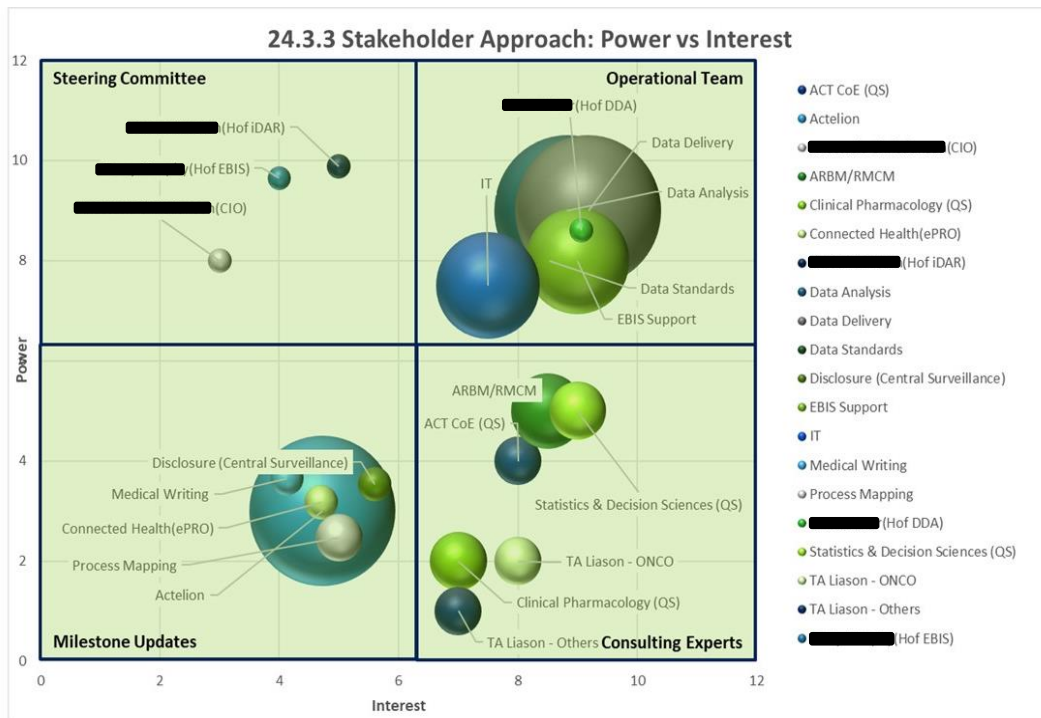
Architecture Principles

13 Architecture principles were defined, debated and agreed by the operational team These enabled effective decision-making when assessing options to progress from the current state to the future vision. Options in conflict with these agreed principles were discounted from outset.
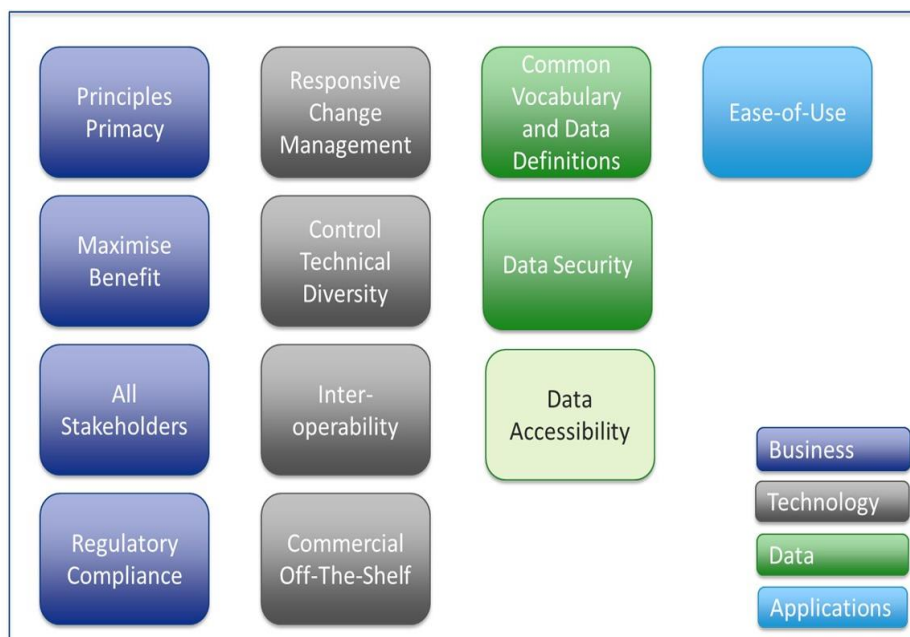
Business Scenarios - Workshop

Each stakeholder contributed ideas about the nature of the problem and about how the situation could be improved. Achieve Intelligence facilitated a scenario-based discussion and assisted the organization in identifying and classifying the problems; identifying and assessing possible solutions; and then distilling those discussions into 20 options, split across 4 business scenarios.

A "Business Scenarios" workshop was held to further categorize those solutions as:
- **x** unworkable from the outset,
- **T** tactical adoption, or
- **S** strategic direction

Vision State Block Diagram

A high-level Vision State Block Diagram was defined to enable discussion around the proposed solution. Within each layer a number of more detailed Architecture Building Blocks (ABBs) were defined, and several candidate software solutions were identified for each ABB.
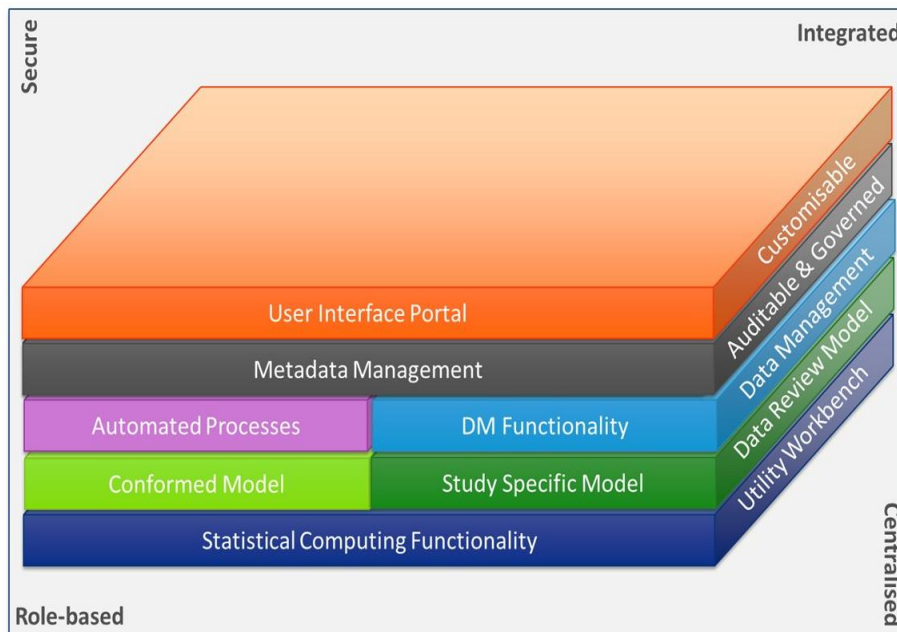
Gap analysis

Achieve Intelligence used Gap Analysis methodology to assess whether current processes, applications, data and technology meet the needs defined by vision state ABBs. This gap analysis suggests which ABBs can continue as-is, which need improving, which can be decommissioned, and which new ABBs are required to achieve the vision state.

Solution Concept Diagram

From the high-level vision-state block diagram, Achieve Intelligence produced a solution concept diagram describing how the ABBs interoperate across the platform.

This lower level architecture blueprint, which can be used by solution delivery teams to begin detailed design and implementation processes.

[Due to confidentiality the Solution Concept Diagram is not provided in this case study.]

Transformational Readiness

Prior to implementation it is imperative to determine the transformational readiness of the organisation. This helps with the planning of the programme, and helps an organization create an atmosphere within which a programme can succeed. Achieve Intelligence were able to identify for Janssen those areas that enabled success of this large-scale transformation, versus those that required modest to substantial attention.

30.3 Business Transformation Maturity Model
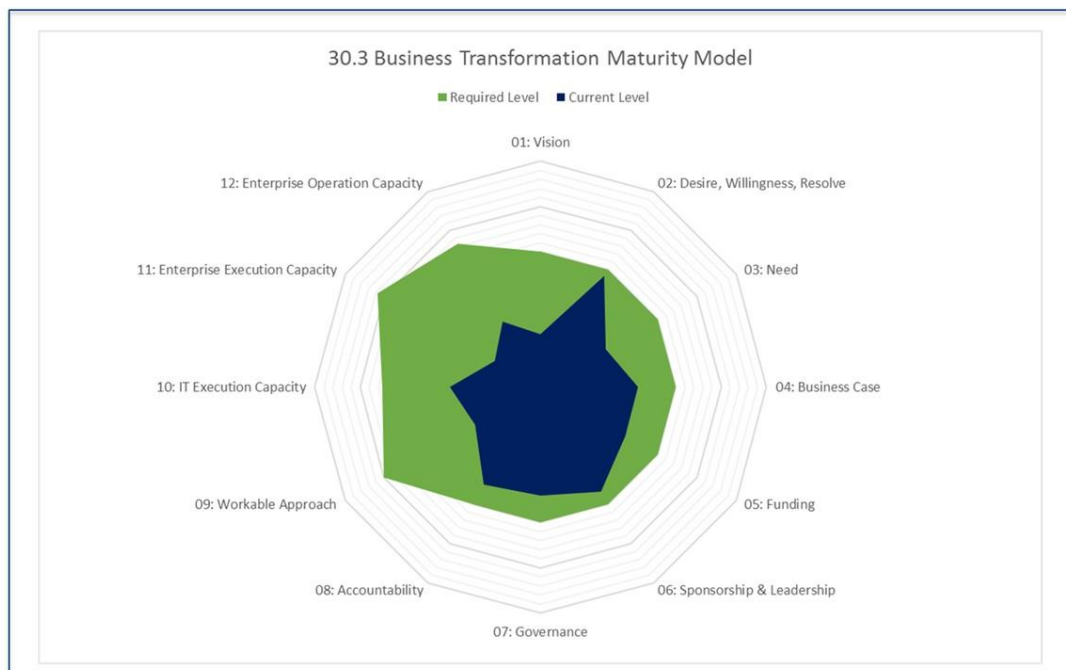
Implementation Plan

Achieve Intelligence provided Janssen with a high-level implementation plan to achieve the vision state within a suitable and feasible timeframe. This was used to estimate the amount of funding required and set expectations of the timescales involved in such an implementation programme.

[Due to confidentiality the Implementation Plan is not provided in this case study.]

Executive Summary

The final step of the process was to package all information into a vision document and an Executive Summary slide deck which the Janssen team used when reporting to senior leadership.

Outcome/Findings

The Executive Summary produced by Achieve Intelligence was used by the Janssen team to inform Senior Leadership of the following:

- Definition of the problem
- Discovery of further problems, hidden behind the original problem
- Evidence of options considered, and choices made
- Indication of funding required and timescales for the transformational programme.

Funding was secured and Janssen are progressing with the transformational programme, using the Enterprise Architecture artefacts that Achieve Intelligence delivered.

Customer Endorsement

"The internal cross functional team that we had addressing this issue seemed often to be side-lined by the necessary focus on delivery. When Achieve Intelligence were engaged there was a rapid and marked refocusing on the problem. In fact, it soon became apparent that there were multiple problems and we were able to prioritise the solutions around a single vision. The work delivered by Achieve Intelligence helped us quantify the problem and secure transformational funding to pursue the Vision."

Darren Weston
Head of iDAR

"Achieve Intelligence provided a structured method of facilitating a space within which the team could focus efforts on the problem head on. During the Business Scenarios workshop session, I particularly appreciated getting everyone together to rapidly surface the problems, while working together to come up with an agreed solution."

Bev Hayes
Head, ED/CP Statistical Programming & Analysis