Big Nasty Pharma Case Study

Salesforce.com Certified Technical Architect Practice Scenario

Candidate Prep Time: 120 minutes

Presentation Time: 45 minutes

Solution should cover:

- Actors and license choices
- System Landscape
- Role Hierarchy
- Data Model
- LDV
- App Design (Declarative and Programmatic Solutions)
- Integrations
- SSO
- Sharing Design
- Governance (if applicable)

Business Overview

Big Nasty Pharma (BNP) USA is a leading manufacturer of prescription and over-the-counter drugs, including Fioxx, Tordaptive and Growpecia. The company is a subsidiary of Big Nasty GmbH headquartered in Germany, which also has multiple other subsidiaries operating globally in EMEA and APJ. Each subsidiary has very different product development and sales processes.

BNP USA operates in a highly regulated industry, where the process of creating new drugs involves lengthy studies, trials and approvals. They are seeking to automate the process of taking a drug from initial concept, through to final FDA approval as well as safety monitoring. BNP is seeking to replace their existing application that manages product development with Salesforce.com.

BNP USA has a Clinical Research department of over 500 staff, who identify, design and develop new drugs for market. Once the initial viability is confirmed, the same researchers perform preclinical research and lab studies. This process confirms that clinical trials on humans can commence.

The clinical trial process is a lengthy one, which is intended to verify drug safety and efficacy amongst humans and many drugs do not complete this process. This process includes recruitment of patients, application of drugs, and review and analysis of trial results.

BNP outsources this lengthy clinical trial process to multiple external agencies, who perform the recruitment, application and data collection process. There are up to 50 agencies, who in total employ up to 100K. This is process is overseen internally by Clinical Trial Managers of which there are 50 users.

BNP utilizes a SmartDose™, an internet-enabled applicator device, which tracks dosage application and history. Recruited patients are able to enter adverse side effects via a portal and a mobile application.

Once the research is completed, the drug is then subject to FDA approval. The FDA (Food Drug Agency) is a government body that scrutinizes new drugs and approves them for sale under the NDA (New Drug Approval) process. On FDA approval, it can then be sold by Big Nasty GmbH and any of its subsidiaries.

In the Post-market phase, the FDA requires safety monitoring of the drug through extracts from external data sources such as MedWatch and Sentinel.

BNP USA wishes to use Salesforce.com to manage the drug development, trial and approval process.

Existing Systems Landscape

myTrialManager

This application is an in-house application that currently manages clinical trials and stores data on patients, trials, the patients assigned to trials, dosage history, side effects and trial results. This serves as input to a proprietary rules engine that performs statistical calculations on drug trial effectiveness.

BNP wishes to replace all the functionality of myTrialManager with Salesforce.com but retain the functionality of the rules engine. myTrialManager provides a SOAP based API for integration at a data layer and has flexibility in changing its web-based UI.

Data Warehouse

BNP USA's data warehouse has data that includes potential patient recruits sourced from multiple external sources. It can be repurposed to store other data if required.

SmartDose(™)

BNP uses a custom-built dose applicator that is internet ready, stores the dose schedule for the patient and able to track dosage application history. This device integrates to wireless and cellphone networks and can send detailed information via REST.

Salesforce.com Sales Cloud

BigNasty GmbH and each of the 3 subsidiaries have their own instance of Salesforce Sales Cloud for managing the sales process of drugs to doctors and pharmacies. Each of these instances support very unique selling and regulatory requirements.

Identity Management

Big Nasty GmbH has a global Active Directory system that manages identity for all internal users for all subsidiaries including PKB USA. Users for external agencies are managed using a custom built LDAP.

Integration Landscape

BigNasty GmbH utilizes a common ESB and ETL platform across the entire enterprise. Each subsidiary and the HQ has their own instance of the integration platform.

To-Be Business Processes

Discovery and Development

- Clinical researchers currently perform the initial discovery and development of new drugs through a two-stage process using spreadsheets and email:
    - **Discovery** - through desk research, clinical researchers review potential combination(s) of compounds that can form new drugs. Initial testing is performed, and if promising the drug goes into a "Development" phase. At the Discovery stage, only the lead researcher and their manager can view the drug information and their compound combinations.

- **Development**
  - when the drug enters the development phase, additional experiments are conducted on dosage, benefits, side-effects, etc. At this stage, the drug is then visible to the entire clinical research team, with the exception of drugs related to the central nervous system, which are only visible to the "Psy choactive" clinical research team.
  - BNP would like recommendations on automating the above process.
- Clinical researchers are split into teams depending on classification (e.g. cardiovascular, gastrointestinal, etc.) and reporting rolls-up to managers of these teams and to a Head of Clinical Research.
- Once development is complete, it must be approved by a designated approver after which it enters the clinical trial phase. Prior to approval, the approver designates a clinical trial manager. The lead researcher and a clinical trial manager is notified upon approval.
- Drugs and their compound relationships are mastered in Salesforce and synchronized to myTrialManager in real time once approval is obtained.

Clinical Trial Design

- When designing a clinical trial, the Clinical Trial Manager creates one or more trials. The trial contains information regarding the drug, the minimum pool size and recommended cohort size.
- A trial consists of a pool of **potential** patient candidates and a cohort of **actual** patients participating in the trial.
- When the trial is ready for potential patient recruitment, the user assigns an agency and a primary agency contact. The agency cannot be assigned if the minimum recruit size or recommended cohort size is not specified.
- Additional agents can also be assigned if the trial is deemed particularly large.
- Agents must sign a nondisclosure agreement prior to commencing the trial and this information must be electronically stored.
- If an agency is not specified within 7 days of creation of the trial record, then a reminder is sent to the clinical trial manager.
- From an agency perspective, only the designated agent(s) and the agency manager are able to view the clinical trial.
- The clinical trial manager can assign other internal managers visibility to the clinical trial.

Clinical Trial Recruitment and Data Collection

- Agencies manage the process of identifying and allocating trial patients
  - Agents can collaborate with the clinical trial manager regarding the trial
  - Patients may be sourced from the internal data warehouse or be recruited by the agency. The data collected also includes information on the patient's disease and medical history.
  - Any patients and their disease and medical history created by an agency will be synchronized in near real-time to the Data Warehouse and myTrialManager.
  - In the recruitment phase, agents allocate a pool of patients to the trial based on their disease and medical history. These are potential candidates for selection and may not actually participate in the trial.
  - Before the trial allocation process can commence, the number of patients allocated to the pool must meet minimum trial pool size requirements. There can be up to 2,000 patients allocated to a single trial.
  - The trial allocation process will randomly select from the pool of patients to the cohort based on the recommended cohort size of the trial. This process also assigns a placebo (a drug with no clinical effect) drug or an actual drug.

    - A placebo drug is assigned randomly so that evaluations can be made as to drug effectiveness.
    - The agent is not able to see if a placebo or the actual drug was assigned
    - Agents cannot view the names of the candidates who are selected in the trial cohort but can view the trial cohort record itself. They can however view and edit dosage and result information as well as view dosage history.
- Patients in the trial cohort can manage their participation in a trial and their dosage history, both using a portal and mobile application.
    - Patients can also view files and short videos related to the trial. These files are > 30MB in size.
    - Patients take their dosage via the SmartDose(™) applicator, which can automatically log dosage history and time of usage via REST integration through a wireless or cellphone connection.
    - They are also able to enter any side effects that they have encountered via a browser or mobile application. Patients are able to take photos of any issues they face and upload it against their patient trial record. They can mark the priority of the side effect as Critical
- Side effects are assigned to the clinical trial manager and they are immediately notified for critical side effects. If the side effect is severe, then the manager contacts the patient to go to the nearest emergency center.
    - If a critical side effect is not reviewed in 8 hours, then a supervisor is alerted.
    - BNP tracks a patient's side effects through different stages, with shorter service levels for high risk patients.
- BNP also requires automated tracking of patients dosage
    - If patients have not taken their dose within a 2 hour window, they are notified automatically.
    - If more than one day has passed, then the agent assigned to the trial is notified to follow-up with the patient. The agent needs to mark that the follow-up has completed.
- When the trial is complete, the agent works with the patient to determine the trial result for that patient and enters it for analysis and review. This process must be very user-friendly, allowing for filtering by various field values and support multi-record updates and pagination.
- If the trial is not completed within 30 days of the scheduled finish, then it is reassigned to a pool of clinical trial managers for follow-up.

Final Analysis, Review and Approval

- When trial results are finalized, the clinical researcher uses myTrialManager to calculate a recommendation for the drug, which includes whether the drug should enter FDA approval. This calculation is based on trial results, dosage history, whether a placebo was used, etc.
- myTrialManager will also calculate summary information such as control comparisons, # of patients and other statistical information against the trial(s).
- The user must not leave Salesforce to initiate the calculation in myTrialManager. However, myTrialManager **does not** provide an API to initiate this calculation.
- The lead clinical researcher submits the drug for FDA approval. This process is currently manual, and involves printing out pre-formatted PDF documents and hand-writing trial data for the drug that is submitted to the FDA. BNP would like this to be automated.
- When FDA approval is obtained, the drug is then available for sale in all of Big Nasty GmbH's subsidiaries.

Safety Monitoring

- Reports regarding problems with drugs are obtained from external data sources MedWatch and

Sentinel.
- If a particular drug has significant side-effects, can result in up to 1MM records generated per month per drug.
- These sources provide a REST-based interface for extracting data.
- BNP would like to be able to report on the total # of problems per month caused by their drugs to determine if any safety action is required.

Data Requirements

- BNP clinical researches creates over 5,000 drugs per year in the development pipeline. Each of these may consist of an average of 10 compounds.
- Only 10% of these make it to through the initial approval process and make it to clinical trial.
- Drugs that enter the clinical trial process can have up to 10 trials, with an average of 2,000 potential patients per trial of which only 1,000 are likely to participate.
- A patient in a given trial can average up to 50 doses for that trial and enter up to 2 side effects. Detailed dose history includes time taken and dosage amount.
- A data load of all patients must be performed prior to go-live. 3 months of historical trial information must also be loaded

Reporting Requirements

- Clinical researchers can view a report of drugs and their stages of development
- Clinical trial managers can report on trials under design and the candidates associated to it
- Patients can view a report of their dose history
- Clinical trial managers view a report of this trial information to determine if FDA submission should progress

Accessibility Requirements

- Clinical trial managers only have visibility to drugs after the development phase is complete and approved and only to those drugs that are assigned to them
- All internal users and agents have visibility to all patients, but only clinical trial managers and agents can edit their information.
- Patients can view only their information and the patient trial they are assigned to.
- Patients can only view the side effects they have raised themselves.
- Clinical researchers only see aggregated information for trials and not detailed information related to patients assigned to the trial.
- External agents and internal staff must be automatically provisioned and de-provisioned from Active Directory and LDAP.
- Patients register and authenticate to the customer portal using Facebook or Google credentials.
- Seamless login is required between Salesforce and myTrialManager. Users of myTrialManager must be active users of Salesforce.
- The mobile application used by patients has a highly customized user experience and is deployed on both the Apple and Google app stores
- The application must support both English and Spanish languages

Other Project Requirements

- Big Nasty GmbH recently hired a Global CIO who is looking to ensure that technology and development best practices are being followed across all subsidiaries as well as reduce any spending redundancies where possible especially around the tools and teams supporting the development process

- The Global CIO does not want to impinge on the flexibility of the subsidiaries and wants to keep the innovative culture across all subsidiaries

- Each subsidiary has SVPs of Clinical Research, Clinical Trials and IT who have been the primary decision makers within their respective domains
    - SVP of Clinical Research has previously been given free reign and frequently uses her large budget to complete projects “under the radar”
    - IT offshores all Salesforce development and treats the development process as a black box. Production bug count is noticeably higher than industry average

- myTrialManager and SmartDose are heavily validated (regulated) systems and are considered mission critical. Due to changing regulations, these systems are updated 1-2 times/year and any Salesforce processes that interface with these systems needs to undergo extensive validation before release

- Outside of the mission critical systems, Big Nasty GmbH wants to increase its technology innovation and is encouraging all teams to devote a portion of their working day to brainstorming ideas
    - All ideas need to be tracked and retained
    - Any idea accepted into development needs to traced all the way through deployment and reported on at any stage in the process
    - Teams are encouraged to release every month for non-mission critical systems
    - Some projects are consider R&D and will only be incorporated into main system when deemed viable by management

- Big Nasty GmbH would like you to recommend the following:
    - Identify significant risks impacting the project
    - An appropriate methodology to manage the development of the project and ensures traceability throughout the project lifecycle
    - A test methodology for the project that mitigates significant technical risk
    - Project and technical governance functions to manage change and mitigate risk
    - A deployment, release and environment strategy that includes recommendations on environments, source control and deployment techniques