Learnings from a practical experience of using NLP/AI in Medical Affairs

Digital Strategy FAWG
April 2021

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Educational Objectives

This session will provide a learning opportunity for our audience by:

- Demonstrating the use of technology to automate part of the MLR Review and Approval process
- Providing details of a proof-of-concept to test AI-enabled technology in Medical Affairs
- Understanding the roadmap for the future in usage of automation

Problem definition

MLR Review | Industry-wide Challenges

Onerous, time-consuming, multi-stakeholder process to manage compliance, regulatory and competitive risks

Increasing Complexity

- Multiple partners and deliverables for each brand
- Ability to perform reviews on deliverables of varying complexity
- Need for review of umpteen number of jobs across franchises

Longer Time To Market

- Time intensive launch includes time spent on reviews, approvals
- Hundreds of hours spent in PRC meetings
- Several calendar days from first submission to market

Multi-stakeholder Process and Complex Technologies

- Multiple reviewers, brand teams, agencies involved
- Frequent reorganizations/restructuring within pharma
- Off-the-shelf, cumbersome workflow tools need a lot of training

In Our Experience…

50-60 days

Average MLR review cycle *per job* for mid and large sized pharma

250-350 hours

Spent every month in MLR meetings, across stakeholders, across all BUs

50%

Iterations due to incorrect implementation/ non-implementation/ unrequested changes post-MLR review

50%-80%

Occurrence of preventable errors in agency submissions

5%-10%

FDA Late submissions per year

25%

Post production files have errors introduced

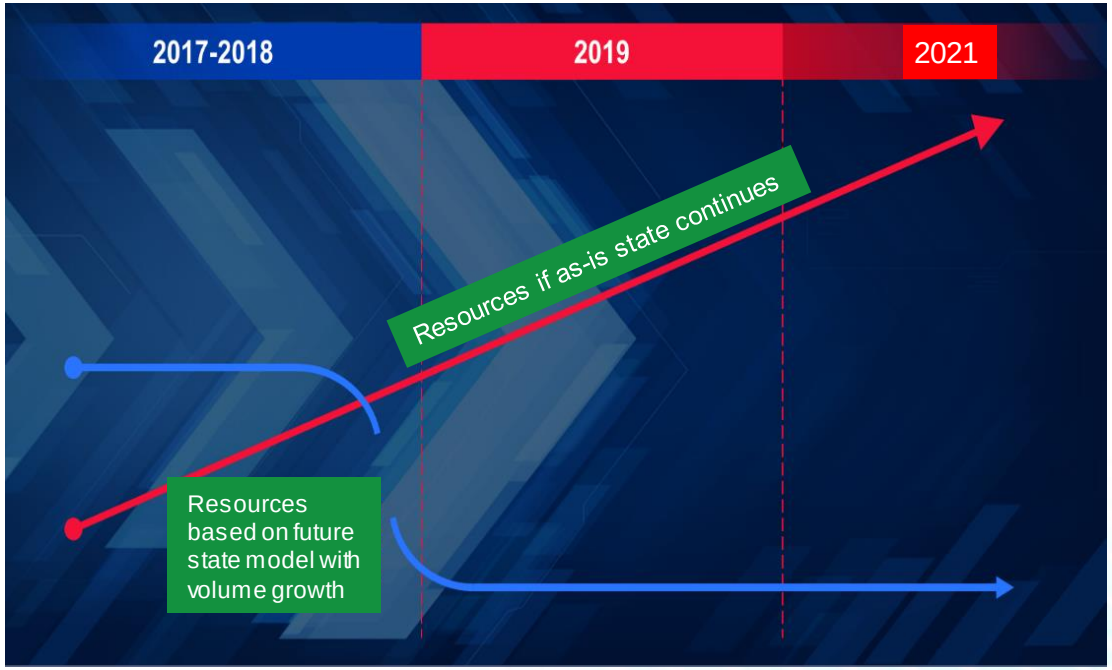
30%-40%

Agency files submitted for Review do not follow submission guidelines

MLR Process

Currently:
A bottleneck in the content supply chain

Future:
A key enabler to unlock enterprise value



How might we optimize the PMR operating model to meet growing digital demand in a faster, flexible, cost-conscious manner?

Polling Question #1

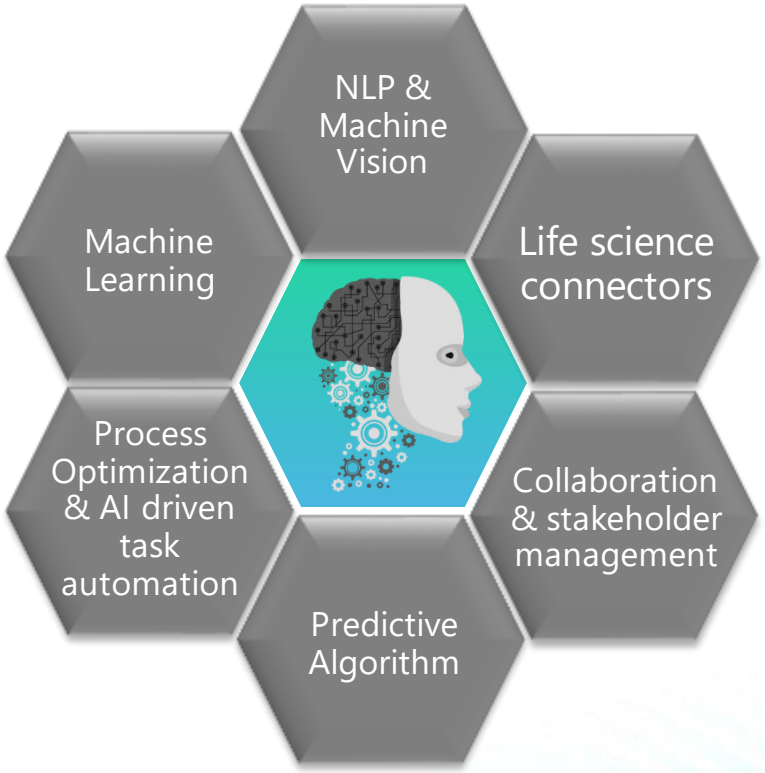
Is the state of MLR Review and Approval in your organization becoming challenging due to the volume increase in deliverables in this digital age?

1. Yes, it is absolutely
2. Yes, it is partially
3. No, it is not
4. I have no view

Hypothesis

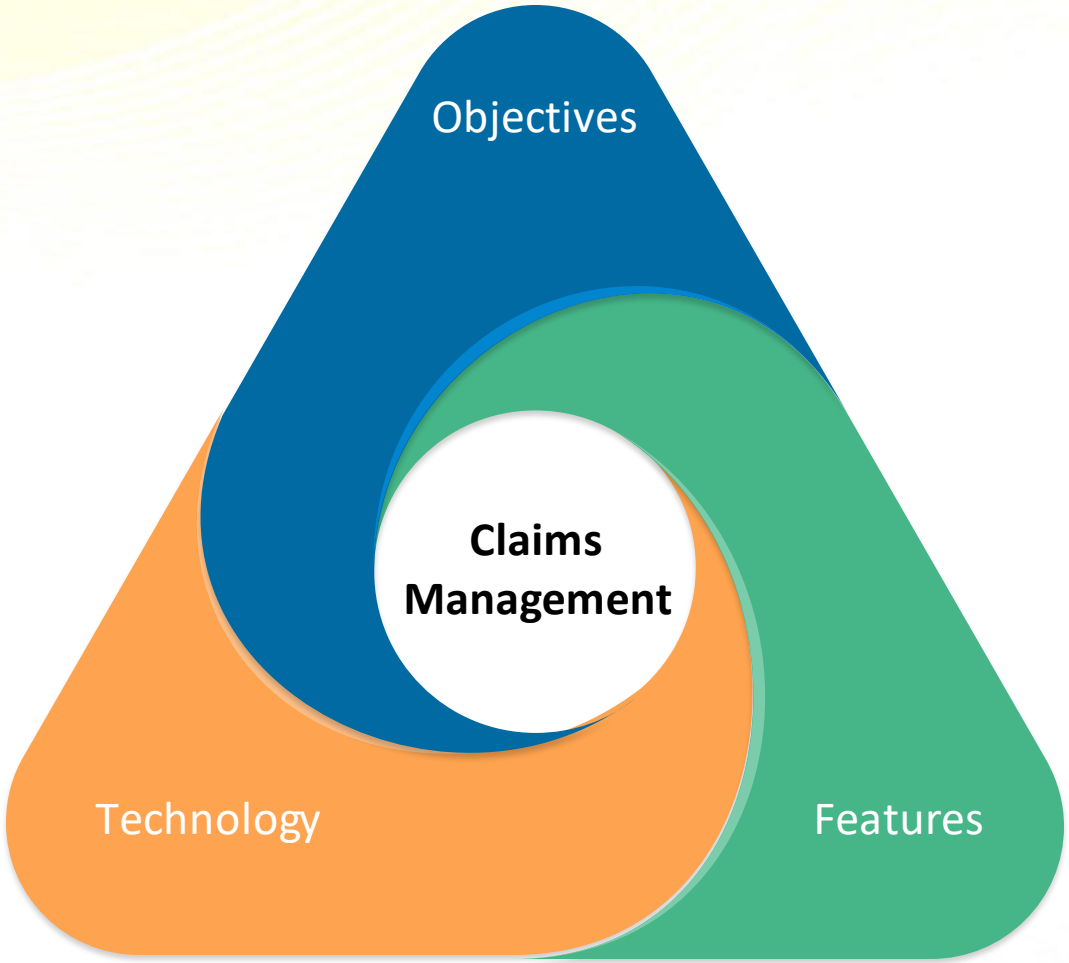
Leveraging AI…1/3

Augment MLR Experts with a Medically Contextualized Modern Technology Platform to Simplify Process, Reduce Time to Market, Improve Accuracy, Enhance Productivity and Efficiency, while maintaining 100% compliance.



- **Simplification**
- **Time to Market**
- **Accuracy**
- **100% Compliance**
- **Productivity**
- **Efficiency**
- **Cost**

Leveraging AI…2/3



Objectives

- Identify, extract claims and reference, supporting elements (Text/Sub-claims/Footnotes/Disclaimers/Graphics)
- Create approved claims database from existing organizational assets.
- Review assets faster by auto validation of claims

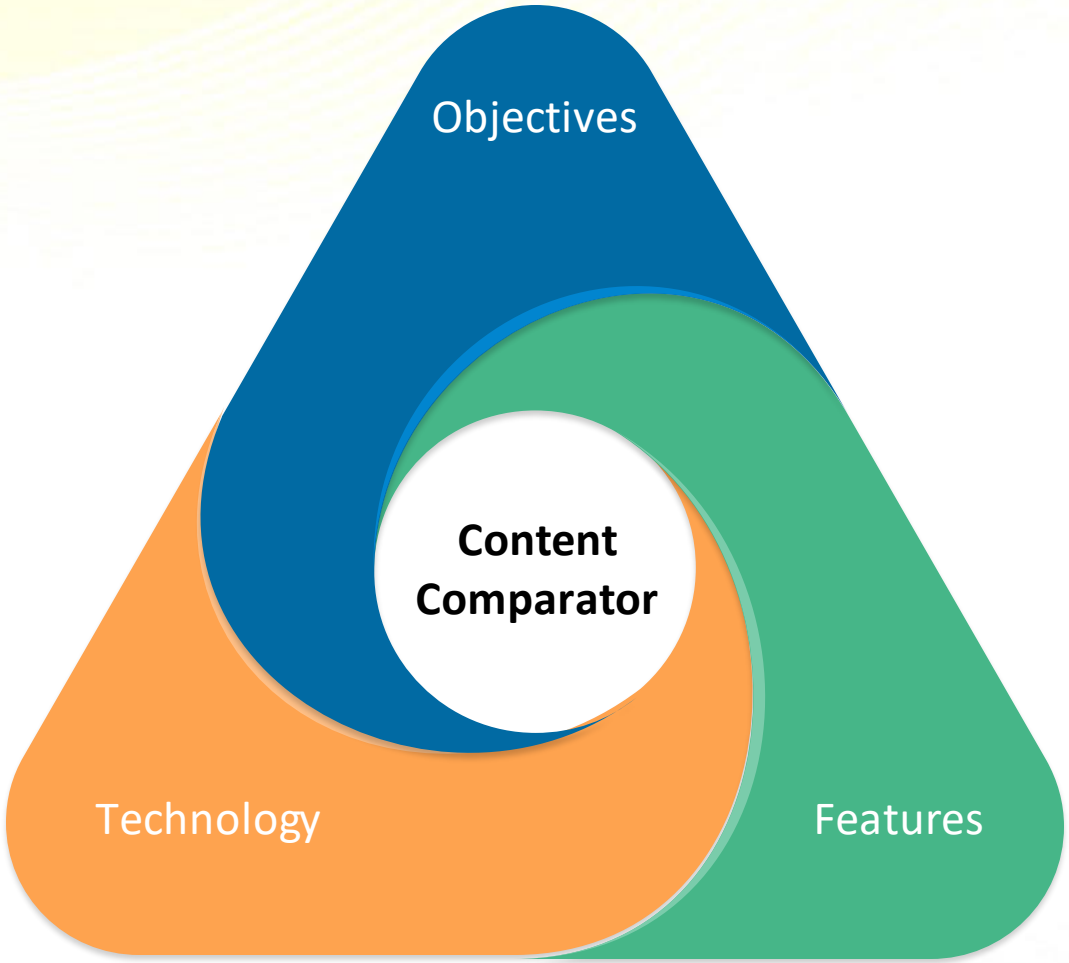
Features

- Define Claims Elements:
  - Mandatory & Optional Components
  - Business Rules pertaining to claims usage
- Create and maintain Claims Database and search the database with filters Claims Lifecycle Management → Depreciation of Claims (Retire/expire the Inactive claims)
- Auto Review new assets against approved claims in database, Flag and annotate non-validated claims that require reviewer's attention
- Claims Analytics → Usage in Asset (No of times used, geography)
- Meta Tags defined to differentiate claims at various levels

Technology

- Automated Slicer: identifies different segments/text/graphics from asset
- ML Model: classify this segments into relevant Claim component categories
- Python based application
- AWS hosted

Leveraging AI…2/3



Objectives

- Compare versions during the MLR process itself
- Compare pre-MLR to post-MLR asset versions.
- Highlight and Colour code mismatched content and display variations side by side

Features

- Allows user to upload two different versions of promotional material (e.g.: pre-MLR and post-MLR review)
- Compare and view detailed, highlighted, and annotated renditions of the two documents capturing the discrepancies identified by the tool in them.
- Highlight and annotate mismatched content
- Discrepancy analytics: Graphical representation of viewing the count of discrepancies (text & image)
- Reporting option: View/download the report with/without annotations

Technology

- Automated Slicer: identifies diff segments/text/graphics from asset
- Comparator Module: compare & highlight the differences (text/graphics)
- Python-based application
- AWS hosted

Polling Question #2

Which of the following statements reflect your understanding of the attempts made in your organization for improving MLR Review and Approval?

1. My organization has already implemented automation and/or technology solutions to improve the MLR process
2. My organization is currently implementing automation and/or technology solutions to improve the MLR process
3. My organization is considering implementing automation and/or technology solutions to improve the MLR process
4. My organization has no plans to consider automation and/or technology solutions to improve the MLR process

Proof of Concept Investigational Objectives

Relieve Burden on Internal Team

Elevate Strategic Role

- Desire to focus on more value-adding and strategic tasks
- Allow Medical Affairs teams spend time in activities that help build relationships with KOLs

Avoid Mundane Tasks

- Considerable review time is spent in correcting errors in grammar, style, and referencing
- Wide disparity in submission quality between vendor partners

Over The Fence

- "Gold plating" every asset even if only a cursory review is required
- Expectation that medical will identify all errors
- Onus on the reviewer to ensure all comments are addressed

The Ideas We Were Looking to Test…

1. How can it help medical reviewers in their busy day in reviewing the assets thereby leading to productivity improvement?
2. How can it help originators and agencies by having a handy list of claims thereby ensuring correctness at the origin?
3. How can we create a claims database rapidly from historical assets rather than spending hours manually to create the excel files?
4. How can organizations create a global claims list rapidly, and regions and affiliates inherit the same and tailor accordingly thereby reducing detailed reviews at every affiliate level?
5. Can medical reviewers do a quick comparison of two versions assets to see if their annotations are being taken into consideration and no new content is introduced before finally signing-off?

Claims Database

Setting up the Proof-of-Concept Project

- Decided to build 2 separate product databases to compare feasibility of the database build for products in different life cycle. Materials in scope were generated by commercial teams.

  - ***Product A*** – ***Well-established*** *product with big historical material volume*
  - ***Product B*** – ***Newer*** *product with fresher content*

- Started with sample materials from both products to assess document quality, type and feasibility.

- Once verified document suitability then the last 6-9 months of materials were used to build the claims database for both products.

Learnings from Claims POC - Preparation

Material **volume** and **quality** was critical in the creation of the database.

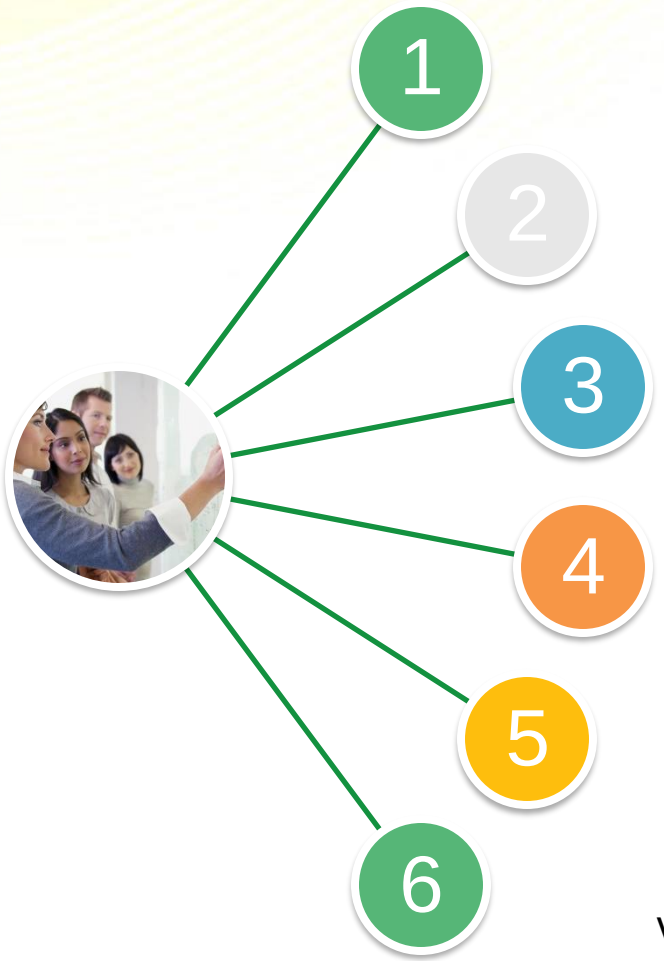
Material quality

- Materials needed to be of a traditional promotional structure – Core claims focused with referencing placed as superscripted after sentence end. Other types of materials used from commercial teams did not facilitate in the creation of the database.
- Website content was not optimal at a document type due to page size / visual aspects that created issues in claim identification.
- A substantial number of materials were not suitable and thus could not be used in the building of the database

Material volume

- Significant volume of materials is required to build the database and train the AI to identify claims.
- Even slightly different versions of the same core material help in creating the repetition required to train AI.

Learnings from Claims POC – User testing



Once a substantial database is created the claim verification allows for quick visual separation of already approved vs new claims and thus allow to focus and spend more time on new claims

Need to critically **select** the **types materials** that can be best reviewed from the system based on previous experience

System allows for a **quick review of Core claims** against previously approved claims with a visual percentage (%) match value that gives a good reference on the difference/risk

Check on references allows to **compare references used** in validated database vs new document and thus facilitates up-to-date usage of references (e.g. poster vs. manuscript)

Small changes and differences in language cause a % percentage miss match – potentially critical but sometimes difficult to identity small grammatical differences such as a double space

Veeva API implementation to allow quick import of materials and comment transfer will greatly improve user experience

Content Comparator

Setting up the Proof-of-Concept Project

- Similarly, to the previous project focused on two product and this time used medical materials as the basis for the content comparison.

- Focused on presentations for the comparison test and two different types of comparisons were made:

- *Comparisons of different versions through the* ***review workflow***
- *Comparison of* ***versions*** *of documents* ***over time***

- Several "pairs" of documents were selected for the project

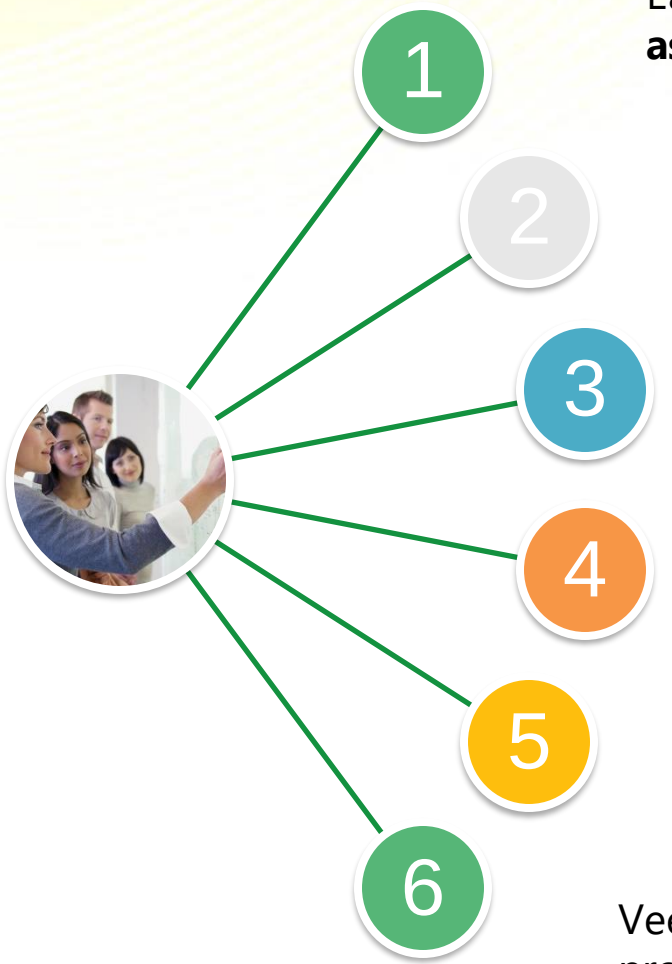
Learnings from Content Comparator POC - Preparation

Easier POC to implement, material volume was not as important and machine learning was already almost ready to go.

Material volume

- Less taxing volume of materials was required to establish a basis for platform readiness.
- Traditional presentation/ slide deck medical materials were used to train the platform
- Several pairs of presentations were used with only a small number of material incompatibility

Learnings from Content Comparator POC – User testing



Easy way to effectively compare two separate files with **great visualization aspects**

Can be used for both approval workflows and historical comparison of different versions of the same materials

Slight issue with page number accuracy that caused some comparisons to be rejected, this is more frequent with over-time historical version comparison

Image comparison works great with only one file type (not common) of image causing slight comparison issue.

Workflow version comparison was the most valuable aspect and will be implemented to allow quick review of updates

Veeva API implementation was not available for version 1 but it is in the process that will speed up the process significantly

Summary and next steps

Key Takeaways

Material volume and **quality** was critical in the creation of the claims database

AI still needs a lot of similar materials to train effectively, with repetition of claims facilitating and expediting machine learning – **90 assets** were used to identify approximately **400 claims** (incl. duplications)

Once the database is built and AI is trained it becomes effective in identifying the core claims in commercial items and thus help streamline the review process significantly -at the moment **claim recognition accuracy** is around **80%**

Content comparator was an **easier tool** to implement and the day-to-day value to the team was apparent from the first test

Veeva API implementation will benefit both platforms on user experience

Polling Question #3

Which of the following statements reflect your mind at the end of this webinar?

1. I have gained a better understanding of how automation and/or technology solutions can improve the MLR process
2. I have somewhat understood how automation and/or technology solutions can improve the MLR process
3. I am not sure I understand how automation and/or technology solutions can improve the MLR process
4. I have yet to form an opinion in this matter

V2 Improvements Based on Feedback

Create Claims Family Database	Machine identifies claims components as claims family from asset: • Key claims • Sub claims • Supporting text (Footnotes, Abbreviations, Disclaimer, Business Rule, Study Design) • Supporting graph/ infographics • References
	• Machine identifies different types of claims (Safety, Efficacy, MOA) • Identifies claims from different types of assets (iDetail, Email, Website, Banner, etc.)
	User identifies the type of component & define mandatory and optional components for each claim component
	Add meta data to each claims component / claims family
Search & Edit Database for Claims Family	Add components to claims family & Create new versions of claims family
	Change the optional/mandatory field of the claims component
	Change the status of component to active/inactive
	Edit/add meta data to any components or the claims family
Claims Validation	Machine identifies the claims family & Compares it with the claims family DB
	Machine highlights missing/additional components from the claims family compared against matching (suggested) claims family in claims database.
Claims Analytics	View audit trail of claims family
	View usage of claims family (frequency, asset name, asset type)

Thank you!

Questions?