

Semi- Autogenerated Narratives



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Semi-Autogenerated Narratives

Agenda



The Case



The Concern



The Complexity



The Complete Solution

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Request

- For a development programme Ferring was requested to produce narratives for all subjects with a positive outcome related to the primary endpoint

Requirements

- Include clinical data, like medical history, adverse events etc.
- Include treatment information and actual exposure data
- Submission ready

Estimates

- 2-3 hours per narrative
- 3-4 narratives per day
- approx 800 narratives needed
- 1 years work (at least)

JAN FEB MAR APR MAY JUN JUL AUG SEP OCT NOV DEC

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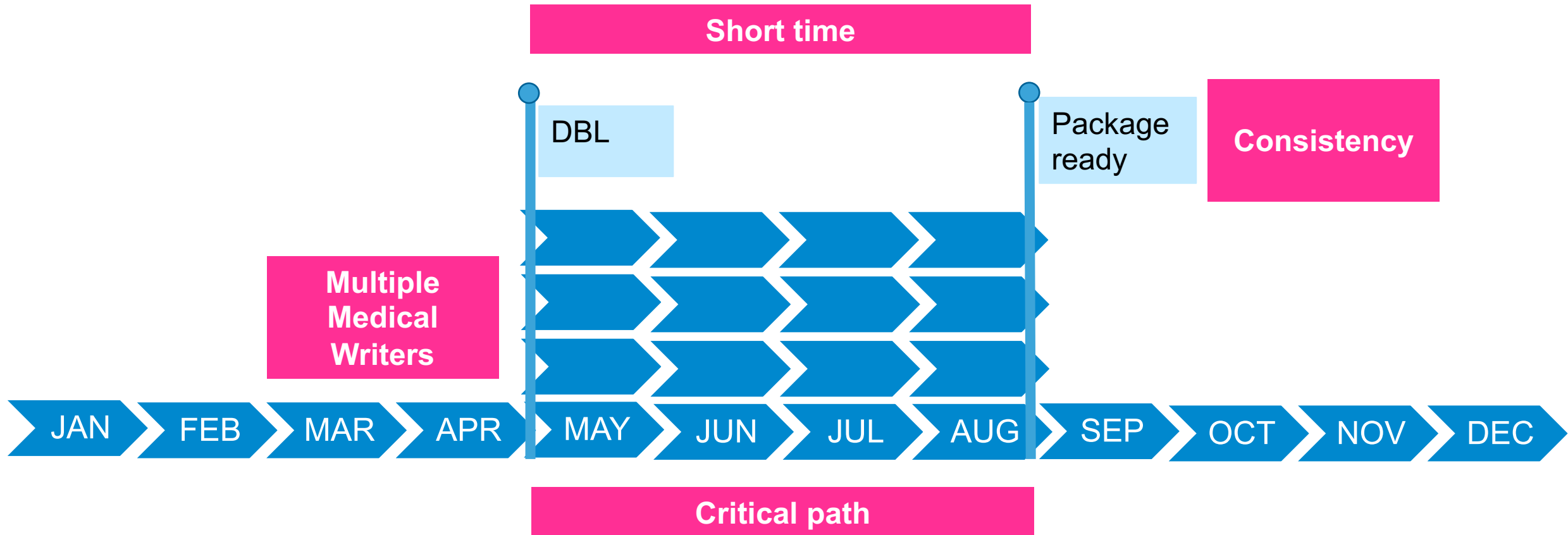


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Fully Autogenerated Narratives

Concern

- Consistency

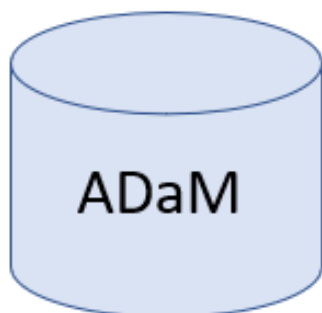
Evaluation

- Analyze trial data
- Identify Scenarios

Solution

- Develop and use templates

Input



Narrative template

Subject ID: <SUBJID>
Category: SAE
Preferred term: <PT>
Trial code: <XXXXXX>
Treatment allocation: <IMP / DOSE>

A XX-year-old <GENDER> experienced <PT> while participating in the <TRIALNUMBER> trial. The subject was randomised to treatment with <IMP> at a daily dose of <XX>. First exposure day was <DD Month YYYY> and treatment duration was <XX> days with last exposure on <DD Month YYYY>. The medical history is summarised in Table 1.

Table 1: Medical History

Medical History	Occurrence
<PT>	<TIMING>
<PT>	<TIMING>

Autogenerated narrative

Subject ID: SITE01-123
Category: SAE
Preferred term: Procedural pain
Trial code: 123456
Treatment allocation: DRUG A / 200 Units

A 28-year-old women experienced procedural pain while participating in the 123456 trial. The subject was randomised to treatment with DRUG A at a daily dose of 200 units. First exposure day was 02 June 2019 and treatment duration was 11 days with last exposure on 12 June 2019. The medical history is summarised in Table 1

Table 1: Medical History

Medical History	Occurrence
Epstein-Barr virus infection	Before
Migraine	Ongoing

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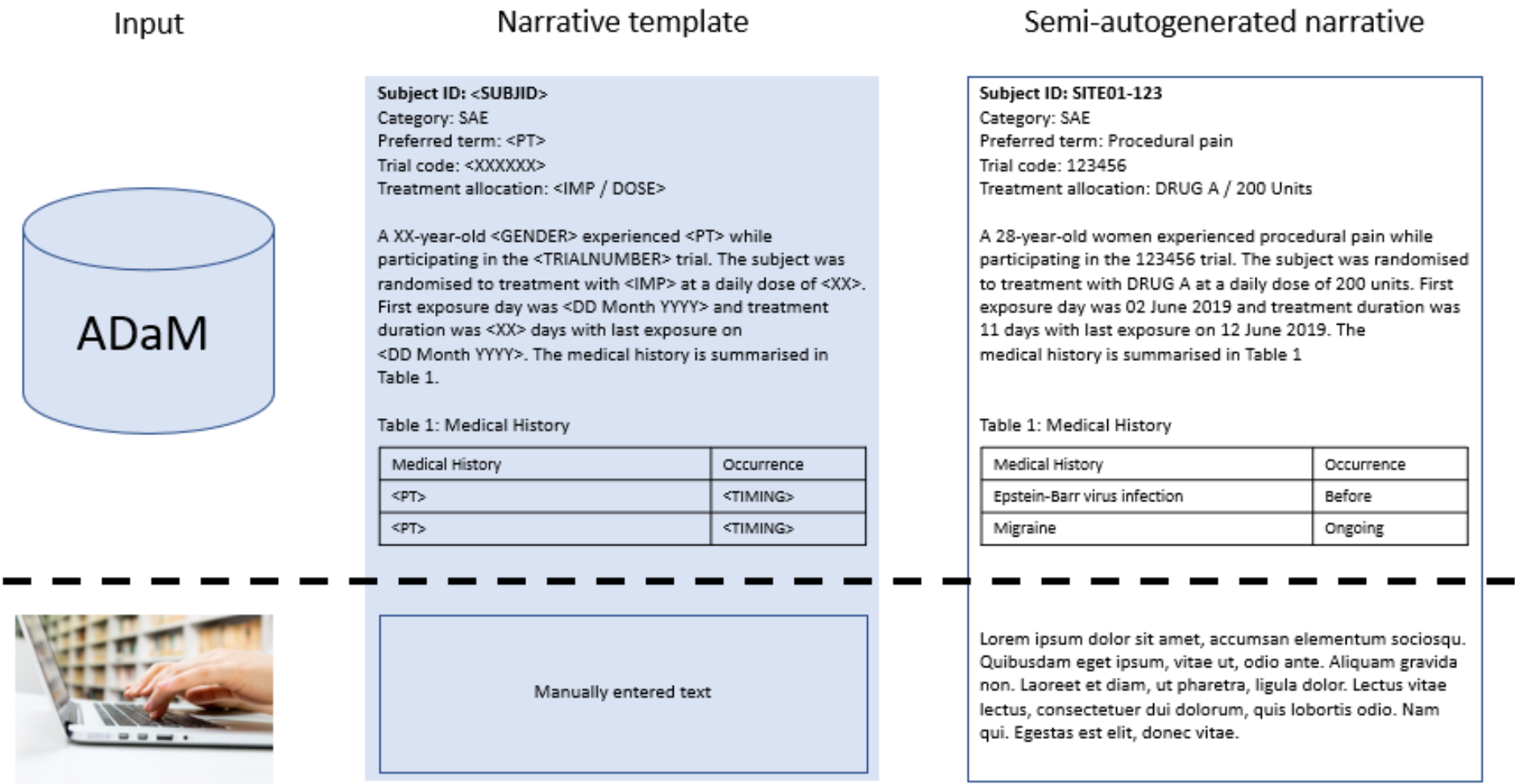


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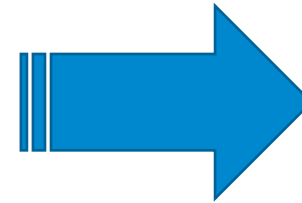


Semi-Autogenerated Narratives



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Autogenerate text	Autogenerated text
Autogenerate tables	Autogenerated tables for instance showing medical history
Autogenerate figures	Autogenerated plots showing for instance an overview of adverse events relative to IMP exposure
Manual text	It should be possible to enter manual text to further describe a case for a subject if needed
MS Word like interface	The interface for entering manual text should be very close to MS Word
Multiple templates	It should be possible to work with different templates depending on the type of narrative needed
Independent updates	It should be possible to update the manual part and the auto-generated part independently
Controlled dataflow	The data flow both with respect to the clinical data and the manual input should be tightly controlled
Track changes	Following a refresh of the clinical data, it should be possible to track if a narrative has changed



Search for a tool

Semi-Autogenerated Narratives

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TCS ADD Platforms | A Credible Partner



6

Core Modules

17

Global Customers

200

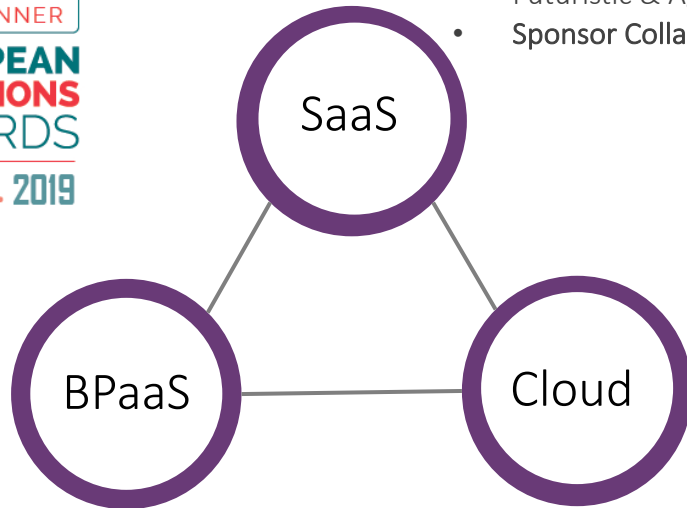
Experienced Consultants

200+

Trials Executed

15+

Sponsors Audit



- Futuristic & Agile
- Sponsor Collaboration

- Deep Domain Expertise
- Cross Functional Teams

- Global Cloud Hosting
- GxP and 21 CFR Compliant

6 Core Modules of ADD Platform – our suite of validated platforms offered to customers

Metadata Registry and Transformation

Clinical Data Management And Medical Writing

Clin-Ops and Insights

Connected Clinical Trials

Patient Safety

Regulatory Insights

Automation in Clinical Research

Standards driven clinical data flow

Analytics Driven Implementation

Data driven feasibility, study performance analytics, regulatory insights

Patient Centricity

Patient-centric, digital clinical trials, leveraging digital end points and connected devices

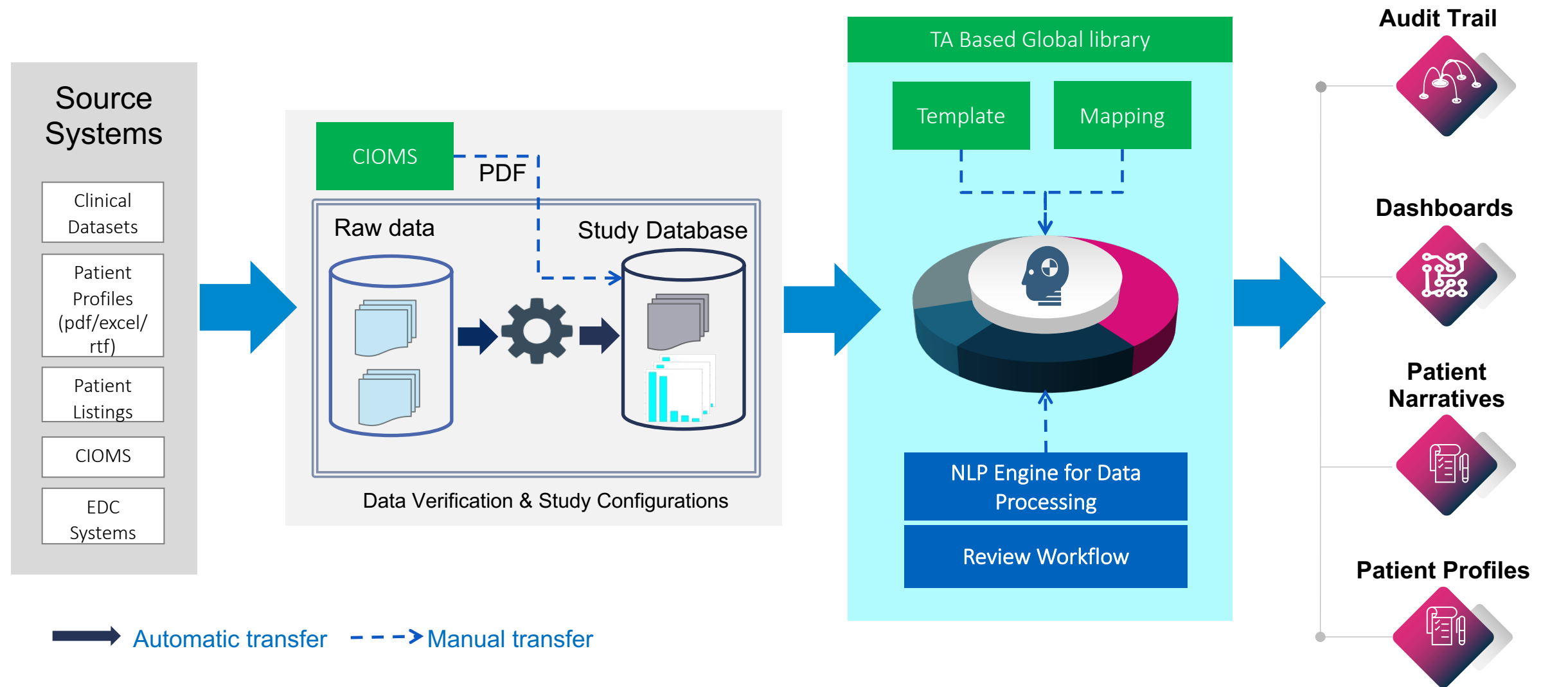
Next-Gen AI / Cognitive Engine

Disrupting clinical research space

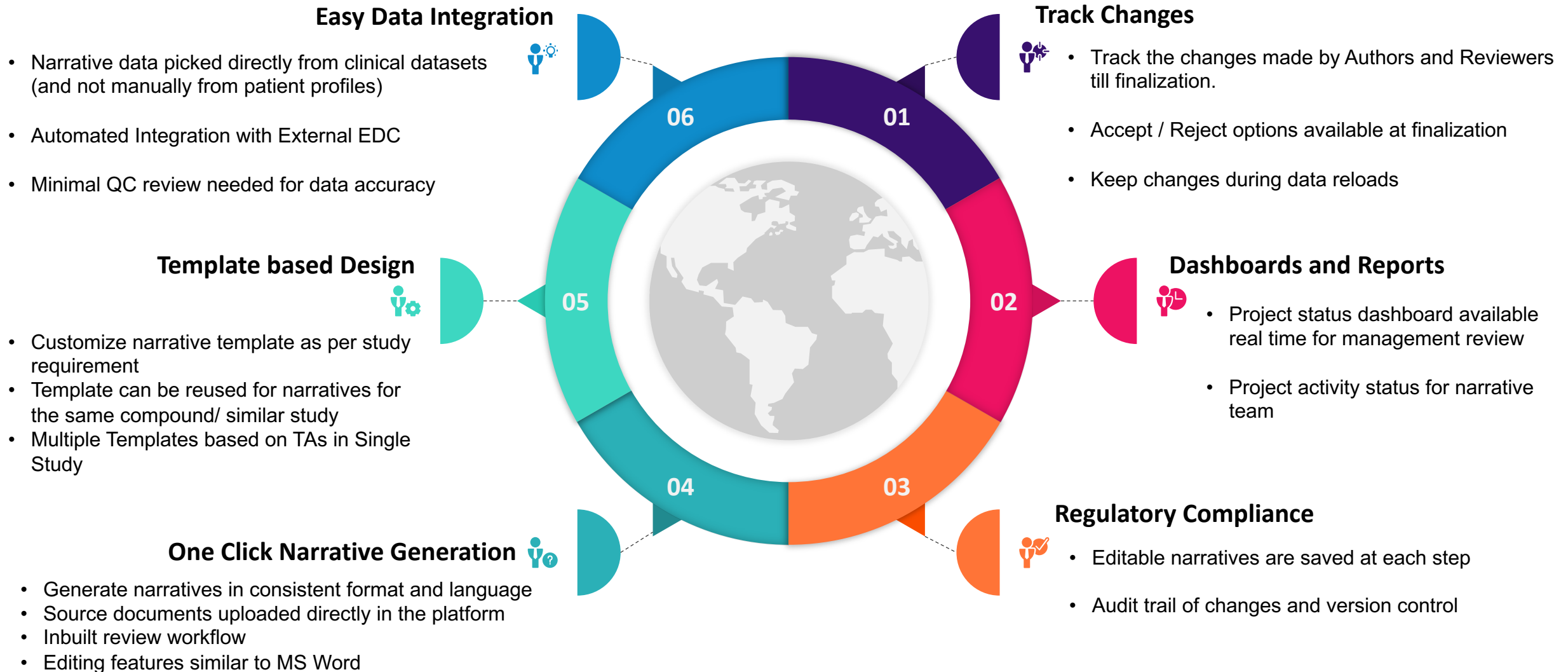
Integrated ADD Platform Solution applies **Machine First Delivery Model™**

A delivery model that optimizes human-machine collaboration to drive Business 4.0

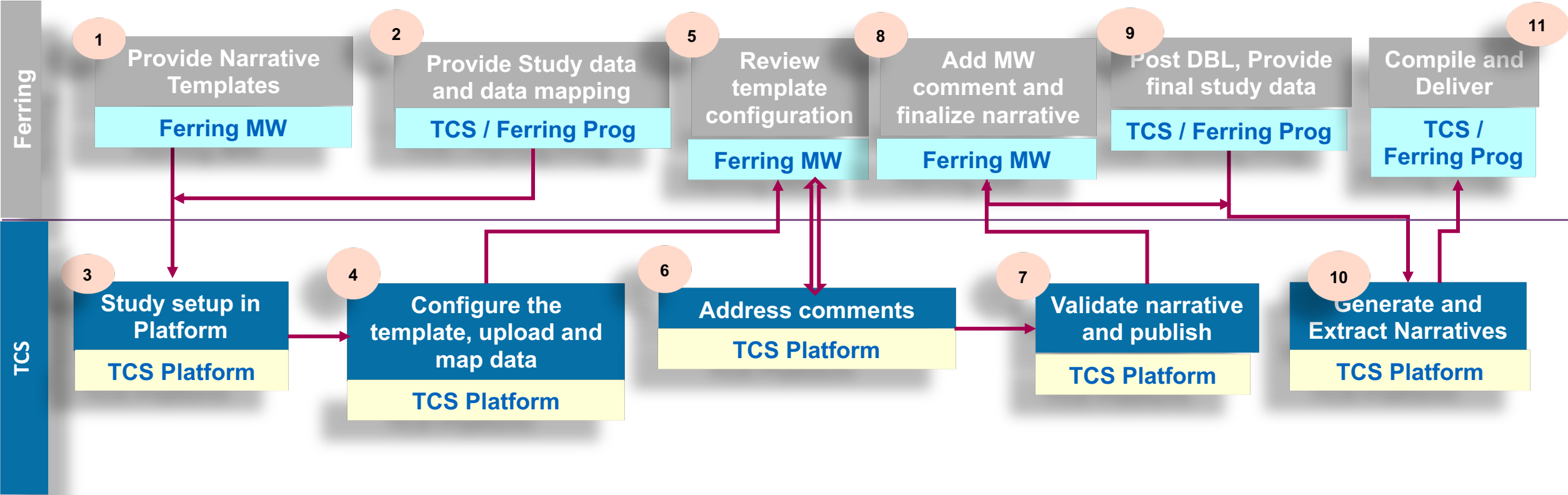
TCS ADD ANW – Solution Architecture



ADD ANW : Key Features



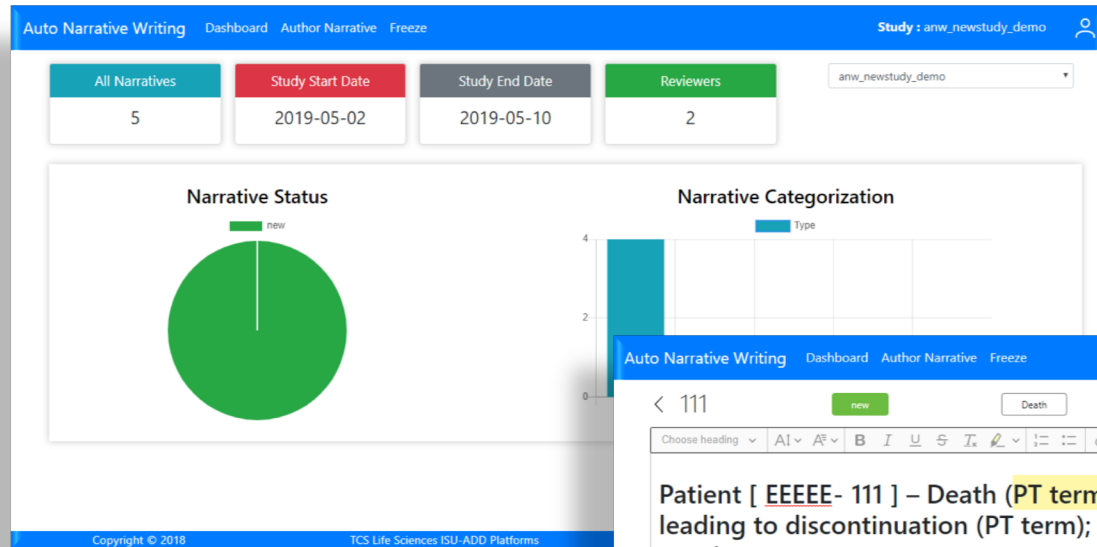
Implementation for Ferring



TCS ANW Platform | Mapping to Ferring Requirements

Ferring's Requirement	Available	Implementation in TCS ANW platform
Auto-generated text	✓	Built in feature
Auto-generated tables for instance showing medical history	✓	Built in feature
Auto-generated plots showing for instance an overview of adverse events relative to IMP exposure	✓	Built in feature
It should be possible to enter manual text to further describe a case for a subject if needed	✓	Built in feature, CIOMS data can be preloaded in the manual text field
The interface for entering manual text should be very close to MS Word	✓	Built in feature
It should be possible to work with different templates depending on the type of narrative needed	✓	Built in feature, configurable based on the study context
It should be possible to update the manual part and the auto-generated part independently	✓	Built in feature
The data flow both with respect to the clinical data and the manual input should be tightly controlled	✓	Data flow from clinical data to TCS ANW Platform is controlled via a process where FTP server was used to share the data. Manually added data was tracked and reviewed via the platform itself
Following a refresh of the clinical data, it should be possible to track if a narrative has changed	✓	Each data load was shared by the Ferring statistical programmer so changes in clinical data was tracked during the data exchange process

TCS ANW – Select Screens



Auto Narrative Writing

Study : 000273



S.No.	Subject-ID	Site	Status	Action
1	8101-101	8101	Fresh	
2	8101-503	8101	Fresh	
3	8101-506	8101	Fresh	
4	8101-507	8101	Fresh	
5	8101-514	8101	Fresh	
6	8104-511	8104	Fresh	
7	8107-509	8107	Fresh	
8	8107-511	8107	Fresh	
9	8107-513	8107	Fresh	

Auto Narrative Writing Dashboard Author Narrative Freeze Study : anw_newstudy_demo

Clipboard Font Paragraph Styles Editing

Calibri Light 13 A A A

Heading 2 Normal No Spacing Heading 1 Heading 3 Title Subtitle Subtitle Em...

Find Replace Select

Patient [EEEEE- 111] – Death (PT term); SAE (PT term); AE leading to discontinuation (PT term); AE of special interest (PT term)

Patient: 67 year old, M , White- White/Caucasian/European Heritage

Treatment group: Blinded

The patient entered the study with hepatitis B virus infection and was diagnosed on 30-Apr-2008 .

Prior treatment included xx, which was discontinued on ddMmmmyyy, due to lack of efficacy (or adverse event or for other reasons) (or The patient never received disease-modifying treatment prior Day 1).

y included decreased appetite, pain, chills, cholecystectomy, ache, pain in extremity, dizziness, neck pain, paronychia, pruritus, g, weight decreased, xerosis. . The patient's relevant medical benign prostatic hyperplasia, generalised erythema, fatigue, a, atrial septal defect, raynaud's phenomenon, patient received treatment with cefalexin, lisinopril, e, oxycodone hydrochloride, oxycodone/apap hydrochloride, phenoxymethylpenicillin potassium, throat

139% Tools Fill & Sign Comment

Remove "/Caucasian/European"

Remove space

Study : 000273

Auto Narrative Writing

Study : anw_newstudy_demo

Choose heading A I U B I U S T

Patient [EEEEE- 111] – Death (PT term); SAE (PT term); AE leading to discontinuation (PT term); AE of special interest (PT term)

Patient: 67 year old, M , White- White/Caucasian/European Heritage

Treatment group:Blinded

The patient entered the study with hepatitis B virus infection and was diagnosed on 30-Apr-2008 .

Prior treatment included xx, which was discontinued on 4-Jan-11 , due to lack of efficacy (or adverse event or for other reasons).

The patient's relevant medical history included decreased appetite, pain, chills, cholecystectomy, constipation, cough, vomiting, headache, pain in extremity, dizziness, neck pain, paronychia, pruritus, rash, abdominal pain upper, vomiting, weight decreased, xerosis. . The patient's relevant medical conditions included abdominal pain, benign prostatic hyperplasia, generalised erythema, fatigue, hypertension, hypothyroidism, nausea, atrial septal defect, raynaud's phenomenon, lymphoedema. (since year) for which patient received treatment with cefalexin, lisinopril, metoclopramide, oxycocet, oxycodone, oxycodone hydrochloride, oxycodone/apap /01601701/, paracetamol, pethidine hydrochloride, phenoxymethylpenicillin potassium, throat preparations. .

The patient received the first dose of study medication on Day 1 (10-Jan-11).

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The patient received the first dose of study medication on Day 1 (10-Jan-11).

Semi-autogenerated Narrative

Examples

Number of narratives	Manual (estimate)	Automated (actual)	Time saved at medical writing
1.075 Narratives for subjects with positive outcome	~ 2-3 hours per QC'ed narrative ~ 2.600 MW hours	~ 10 mins per QC'ed narrative ~ 200 MW hours	~ 2.400 hours
442 SAE Narratives	~ 4-6 hours per QC'ed narrative ~ 2.250 MW hours	~ 0.25 hour per QC'ed narrative ~ 110 MW hours	~ 2.000 hours
1.159 AE Narratives	~ 2-3 hours per QC'ed narrative ~ 2.900 MW hours	Random QC spot check < 100 MW hours	~ 2.800 hours

Semi-Autogenerated Narratives

Conclusion



The Case

Narrative writing



The Concern

Short time
Critical path
Consistency
Resource heavy



The Complexity

Include manual text
Independent updates
User friendly interface
Track changes



The Complete Solution

Fast
Controlled
Consistent
Efficient

Connect with us!



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