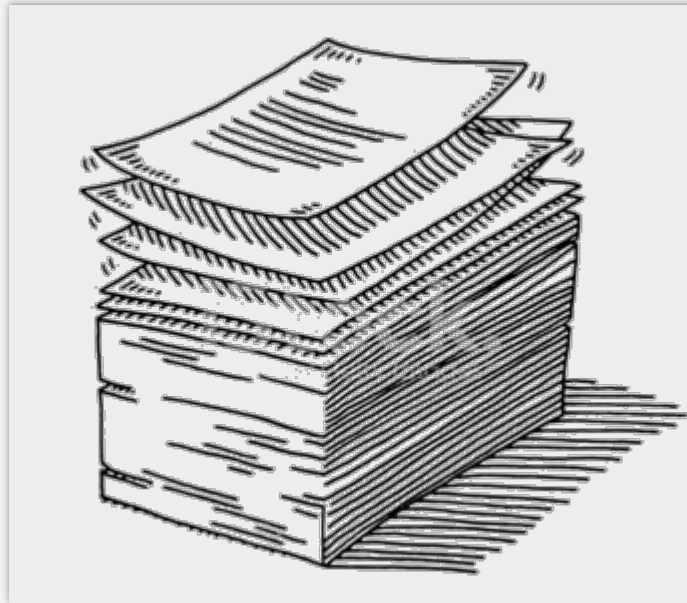




patient narrative + story

Sam Tomioka, Sr. Director, Data Services/Tech – Data Science  
Shiva Katepalli, Associate Director, Data Services/Tech – Data Science

# Patient narrative writing takes time



Listings, CIOMS etc...



NARRATIVE SUMMARY SUBJECT: SEP0001-0105-0007

(CRF, Patient Profile)  
Program-specific (link)  
Program-specific (link)  
Link to additional program-specific data, the blue text is deleted

**Reason for Narrative:**  
Adverse event leading to discontinuation of study drug of placebo (verbal term: bilateral placetone).

**Event History:**  
Adverse event leading to discontinuation of study drug of placebo (verbal term: bilateral placetone) was received from an investigator in study SEP0001-0105-0007 regarding a 35-year female. The subject was 20 years old at study entry. The subject had received SEP-400 200 mg from 10 FEB 2019 to 17 FEB 2019.

On 15 FEB 2019 (Study Day 6), the subject experienced non-serious adverse event of placebo that the investigator considered moderate in intensity and definitely related to study drug. The study drug dose was withdrawn. The event of placebo resolved on 03 MAR 2019.

During the course of the study, the subject also experienced other serious treatment-emergent adverse events.

| Adverse Event Term | AE Onset Date | Date Level of Interest                          | Severity | Causality |
|--------------------|---------------|-------------------------------------------------|----------|-----------|
| Breast enlargement | 05 MAR 2019   | Study drug 200 mg was last taken on 17 FEB 2019 | Mild     | Probable  |
| Hypertension       | 22 FEB 2019   | Study drug 200 mg was last taken on 17 FEB 2019 | Moderate | Definite  |
| Migraine           | 19 FEB 2019   | Study drug 200 mg was last taken on 17 FEB 2019 | Severe   | Possible  |
| Tension headache   | 18 FEB 2019   | Study drug 200 mg was last taken on 17 FEB 2019 | Moderate | Possible  |

The subject was discontinued from the study due to placebo on 20 FEB 2019 (Study Day 10).

**Presenting and Past Medical History:**  
Medical history pertinent to this event included asthma (since 2004), bilateral vaginitis (since 2010), breast operation (in 2012), breast operation (in 2012), breast operation (in 2012), breast operation (in 2012), and seasonal allergy (since 2010).

**Presenting and Past Psychiatric History:**  
Psychiatric history pertinent to this event included severe bipolar I disorder without rapid cycling (since unknown), current depressive episode of bipolar I disorder (since 2017), initial onset of bipolar I disorder (since 2017), and last manic episode of bipolar I disorder (since 2017).

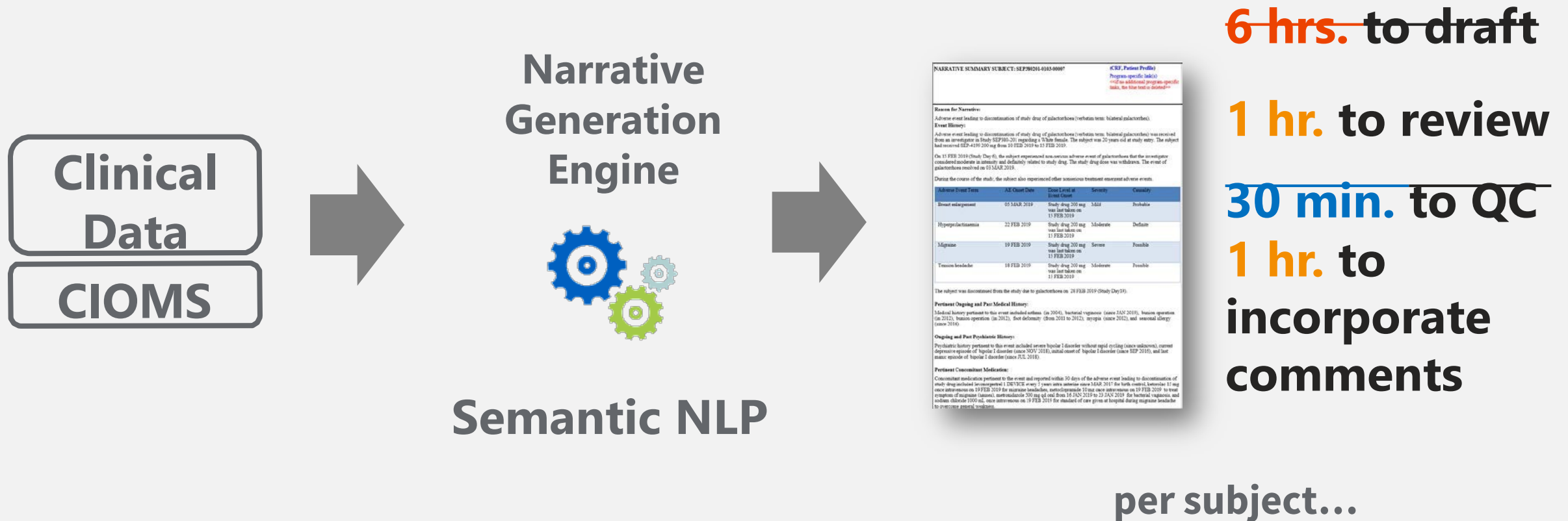
**Presenting and Past Medication:**  
Concomitant medication pertinent to the event and reported within 30 days of the adverse event leading to discontinuation of study drug included levothyroxine 1.25 mg once daily since 1 MAR 2017, the last manic episode of bipolar I disorder 10 mg once daily since 19 FEB 2019 for the migraine headache, metoprolol 50 mg once daily since 19 FEB 2019 to treat symptoms of migraine (headache), metoprolol 50 mg once daily from 16 JAN 2019 to 12 JAN 2019 for the breast vaginitis, and sodium chloride 1000 mL once intravenous on 19 FEB 2019 for the standard of care given at hospital during migraine headache to prevent further symptoms.

**6 hrs.** to draft  
**1 hr.** to review  
**30 min.** to QC  
**1 hr.** to incorporate comments per subject...

**A typical PoC or pivotal study includes 20-50 narratives**

**NDA includes up to 2000 narratives for deaths, SAE, and AEs leading to study discontinuation**

**We apply semantic NLP\* on top of flexible Narrative Generation engine that can adopt new requirements to fully automate writing of first draft narrative**



## \*Natural Language Process

# Sample output from Narratory\*

NARRATIVE SUMMARY SUBJECT: [REDACTED]

(CRF, Patient Profile)  
Program-specific link(s)  
<<if no additional program-specific links, the blue text is deleted>>

Reason for Narrative:

Adverse event leading to discontinuation of study drug of galactorrhoea (verbatim term: bilateral galactorrhea).

Event History:

Adverse event leading to discontinuation of study drug of galactorrhoea (verbatim term: bilateral galactorrhea) was received from an investigator in Study [REDACTED] regarding a White female. The subject was 20 years old at study entry. The subject had received [REDACTED] mg from 10 FEB 2019 to 15 FEB 2019.

On 15 FEB 2019 (Study Day 6), the subject experienced non-serious adverse event of galactorrhoea that the investigator considered moderate in intensity and definitely related to study drug. The study drug dose was withdrawn. The event of galactorrhoea resolved on 03 MAR 2019.

During the course of the study, the subject also experienced other nonserious treatment emergent adverse events.

| Adverse Event Term  | AE Onset Date | Dose Level at Event Onset                       | Severity | Causality |
|---------------------|---------------|-------------------------------------------------|----------|-----------|
| Breast enlargement  | 05 MAR 2019   | Study drug 200 mg was last taken on 15 FEB 2019 | Mild     | Probable  |
| Hyperprolactinaemia | 22 FEB 2019   | Study drug 200 mg was last taken on 15 FEB 2019 | Moderate | Definite  |
| Migraine            | 19 FEB 2019   | Study drug 200 mg was last taken on 15 FEB 2019 | Severe   | Possible  |
| Tension headache    | 18 FEB 2019   | Study drug 200 mg was last taken on 15 FEB 2019 | Moderate | Possible  |

The subject was discontinued from the study due to galactorrhoea on 28 FEB 2019 (Study Day19).

Pertinent Ongoing and Past Medical History:

Medical history pertinent to this event included asthma (in 2004), bacterial vaginosis (since JAN 2019), bunion operation (in 2012), bunion operation (in 2012), foot deformity (from 2011 to 2012), myopia (since 2012), and seasonal allergy (since 2016).

Ongoing and Past Psychiatric History:

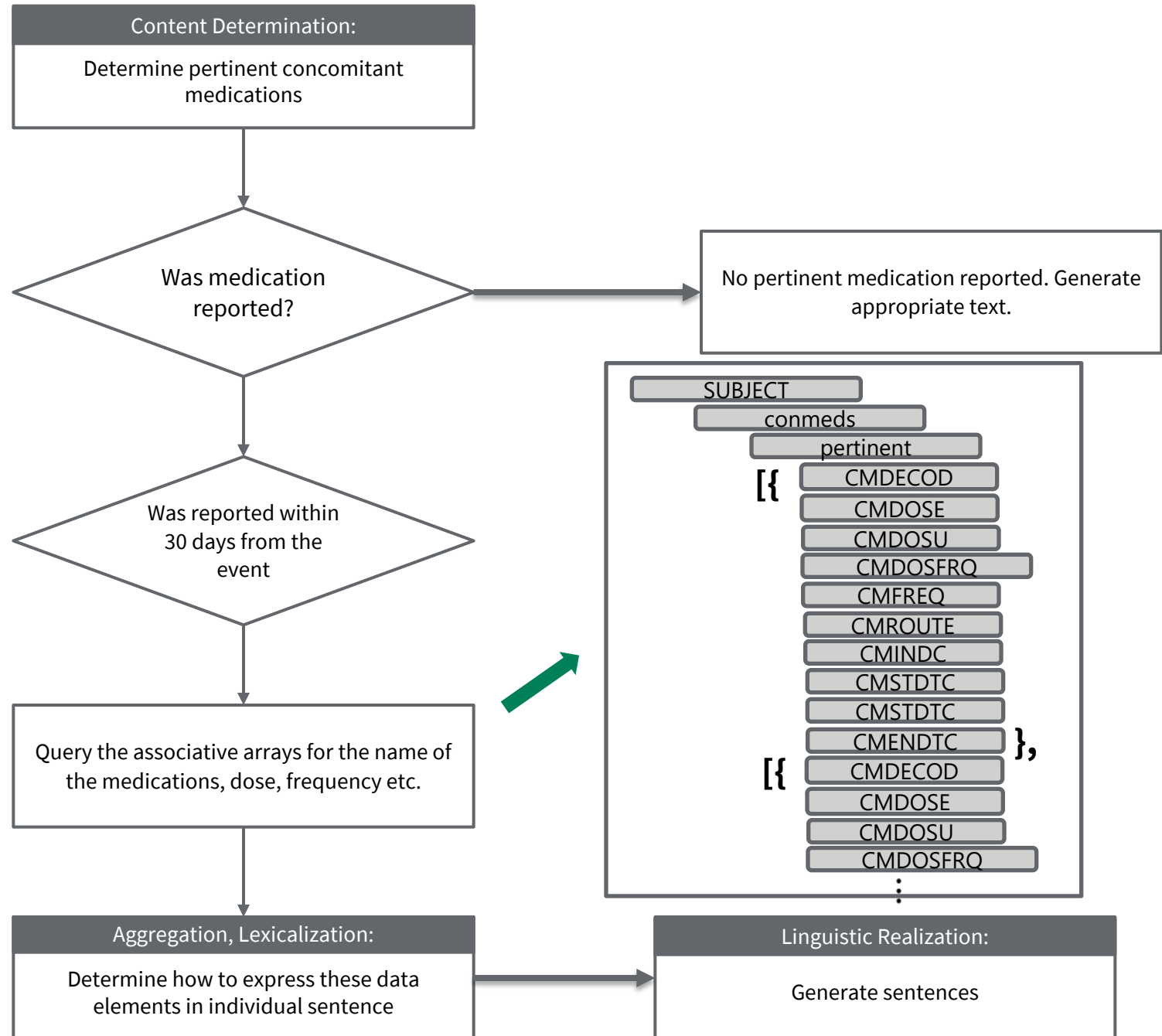
Psychiatric history pertinent to this event included severe bipolar I disorder without rapid cycling (since unknown), current depressive episode of bipolar I disorder (since NOV 2018), initial onset of bipolar I disorder (since SEP 2016), and last manic episode of bipolar I disorder (since JUL 2018).

Pertinent Concomitant Medication:

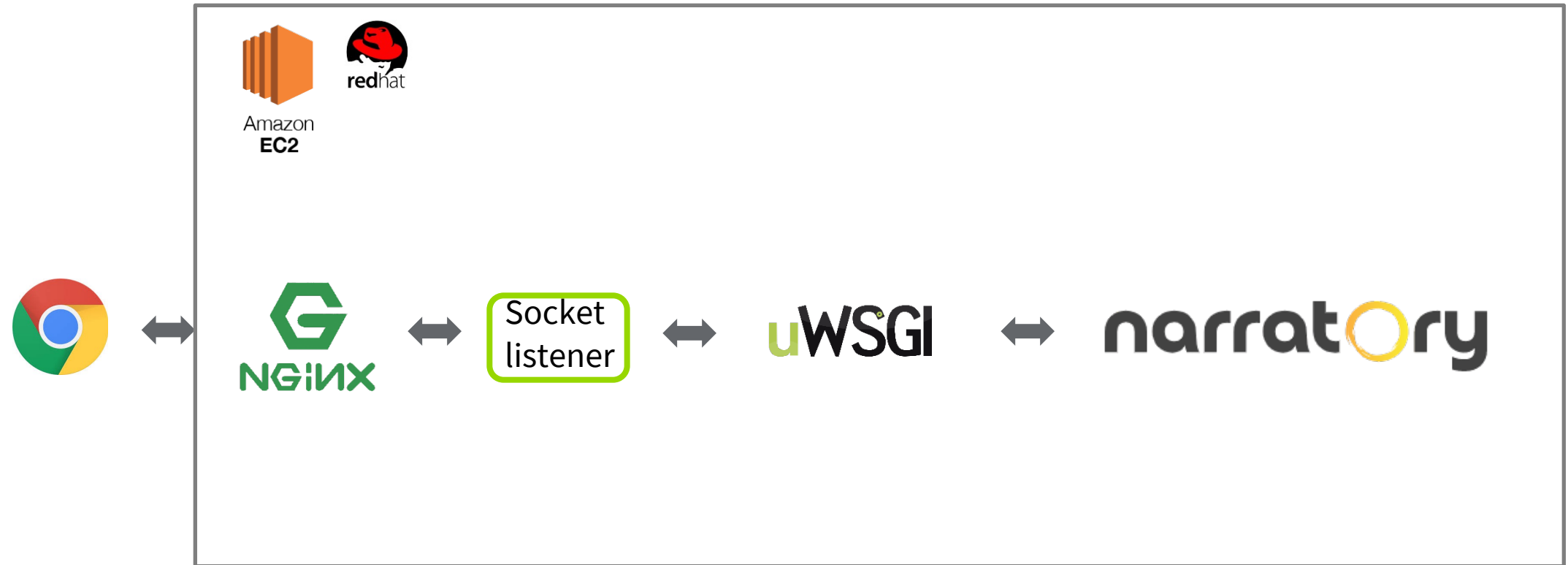
Concomitant medication pertinent to the event and reported within 30 days of the adverse event leading to discontinuation of study drug included levonorgestrel 1 DEVICE every 5 years intra uterine since MAR 2017 for birth control, ketorolac 15 mg once intravenous on 19 FEB 2019 for migraine headaches, metoclopramide 10 mg once intravenous on 19 FEB 2019 to treat symptom of migraine (nausea), metronidazole 500 mg qd oral from 16 JAN 2019 to 23 JAN 2019 for bacterial vaginosis, and sodium chloride 1000 mL once intravenous on 19 FEB 2019 for standard of care given at hospital during migraine headache to overcome general weakness.

\* Outputs were reviewed by Sunovion Medical Writer and the natural language generation engine has been fine tuned.

# Concomitant Medication Example...



# Deployment



## Nginx

Socket management  
HTTP parsing  
Rule matching

## uWSGI

Socket management  
Process management

# Main components of the application

- **Narrative Template**

Programable template is generated and stored for each study using standard MW template for patient narratives, minor changes e.g. adding new section, removing section, minor alterations to existing section(s) are manageable for study specific requirements. Making a completely new template will take some time.

- **Narrative Data Model**

This is one of the core components of application, standard SDTM data and Safety data are engineered to generate natural language to present in patient narratives. The data are converted to associative arrays.

- **Narrative Generation Engine**

The Narrative Generation Engine takes the instructions from Narrative Template and applies NLP techniques on associative arrays to generate narratives

- **Push Narratives to application**

Once narratives are generated by backend application these are pushed into frontend application to allow users to review/edit and publish narratives, need some updates if Narrative Template is updated otherwise this is simple task to finish.

# Study setup can take anywhere from 1 hours to up to 5 days.

1 hr ~ 5 days\*

## Backend

- 1 Study setup**
  - Stage study data
  - Set study parameters
  - Tune narrative template
- 2 Data pushed to the app server**

## In the app

- 1 Register Study**
- 2 Confirm access**

\*Extra days are necessary to accommodate complex study specific requirements (e.g. study with special AE of interest, linking an unique subject from multiple studies)

## KEY FEATURES

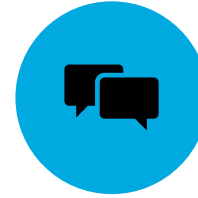


### **Smart and robust**

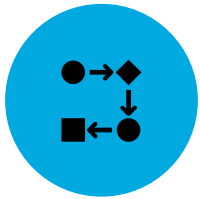
Natural Language Generation and semantic cleaning



**Flexible** for study requirements



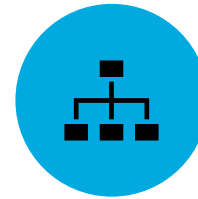
**Collaboration** platform for editing/review



**Workflows** for in-house and outsourced studies



**Publish** documents quickly



**Admin module** for study/user management and **audit trail**



Reduce cost and time

**Narratory provides platform for collaboration. It can be used to review and edit machine generated narratives by multiple users.**

Select Subject

> Death 6

> SAE 51

> AE discontinuation 170

> All 203

██████████-4003-001

⌵

Previous Subject Identifier: ██████████201-4003-001, ██████████301-4003-702

Narrative Reason

Save

Reset

B

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≡

?

Adverse events leading to discontinuation of study drug of nausea and vomiting (verbatim term: vomiting).test

Compare with ...

▼

Adverse events leading to discontinuation of study drug of nausea and vomiting (verbatim term: vomiting).test  
vomiting).

Comments

test\_mw 2020-12-11 10:20:27

please review narrative reason

stomioka 2020-12-10 20:47:40

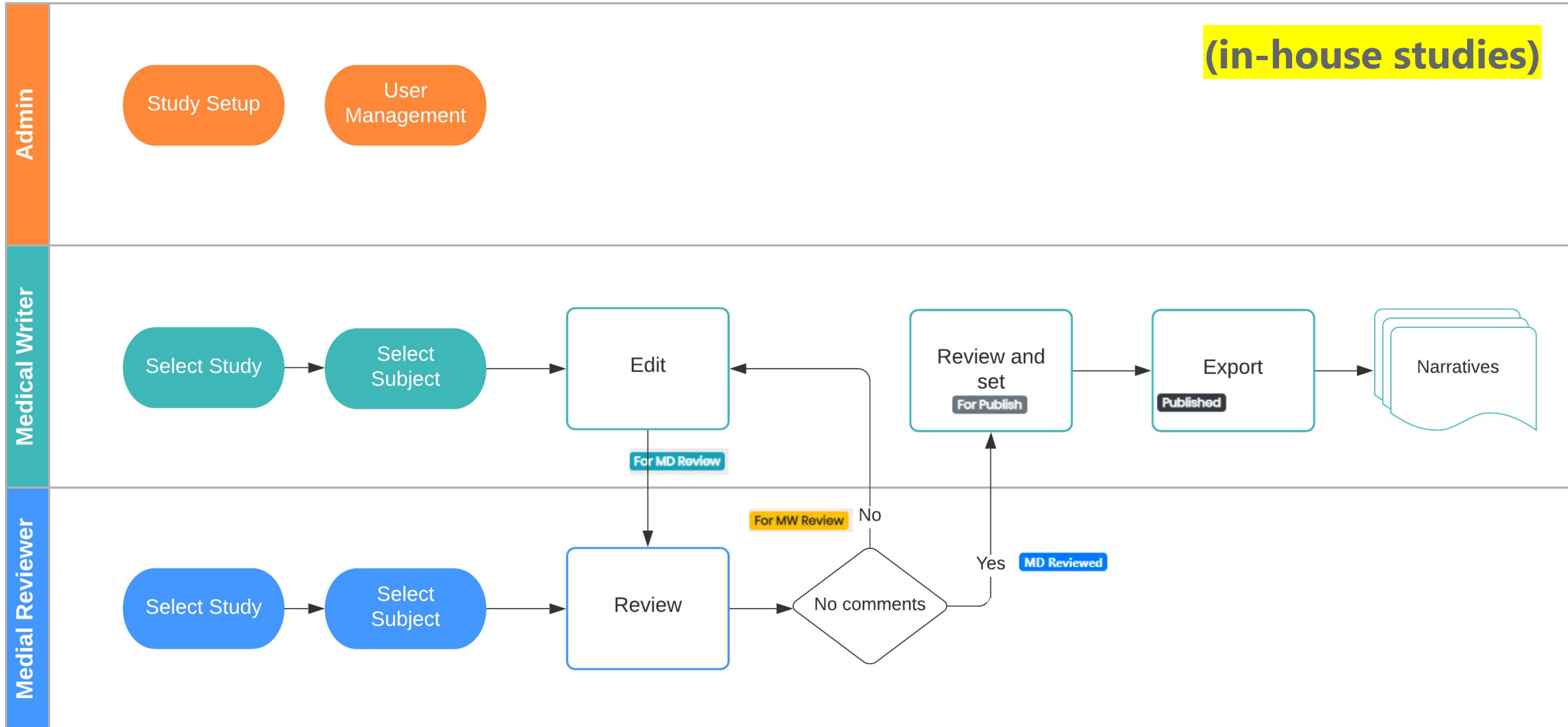
beta

💬

All saved versions are stored in the database and be able to compare

# Narratory enables customizable semi-automation of process

(in-house studies)



# Narratory can quickly publish MS-WORD files

Show 10 entries

| Subject                                     | Death | SAE | AE Discontinuation | Status    |
|---------------------------------------------|-------|-----|--------------------|-----------|
| <input type="radio"/> [REDACTED] 0103-00007 |       |     | ✓                  | Published |
| <input type="radio"/> [REDACTED] 0104-00015 |       |     | ✓                  | MD Review |
| <input type="radio"/> [REDACTED] 0107-00008 |       |     | ✓                  | MD Review |
| <input type="radio"/> [REDACTED] 0203-00001 |       |     |                    |           |
| <input type="radio"/> [REDACTED] 0209-00007 |       |     |                    |           |
| <input type="radio"/> [REDACTED] 0301-00007 |       |     |                    |           |
| <input type="radio"/> [REDACTED] 0406-00005 |       |     |                    |           |
| <input type="radio"/> [REDACTED] 0410-00004 |       |     |                    |           |
| <input type="radio"/> [REDACTED] 0507-00009 |       |     |                    |           |
| <input type="radio"/> [REDACTED] 0509-00009 |       |     |                    |           |

Showing 1 to 10 of 22 entries

[Edit](#) [Publish](#) [Download All](#)

narratory

Study SelectionEditTrackerPublish

SEP380201-0103-00007test\_mw

Subject

> Death

> SAE

> AE discontinuation

> All

SEP380201-0103-00007

Load

Preview

Edit

Publish

NARRATIVE SUMMARY SUBJECT: [REDACTED] 0103-00007

Reason for Narrative:  
Adverse event leading to discontinuation of study drug of galactorrhoea (verbatim term: bilateral galactorrhoea). The subject discontinued 2 days after the event.  
TEST TEST

Event History:  
Adverse event leading to discontinuation of study drug of galactorrhoea (verbatim term: bilateral galactorrhoea) was received from an investigator in Study SEP380-201 regarding a White female. The subject was 20 years old at study entry. The subject had received SEP-4199 200 mg from 10 FEB 2019 to 15 FEB 2019. On 15 FEB 2019 (Study Day 6), the subject experienced non-serious adverse event of galactorrhoea that the investigator considered moderate in intensity and definitely related to study drug. The study drug dose was withdrawn. The event of galactorrhoea resolved on 03 MAR 2019. During the course of the study, the subject also experienced other nonserious treatment emergent adverse events. ttt test

| Adverse Event Term  | AE Onset Date | Dose Level as Event Onset                       | Severity | Causality |
|---------------------|---------------|-------------------------------------------------|----------|-----------|
| Breast enlargement  | 05 MAR 2019   | Study drug 200 mg was last taken on 15 FEB 2019 | Mild     | Probable  |
| Hyperprolactinaemia | 22 FEB 2019   | Study drug 200 mg was last taken on 15 FEB 2019 | Moderate | Definite  |
| Migraine            | 19 FEB 2019   | Study drug 200 mg was last taken on 15 FEB 2019 | Severe   | Possible  |

# Narratory keeps audit trail, and admin can retrieve and export audit trail

narratory

ProfileAudit HistoryStudy RegistrationUser Registration

stomioka

User

All

Start

11/30/2020

End

12/05/2020

SUBMIT

Audit History

Search:

| username | event                       | subject              | study     | timestamp           |
|----------|-----------------------------|----------------------|-----------|---------------------|
| stomioka | Status Updated to forReview | CTH-300-1021-001     | CTH-301   | 2020-11-30T01:14:02 |
| stomioka | Login successful            |                      |           | 2020-11-30T22:02:49 |
| stomioka | Status Updated to published | CTH-201-4003-006     | CTH-301   | 2020-11-30T22:03:33 |
| stomioka | Status Updated to forReview | SEP361201-0203-00004 | SEP361201 | 2020-11-30T22:05:17 |
| stomioka | Status Updated to published | SEP361201-0203-00004 | SEP361201 | 2020-11-30T22:05:50 |
| stomioka | Status Updated to forReview | CTH-201-4003-006     | CTH-301   | 2020-11-30T22:28:23 |
| stomioka | Event history updated       | CTH-201-4003-006     | CTH-301   | 2020-11-30T22:28:23 |
| stomioka | Login successful            |                      |           | 2020-12-01T17:09:35 |
| stomioka | Logout                      |                      |           | 2020-12-01T17:31:32 |
| stomioka | Login successful            |                      |           | 2020-12-01T17:31:37 |

Showing 1 to 10 of 37 entries

Previous1234Next

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Detail events are captured at study subject level. Can be exported as an Excel file.

# User access can be controlled at an organization level

narratOry

ProfileStudy Registration

stomioka

Registered Study

|                       | Project    | Study ID   | Resource Type | Status |
|-----------------------|------------|------------|---------------|--------|
| <input type="radio"/> | APL-130277 | CTH-301    | CRO1          | Active |
| <input type="radio"/> | SEP-4199   | SEP380-201 | Sunovion      | Active |
| <input type="radio"/> | SEP-856    | SEP361201  | CRO1          | Active |
| <input type="radio"/> | SEP-856    | SEP361301  | Sunovion      | Active |

☒ Update  
☐ Add

Submit

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User access to the studies and functions are controlled based on **company** and **role**.

Study will be added to the training database

narratOry

ProfileAudit HistoryStudy RegistrationUser Registration

stomioka

Registered Users

|                       | Username   | Email                    | Role  | Company  | Status |
|-----------------------|------------|--------------------------|-------|----------|--------|
| <input type="radio"/> | test_mw    | test_mw@sunovion.com     | mw    | Sunovion | Active |
| <input type="radio"/> | stomioka   | sam.tomioka@sunovion.com | dst   | Sunovion | Active |
| <input type="radio"/> | test_cromw | test_cromw@sunovion.com  | mw    | IQVIA    | Active |
| <input type="radio"/> | test_md    | test_md@sunovion.com     | md    | Sunovion | Active |
| <input type="radio"/> | test_cromd | test_cromd@sunovion.com  | cromd | IQVIA    | Active |

☒ Update  
☐ Add  
☐ Reset Password

Submit

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# Demonstration