



A journey into web technology for listing generation

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Hyderabad/ Basel
September 2021

All opinions expressed are the author's personal views, and do not reflect the views or opinions of Novartis

Agenda

- Who
- What
- Why
- How
- What next

Who

We are

Standards, Technology and Automation

Tasked with delivering transformative benefits to the Novartis Data Operations Organization by developing tools and investigating the implementation of novel technologies to drive quality and standardization.

Who

The team

With a BIG **Thank You** to all the developers and other contributors to the project within and outside of Novartis

PLG development team:

Srinivas Alla (group lead), Kartik Rajan(product owner), David Barrat (technical lead), Kenneth Golovan, Michal Rafalski, Steve Densham

CDE development team:

Michal Rafalski (product owner/ technical lead), Amal Anandan, Arun Mahesh Chan Le Van, Orlaith Hickey, Michael Kane, Divya A, Puneeth M D

What

We have developed

- Patient Listing generator:
 - An application to allow users to access data from the statistical computing environment.
 - Configure listings based on pre-defined, governance approved templates.
 - Generate SAS-style RTF or excel listings.



Build from scratch

or select existing from the list

AE Adverse Events

AEL001 Adverse events

AEL003 Dose limiting toxicity (DLT) by dose level

AEL009 Case retrieval strategy listing

L_AE_301 Deaths

L_AE_302 Deaths prior to starting treatment

L_AE_304 Adverse events among subjects who were not treated

ANS Analysis Datasets

ANP Antineoplastic data

BMX Biomarkers

DM Demographics

DS Disposition

EG ECG Test Results

EFO Efficacy - oncology

EX Exposure

IMG Imaging

IE Inclusion/Exclusion Criterion Not Met

CO Investigator comments

LB Laboratory Test Results

MH Medical History

PC PK Concentration

Listing xx.x.x-x.x (Page x of x)
Adverse events
Safety set

Planned Treatment for Period 01: Treatment A
AGEORGN: xxxxxx

Country/ Subject identifier	Age/ Sex/ Race	Ser ious/ event	Reported term Preferred term System organ class	Start date time/ day	End date time/ End rel. to ref./ day	Dur ation (day)	Sev ery ty	Toxi city Grade	Cau sal ity	Action taken with med.	Med or ther. taken	Out come	Time to AE (day)	Date of most recent dose
AUT/004 /0007	25/M /WH	Y	Fainting/Syncope /Gastrointestinal disorders	yyyy-mm -dd/38	yyyy-mm -dd /During /78	19	Sev G1	1		5	10	3	12	yyyy-mm -dd
AUT/001 /0001	34/F /BL	Y	Pain in head/Headache /Nervous system disorders	yyyy-mm -dd/67	yyyy-mm -dd /Before /70	14	Mod G3	1		1	1	9	31	yyyy-mm -dd
AUT/007 /0001	25/M /WH	Y	Pain in head/Headache /Nervous system disorders	yyyy-mm -dd/36	yyyy-mm -dd /Before /62	28	Mod G3	2		4	1	3	24	yyyy-mm -dd

- Day is relative to the reference start date. Missing dates are based on imputed dates.
- Severity: MILD=Mild, MOD=Moderate, SEV=Severe.
- Relationship to study treatment (causality): 1=No, 2=Yes, 3= Yes, investigational treatment,
4= Yes, other study treatment (non-investigational), 5= Yes, both and/or indistinguishable.
- Action taken: 1=None, 2=Dose adjusted, 3=Temporarily interrupted, 4=Permanently discontinued, 997=Unknown, 999=NA.
- Outcome: 1=Not recovered/not resolved, 2=recovered/resolved, 3=recovering/resolving,
4=recovered/resolved with sequelae, 5=Fatal, 997=Unknown.
- Medication or therapies taken: 1=No concomitant medication or non-drug therapy, 10=Conc. Med. or non-drug therapy
- Time to AE = Time of AE onset minus time of the most recent dose.

Customize

What

We have developed (continued...)

- Clinical Data Explorer:
 - An application to allow users to interactively explore clinical data from the statistical computing environment from a web-based interface.

All Portfolios

All Datasets

analysis_data/adsl.sas7bdat

Sorting

Default sorting

Filters

No active filters

Tools

Export dataset as XLSX

Columns Selector

Load/Save customise view

Total rows: 1560

USUBJID Unique Subject Identifier	AGEGR2 65 Years and Older	ETHNIC Ethnicity	FASFL Full Analysis Set Population Flag	HEIGHT Height at Baseline (CM)	SAFFL Safety Population Flag	SEX Sex	WEIGHT Weight at Baseline (Kg)
XXXXnnnnXnnnn_nnnn100	N	OTHER	Y	176	Y	M	95
XXXXnnnnXnnnn_nnnn101	Y	OTHER	Y	176	Y	M	79
XXXXnnnnXnnnn_nnnn102	N	OTHER	Y	174	Y	F	62
XXXXnnnnXnnnn_nnnn103	Y	OTHER	Y	175	Y	M	79
XXXXnnnnXnnnn_nnnn104	N	HISPANIC OR LATINO	Y	172	Y	M	81
XXXXnnnnXnnnn_nnnn105	N	OTHER	Y	172	Y	M	74
XXXXnnnnXnnnn_nnnn106	N	OTHER	Y	169	Y	F	78
XXXXnnnnXnnnn_nnnn108	N	OTHER	Y	168.5	Y	M	75
XXXXnnnnXnnnn_nnnn109	N	NOT REPORTED	Y	157	Y	F	53
XXXXnnnnXnnnn_nnnn10A	N	OTHER	Y	181	Y	M	76

< 1 2 3 4 5 ... 156 >

Why

Background

- Access to real-time ADaM and SDTM data typically limited to the programming and biostatistics functions.
- This contains derived information used in analysis and reporting, not available in the raw data, such as:
 - Analysis flags
 - Analysis timepoints
 - Composite and derived analysis endpoint parameters

Why

Need for a solution

- This data may be used in operational or safety decision making. Can be used in writing documents and patient narratives.
- Clinical, medical writing and functions typically do not have real-time access to this data.
- Programming or biostatistics need to generate static analyses to allow review/exploration of this data.

Why

What we hoped to achieve



Early data
insights



Real-time
data access



Learning of
analysis
plans



Reduced
work for
analytics



Allow data
exploration

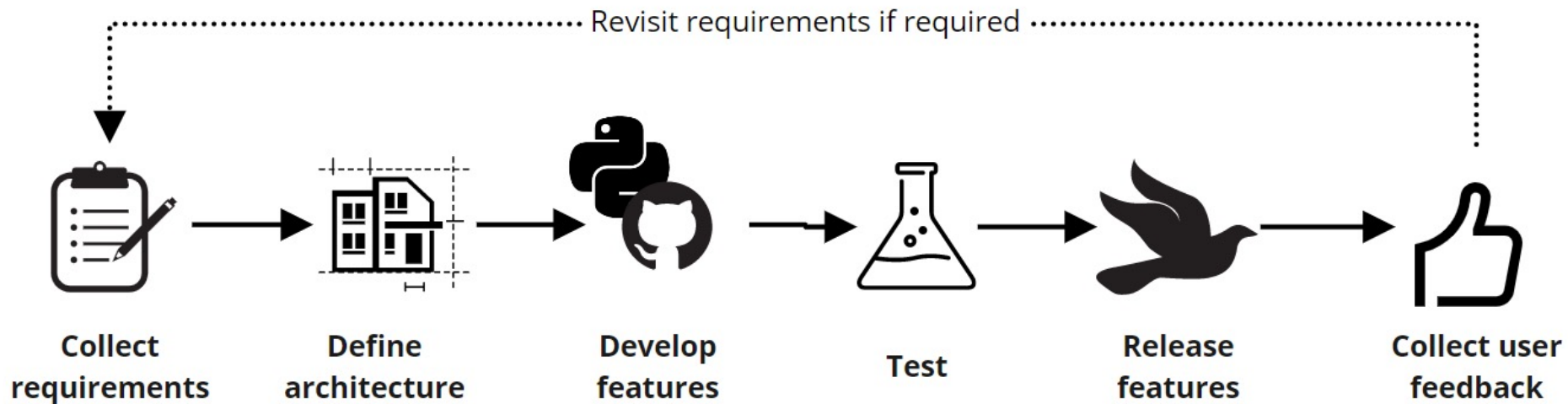
How

Team

- Team had the following roles:
 - Product owner/ Scrum master
 - Developed requirements with the business.
 - Defined priority of features to be developed.
 - Worked with users in testing and collecting feedback during development.
 - Tracked progress, led daily stand-up and scrum meetings.
 - Development team
 - Implement features requested by PO.
 - Design and implement the technical architecture of the application.
 - Document and test features for tool validation.

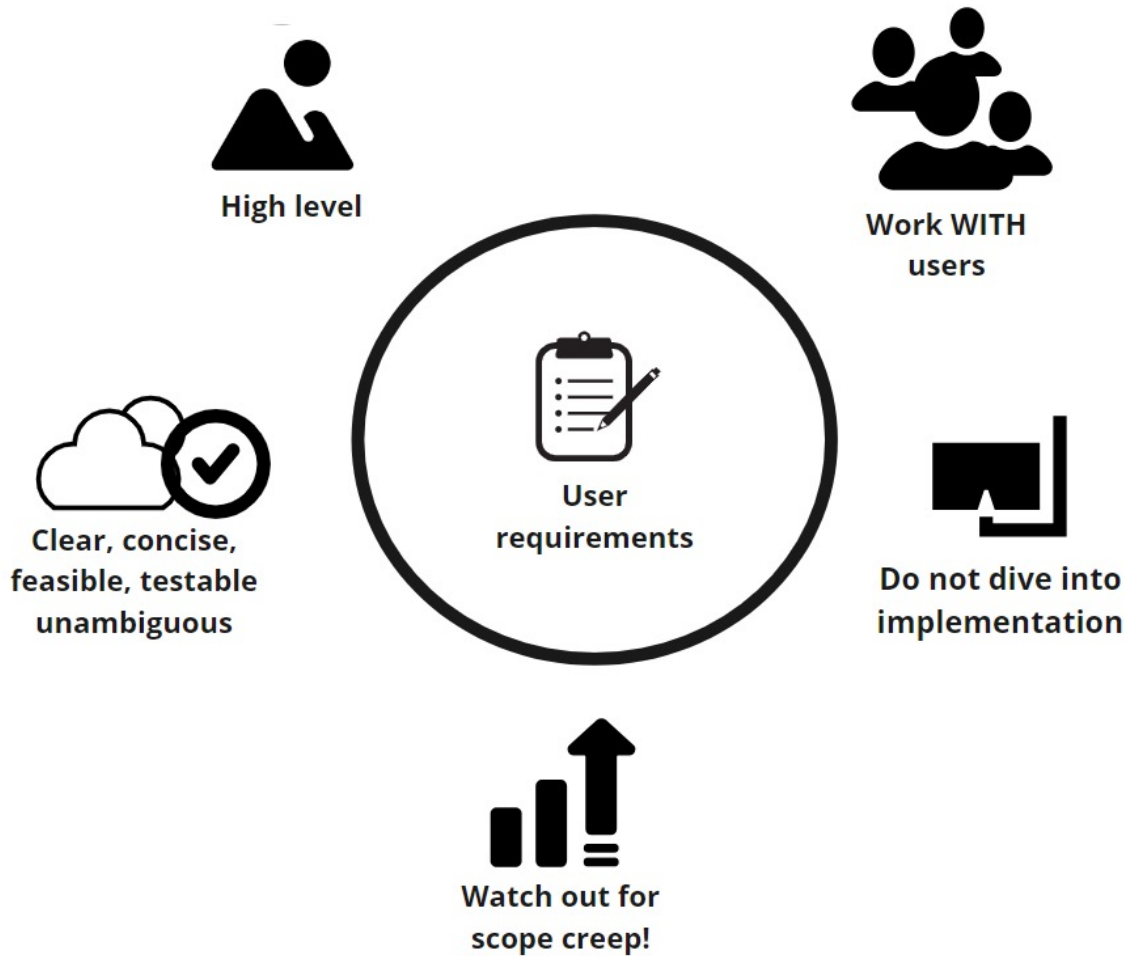
How

High level flow..



How

User requirements



How

Requirements and specifications continued...

Users should be able to sort and filter the data

The table component should have a buttons next to the column name to sort the data by the contents of the column in ascending or descending order. A separate button should allow users to filter, either by specifying a value or picking one from a drop-down

Users should be able to export the data to excel

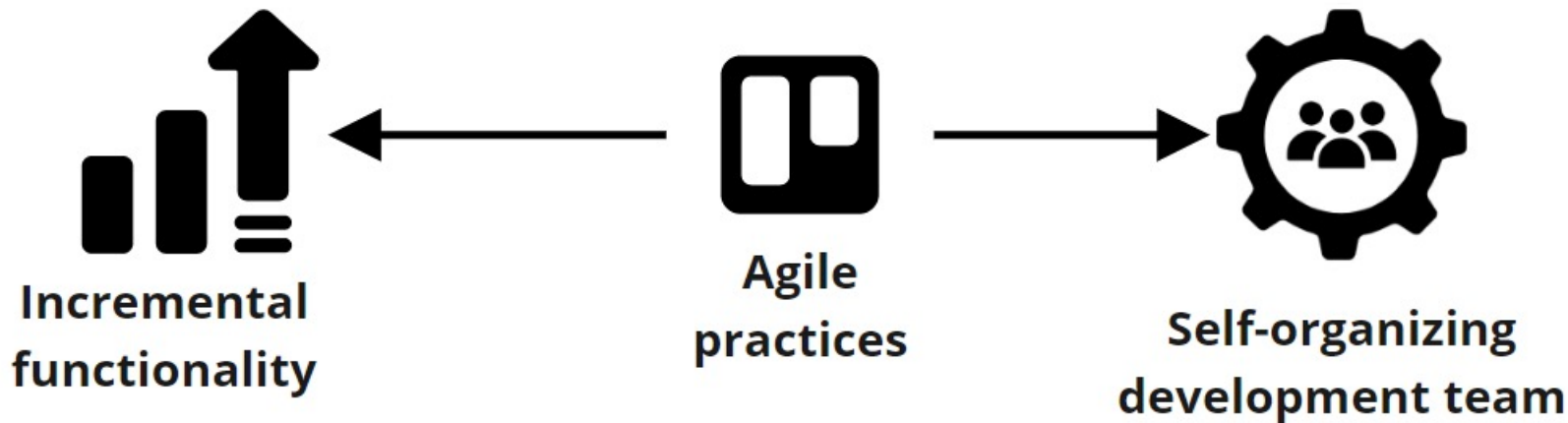
Export should be enabled

Users should be able to join two or more datasets and view the resultant dataset

Using a combine methodology, specifying unique sets of variables in common between two SAS dataset objects, users should be able to define a method derive a new dataset from multiple input SAS dataset objects and view results.

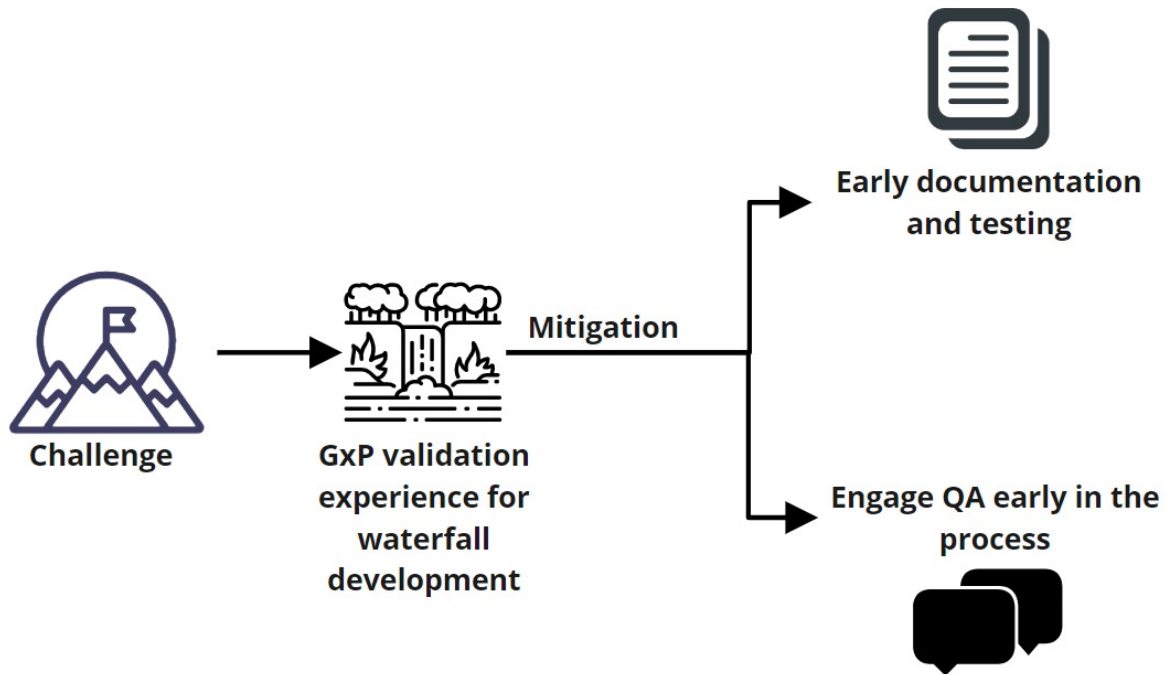
How

Agile development



How

Agile development (continued...)



How

Tools and technologies

Tools

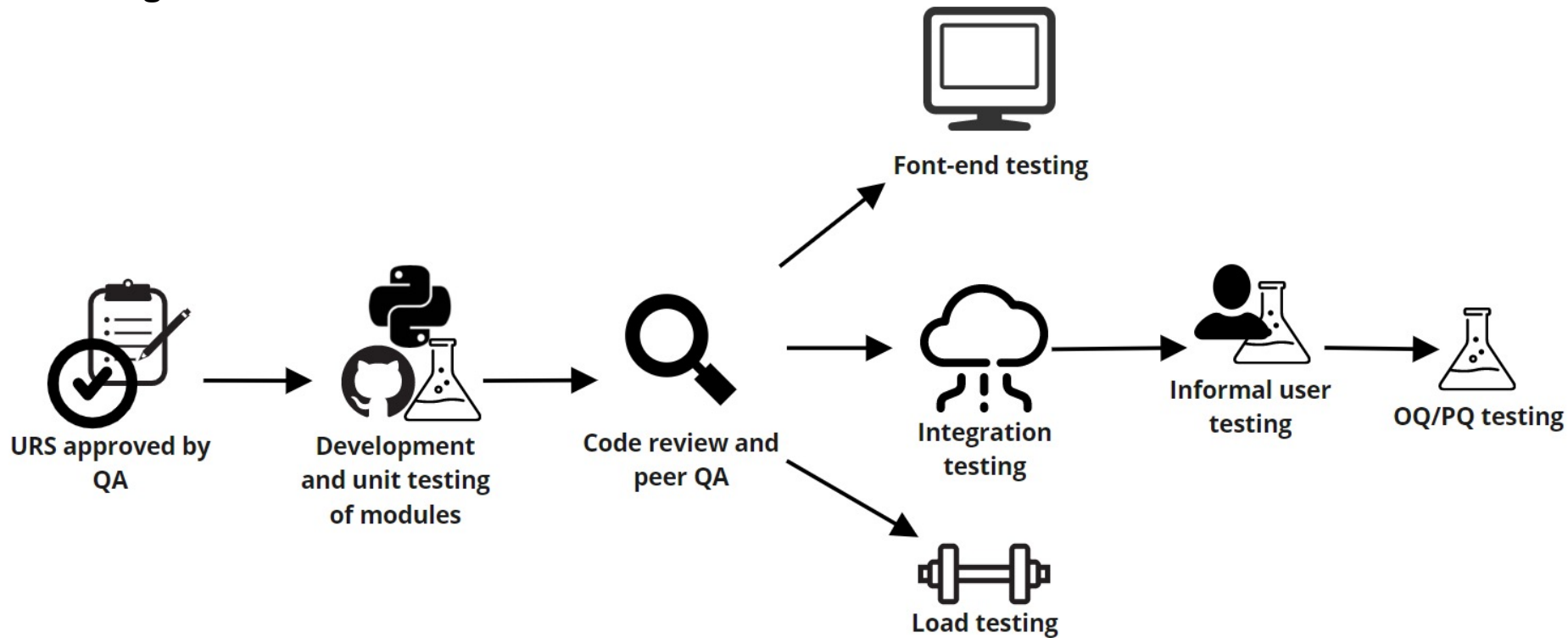
- OpenShift : Open-source platform used to deploy applications.
- GitLab: Used as a code repository, CI/CD pipeline.
- JIRA: Project management tool, used in management of development sprints, creation of tickets and tracking progress.
- ALM: Lifecycle management, tool qualification.

Technologies

- Front-end: REACT and Typescript
- Back-end: Node.js/ Python
- Databases: PostgreSQL/ MONGODB
- Docusaurus: User documentation

How

Testing and validation



How

Release, training,
user support



Engage users



Release
communications



Engage
leadership



Documentation
and training

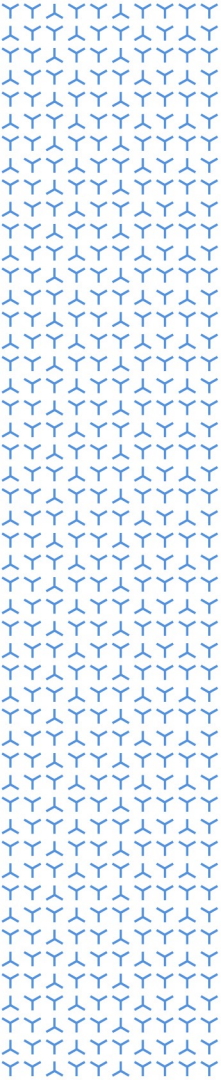


Support

What next

What we learned

- Successes
 - Successfully developed and deployed tools.
 - Demonstrated potential for transformative benefits to organization.
 - Developed capabilities in the team for initiating, managing and executing an agile software project.
 - Expanded capabilities of tools after initial roll-out
- Opportunities
 - Define standards for development, validation and documentation.
 - Define organizational structure around the agile development process.
 - Teething issues around decision making on tools and technologies to be used.



Thank you