



iListing

Get more out of Listings



October 2021 / Katja Glaß





Agenda

- // Introduction
- // iListing
- // Architecture
- // DevOps
- // Project progress
- // Summary



Introduction

iListing - why?

- Listings according ICH E3 for every study
- Reviewer friendly view of clinical database
- Listing of all data, no summaries

16.2. Patient Data Listings

16.2.1 Discontinued patients

16.2.2 Protocol deviations

16.2.3 Patients excluded from the efficacy analysis

16.2.4 Demographic data

16.2.5 Compliance and/or Drug Concentration Data (if available)

16.2.6 Individual Efficacy Response data

16.2.7 Adverse event listings (each patient)

16.2.8. Listing of individual laboratory measurements by patient, when required by regulatory authorities

https://www.ema.europa.eu/en/documents/scientific-guideline/ich-e-3-structure-content-clinical-study-reports-step-5_en.pdf

Introduction

iListing - why?

- **Listings ≠ ADAM** (input datasets)
 - ~ 25% can be taken 1:1
 - Sub-selection (Variables, Observations)
 - Relabeling
- ~75% requires processing
 - Merge
 - Transpose

It's not a view of the data,
some programming is required.

16.2. Patient Data Listings

- 16.2.1 Discontinued patients
- 16.2.2 Protocol deviations
- 16.2.3 Patients excluded from the efficacy analysis
- 16.2.4 Demographic data
- 16.2.5 Compliance and/or Drug Concentration Data (if available)
- 16.2.6 Individual Efficacy Response data
- 16.2.7 Adverse event listings (each patient)
- 16.2.8 Listing of individual laboratory measurements by patient, when required by regulatory authorities





Introduction

iListing - why?

- Listings / Output
 - 12-50 Listings files up to 100MB each, tons of pages

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- Huge Study (no medical devices)
 - 148 listing files
 - 12 documents for “Listing: Clinical laboratory data – Hematology” (up 15k pages each)
 - 66 documents for “Listing: Clinical laboratory data – General chemistry”



Introduction

iListing - why?

- Working with listings?
 - Not possible, slow to open / search
 - Tough to find one subject on split documents
 - Do we need listings? Working group available ([Listings for Clinical Study Report](#))





Introduction

iListing - why?

- What if we could? CSR - Writing
 - Find detailed information about subjects quickly
 - Dig deeper, especially when interested in one subject
 - Quick counts (and get confirmation from Stats)
 - Checkout special Adverse Events of interest

- What if we could? CSR - Checks
 - Cross-check numbers and details





Introduction

iListing - why?

➤ iListing - Super quick navigation of CSR Listings

iListings

Listings		Graphics (ITT analysis set) ⓘ (6564)				
Listing 16.1.4/1: Enrolled subjects by center (all enrolled subjects) (cont.)with sub-title						
Listing 16.1.6/1: Batch listing (all enrolled subjects)						
Listing 16.2.1/1: Subjects who did not complete or pass screening (all screened patients)						
Listing 16.2.1/2: Discontinued subjects (all enrolled subjects)						
Listing 16.2.2/1: Protocol deviations (ITT analysis set)						
Listing 16.2.2/2: Subjects whose actual treatment group was not the randomized (planned) treatment (ITT analysis set)						
Listing 16.2.3/1: Analysis sets (ITT analysis set)						
Listing 16.2.4/1: Inclusion/exclusion criteria						
Listing 16.2.4/2: Inclusion/exclusion criteria not met (all screened patients)						
Listing 16.2.4/3: Informed consent (all screened patients)						
		Age/Sex/Race	Applicable R...	Baseline Hei...	Baseline Wei...	Baseline Bod...
		Search...		Search...	Search...	Search...
		84/M/W	WHITE	165	55	20.2
		76/M/W	WHITE	176	92	29.7
		76/F/W	WHITE	163	76	28.6
		80/F/W	WHITE	164	80	29.7
		64/M/W	WHITE	165	72	26.4
		85/F/W	WHITE	160	56	21.9
		58/F/W	WHITE	162	84	32
		65/M/W	WHITE	176	79	25.5
		72/M/W	WHITE	165	69	25.3
		55/M/W	WHITE	175	65	21.2
		74/M/W	WHITE	175	86.7	28.3
		59/F/W	WHITE	158.6	98	39
		62/M/W	WHITE	183	109.5	32.7
		55/M/W	WHITE	182	95.1	28.7
		60/M/W	WHITE	177.3	96.5	30.7
		60/M/W	WHITE	177	101.8	32.5



Quick Tool Overview

iListing





iListing

Quick Tool Overview

- Table display with filter options
 - Dropdowns, date ranges, larger than, ...
- Global subject filter (show data just for specific subject(s))
- Multi-Table display
- Login (only people with study access)
- Download capability (only use for review)
 - With traceability
- Multi-file listings combined (sometime few re-splits required)





iListing

Quick Tool Overview

>

Listing 16.1/1: Demographics (Intent-To-Treat population) ⓘ (1)

row	Unique Subje...	Planned Trea...	Age	Sex	Race	Ethnicity	Baseline BMI ...	Baseline Heig...
1	01-701-1015	Placebo	63	F	WHITE	HISPANIC OR L...	25.1	147.3

Listing 16.2/2: Adverse events ⓘ (3)

r...	Actu...	Uniq...	Prefe...	Serio...	Anal...	Anal...	Seve...	Invol...	Cong...	Persi...	Resu...	Requ...	Is Lif...	Occu...
1	Placebo	01-701-...	APPLIC...	N	2014-0...		MILD	N	N	N	N	N	N	N
2	Placebo	01-701-...	APPLIC...	N	2014-0...		MILD	N	N	N	N	N	N	N
3	Placebo	01-701-...	DIARR...	N	2014-0...	2014-0...	MILD	N	N	N	N	N	N	N

Listing 16.2/3: Vital signs ⓘ (110)

row	Unique Subject Identifier	Planned Treatment	Analysis Visit	Parameter	Baseline Type
1	01-701-1015	Placebo	Baseline	Diastolic Blood Pressure (mm...	AFTER LYING DOWN FOR
2	01-701-1015	Placebo	Baseline	Diastolic Blood Pressure (mm...	AFTER STANDING FOR 1 M
3	01-701-1015	Placebo	Baseline	Diastolic Blood Pressure (mm...	AFTER STANDING FOR 3 M
4	01-701-1015	Placebo	Baseline	Pulse Rate (beats/min)	AFTER LYING DOWN FOR
5	01-701-1015	Placebo	Baseline	Pulse Rate (beats/min)	AFTER STANDING FOR 1 M
6	01-701-1015	Placebo	Baseline	Pulse Rate (beats/min)	AFTER STANDING FOR 3 M
7	01-701-1015	Placebo	Baseline	Systolic Blood Pressure (mm...	AFTER LYING DOWN FOR
8	01-701-1015	Placebo	Baseline	Systolic Blood Pressure (mm...	AFTER STANDING FOR 1 M
9	01-701-1015	Placebo	Baseline	Systolic Blood Pressure (mm...	AFTER STANDING FOR 3 M
10	01-701-1015	Placebo	Baseline	Temperature (C)	

Options >

Logout

Subject Filter

Select Subject(s) 🔍

01-701-1015
01-701-1023
01-701-1028
01-701-1033
01-701-1034
01-701-1047
01-701-1097
01-701-1111
...

01-701-1015

Table Layout Options

☒ Multi-Table-Display

☒ Empty-Table-Display

Store Settings

Delete Settings



iListing

Quick Tool Overview

➤ Super Quick

- 10 seconds loading +10 second vis preparation for 350k line questionnaire listing
- “standard listings” < 1 second
- Immediate filter
- Infinitive scrolling





iListing

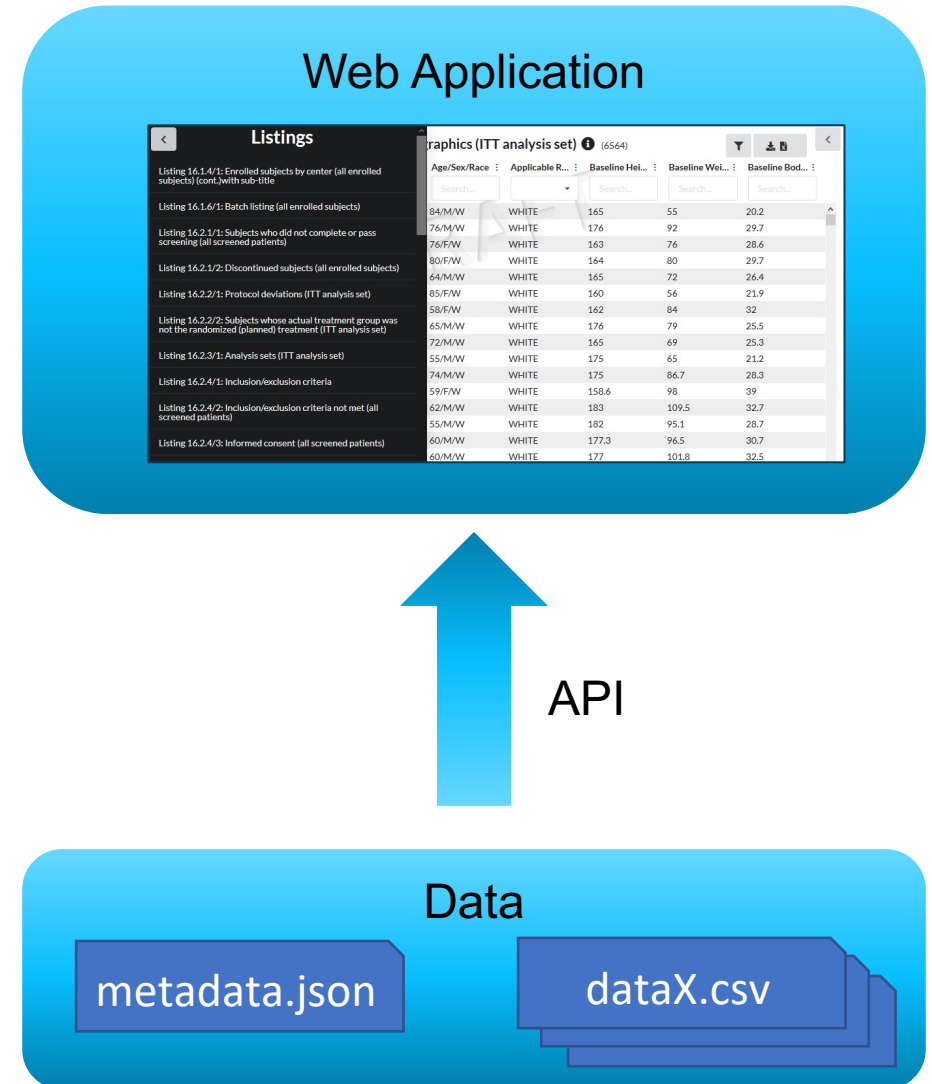
Architecture



iListing Architecture

Tools & Technologies

- Web technology for Display / Core App
 - React as JavaScript library for user interface
 - Redux as state / data container
 - React-virtualized for super performant table rendering
 - Semantic UI for design
- API to access the data
 - **sFTP**, Samba, ... connection possible
- Backend files created with SAS
 - Metadata (JSON) & content files (CSVs)





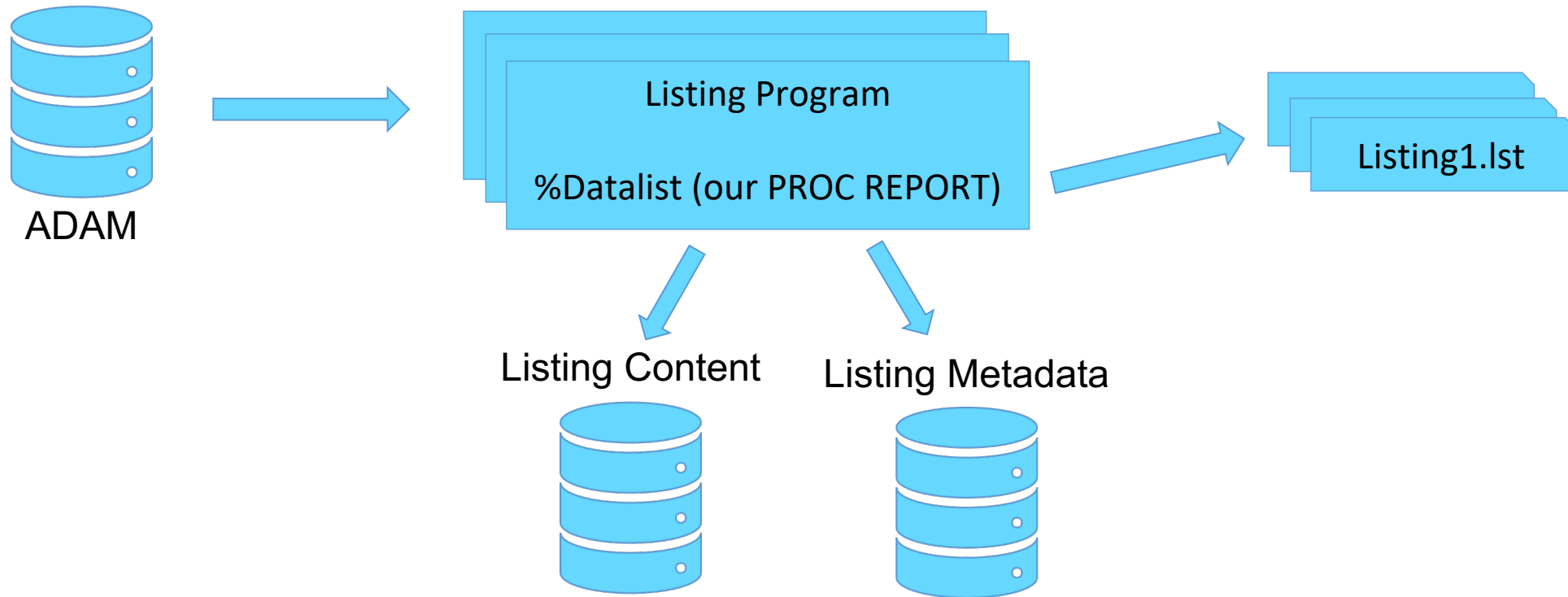
iListing Architecture

Backend / Data Generation

Data

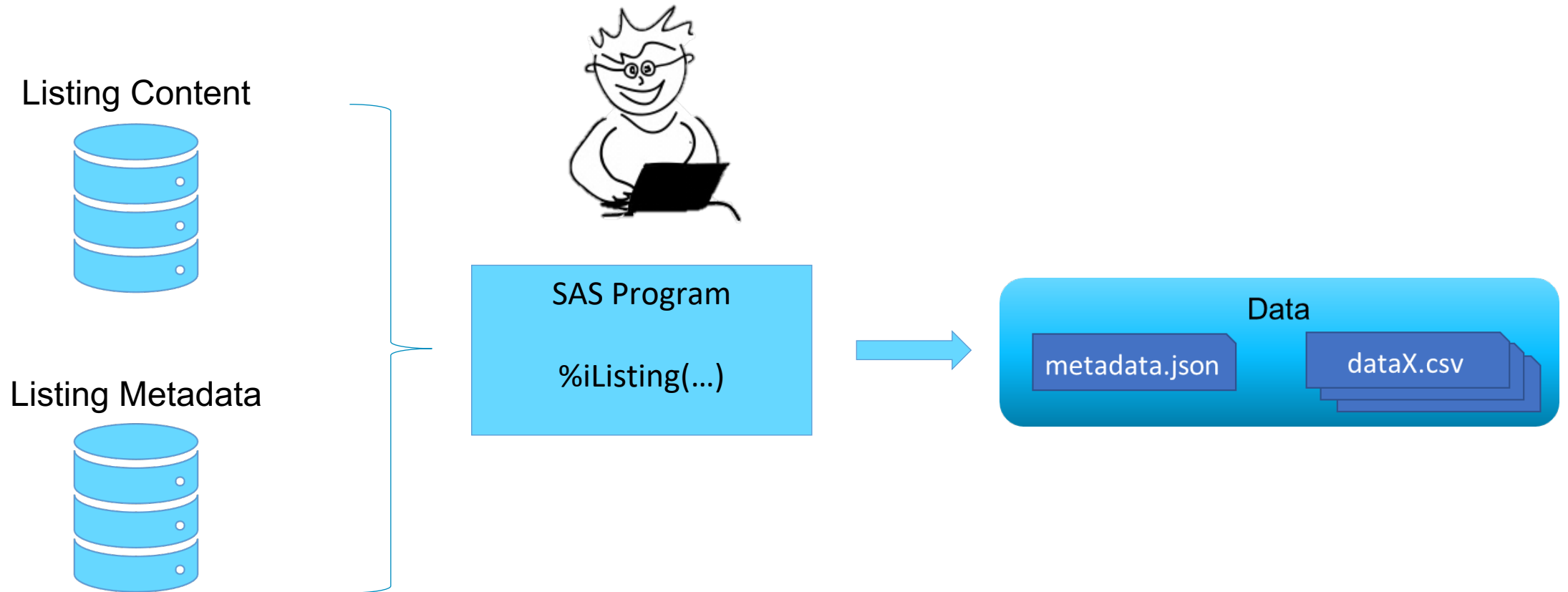
metadata.json

dataX.csv



iListing Architecture

Backend / Data Generation



iListing Architecture

Backend / Data Generation

Data

metadata.json

dataX.csv

metadata.json

- Structure of „Tables“
- Links to content files (*.csv)
- Titles, Footnotes, ...
- Variables
 - Labels
 - isDate
 - isDropdown

	A	B	C	D	E	F
1	TRTA	USUBJID	AESEQ	TERMS	AESER	ASTDT
2	Placebo	01-701-1015	1	APPLICATION SITE ERYTHEMA/APPL N		03.01.2014
3	Placebo	01-701-1015	2	APPLICATION SITE PRURITUS/APPLI N		03.01.2014
4	Placebo	01-701-1015	3	DIARRHOEA/DIARRHOEA	N	09.01.2014
5	Placebo	01-701-1023	1	ERYTHEMA/ERYTHEMA	N	07.08.2012
6	Placebo	01-701-1023	2	ERYTHEMA/ERYTHEMA	N	07.08.2012
7	Placebo	01-701-1023	3	ATRIOVENTRICULAR BLOCK SECONC	N	26.08.2012
8	Placebo	01-701-1023	4	ERYTHEMA/ERYTHEMA	N	07.08.2012
9	Placebo	01-701-1047	1	HIATUS HERNIA/HIATUS HERNIA	N	12.02.2013
10	Placebo	01-701-1047	2	HIATUS HERNIA/HIATUS HERNIA	N	12.02.2013
11	Placebo	01-701-1047	3	UPPER RESPIRATORY TRACT INFECT	N	06.03.2013
12	Placebo	01-701-1047	4	BUNDLE BRANCH BLOCK LEFT/BUNC	N	10.03.2013
13	Placebo	01-701-1118	1	COUGH/COUGH	N	
14	Placebo	01-701-1130	1	URINARY TRACT INFECTION/URINAI	N	09.03.2014
15	Placebo	01-701-1130	2	PYREXIA/PYREXIA	N	09.03.2014



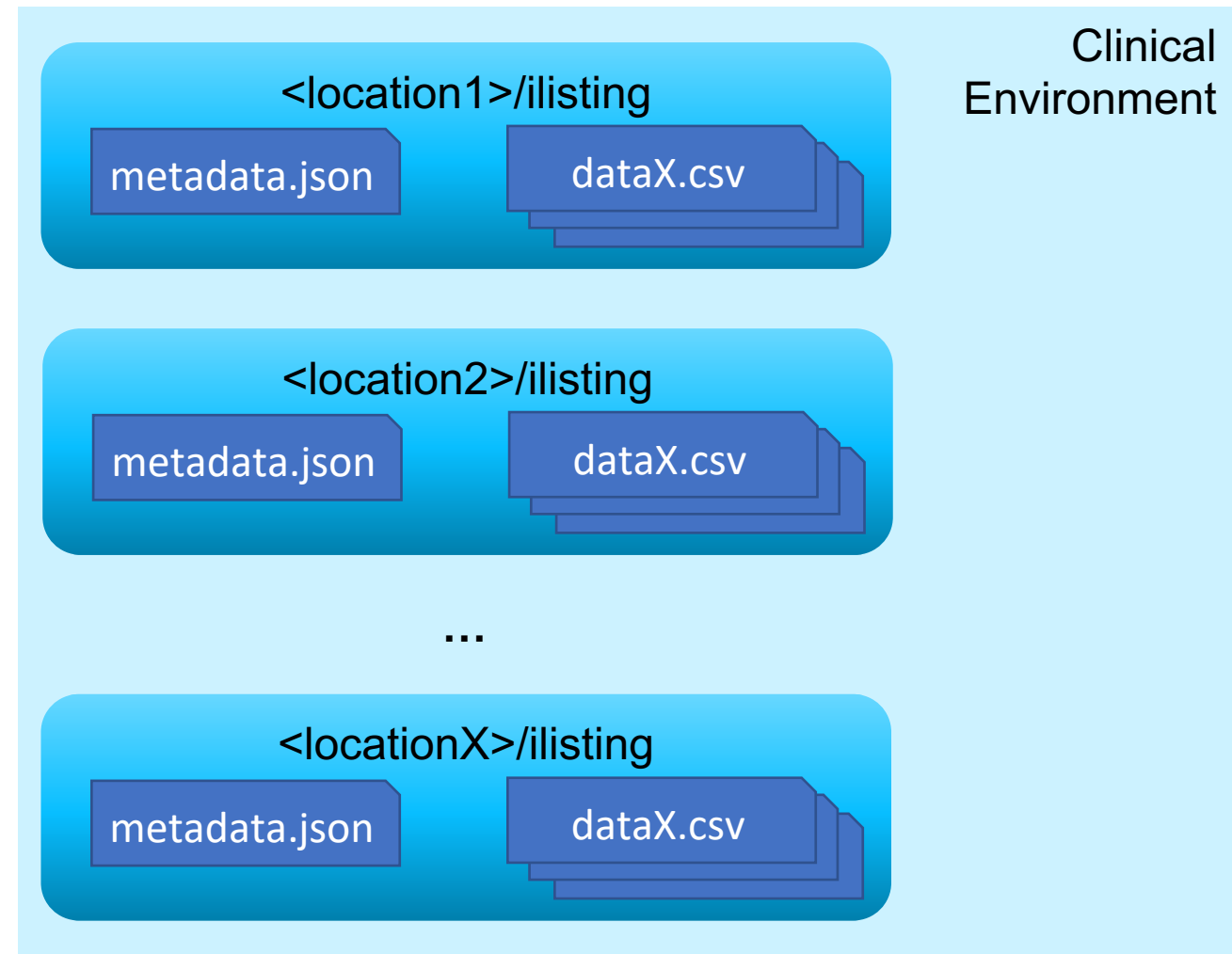
iListing Architecture

API / Data Access

- Storage in Clinical Environment along other study data
- Medical Writing get read-only access granted for specific study(s)
- Generic location through “PATH”-parameter

<https://ilisting.cnb/?path=.../results/ilisting>

- API call via POST request
 - Provide URI sftp://<user>...
 - Single Sign-On under development
- API is inhouse developed





iListing Architecture

Frontend / Visualization

- Frontend reads “Metadata.json” + “subjects.csv” (for global subject filters)
- Display of Subject for filtering
- Display of all Listings
 - onClick -> load & display Listing

The screenshot displays the 'Listings' section of the iListing frontend. It features a dark-themed list of listings, each with a title and a subtitle. A 'Subject Filter' overlay is visible on the right side, showing a search bar and a list of subject IDs.

Listings

- Listing 16.1.4/1: Enrolled subjects by center (all enrolled subjects) (cont.)with sub-title
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- Listing 16.2.3/1: Analysis sets (ITT analysis set)

Subject Filter

Select Subject(s) [Search Icon]

- 01-701-1015
- 01-701-1023
- 01-701-1028
- 01-701-1033
- 01-701-1034
- 01-701-1047
- 01-701-1097
- 01-701-1111
- ...



iListing Architecture

Security

- Data Flow
 - Only stored in Clinical Environment
 - Temporary load to local browser
 - No data storage locally
 - Table data loading just after view request
- Security
 - Study Data Access managed through clinical environment
 - Login, only if access to study, data will be loaded





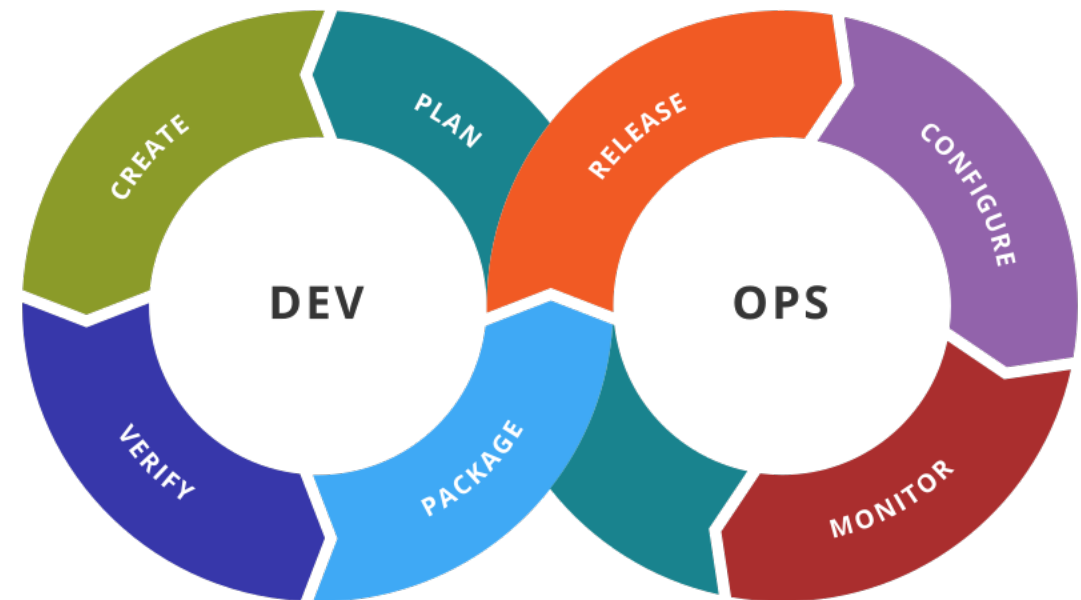
DevOps

Development & Release Pipeline

DevOps

Development & Release Pipeline

- Pilot / Draft
 - Plan: change request list
 - Create: development
 - Verify: checks
 - Package/Release: upload GitLab, run pipeline
 - Configure: n.a.
 - Monitor: n.a.



Kharnagy, [CC BY-SA 4.0](https://creativecommons.org/licenses/by-sa/4.0/), via Wikimedia Commons



DevOps – Plan

GitLab – Documentation of Issues & Features



- ✓ Enter issues/features
- ✓ Assign people
- ✓ Include discussions
- ✓ Follow implementation
(mentioned in commits,
pull-requests, merges)

Update to new YAVIN adapter

#69 · opened 1 week ago by Katja Glass

Download Disclaimer

#68 · opened 2 weeks ago by Katja Glass

feat: add download all button

#59 · opened 3 months ago by Amrit Singh

feature

DevOps – Code Development

VSCode & NPM

- SAS backend scripts are developed in Clinical Environment
- Frontend is developed locally, code uploaded to cloud
 - Code storage, version control etc. in GitLab
 - Development with Visual Studio Code (nice IDE)
 - Command line tools for easy development and package management (NPM)
 - Download and install packages in specific version
 - Run development server (npm in built services)



```
render() {  
  return (  
    <div className="fullHeight" onMouse  
      <Sidebar.Pushable as={Segment}  
        <SideNavigation />  
        <Sidebar.Pusher className="  
          <ContentPane />  
        </Sidebar.Pusher>  
        <SideNavigationRight />  
        <ModalIssues/>  
        <ModalTableInfo/>  
      </Sidebar.Pushable>  
    )  
  )  
}
```

DevOps – Code Development

GitLab – Version Control



- ✓ What has been added?
- ✓ What has been removed?
- ✓ Which files changed?
- ✓ Easy rollback



```

59 59      }
60
61      this.setState((prevState) => ({ isLoading: !prevState.isLoading }));
62  }
63
64  handleLogoutSubmit() {
65      this.props.updateLogin(null);
66      this.setState((prevState) => ({ isLoading: !prevState.isLoading }));
67  }
68
69  keyPress(e) {
70      @@ -99,7 +102,11 @@ class LoginAndLoad extends React.Component {
71
72      </tr>
73      <tr>
74          <td>
75              <Button fluid onClick={this.handleLoginSubmit}>
76                  <Button
77                      fluid
78                      onClick={this.handleLoginSubmit}
79                      className={this.state.isLoading ? "loading" : ""}
80                  >
81                      <Icon name="sign-in" /> Login
82                  </Button>
83              </td>

```

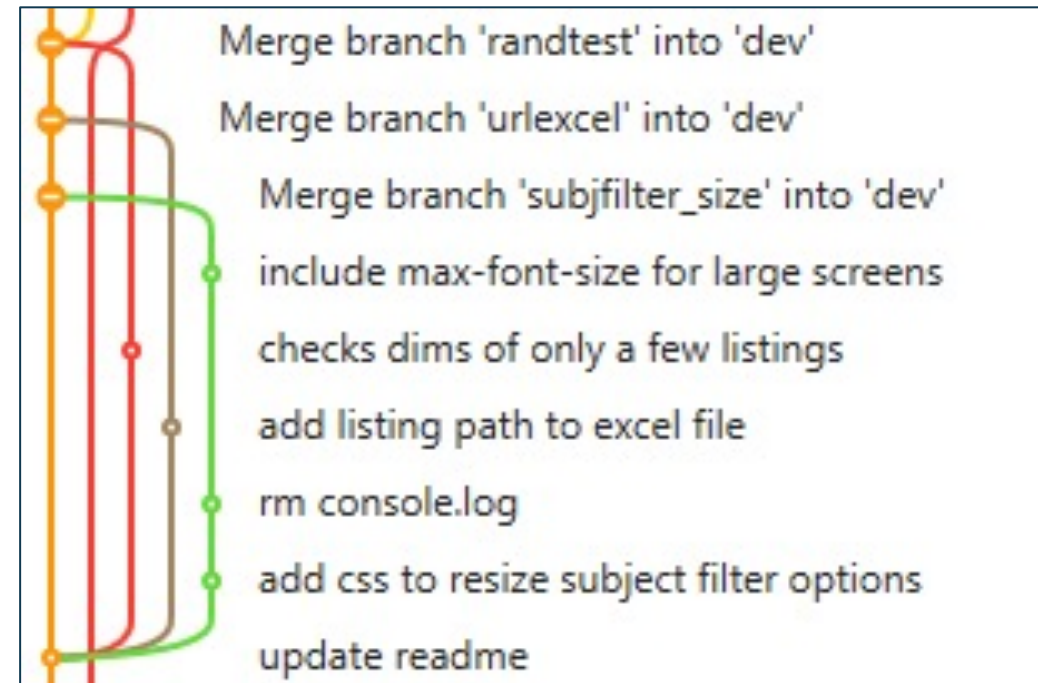


DevOps – Code Development

GitLab - Branches



- ✓ Independent development of features
- ✓ Checkout features, decide on include/skip
- ✓ Merge through Pull-Requests



Cypress

- ✓ Setup tests along with code
- ✓ Test code in GitLab
- ✓ Execution interactively or on command line

```

4 describe("General Checks", function () {
5     const iListings = new Page();
6     const env = Cypress.env("ENVIRONMENT");
7
8     it("Check Layout - open panes", function () {
9         cy.visit("/");
10        cy.get('#contentPane').should('be.visible');
11        cy.get('#leftNavigationPane').should('be.visible');

```

The screenshot shows the Cypress test runner interface on the left and the application being tested on the right. The test runner window is titled 'iListings' and shows a list of tests under 'General Checks'. The tests are as follows:

Test Name	Status
Check Layout - open panes	✓
Check Layout - closed pane	✓
Invalid Login - no credentials	✓
Invalid Login - no username	✓
Invalid Login - no password	✓
Invalid Login - short username	✓
Invalid Login - short password	✓
Invalid Login - invalid credentials	✗
Invalid Login - user with no access	✗

The application being tested is 'iListings' and is running on 'http://localhost:3000/'. The application interface shows a 'Listings' section with a 'Please login first' message, a 'Login' form with fields for 'CWID' and 'Password', and a 'Watch demo video' button. The application also has a 'Docs' link and an 'Additional features' section.

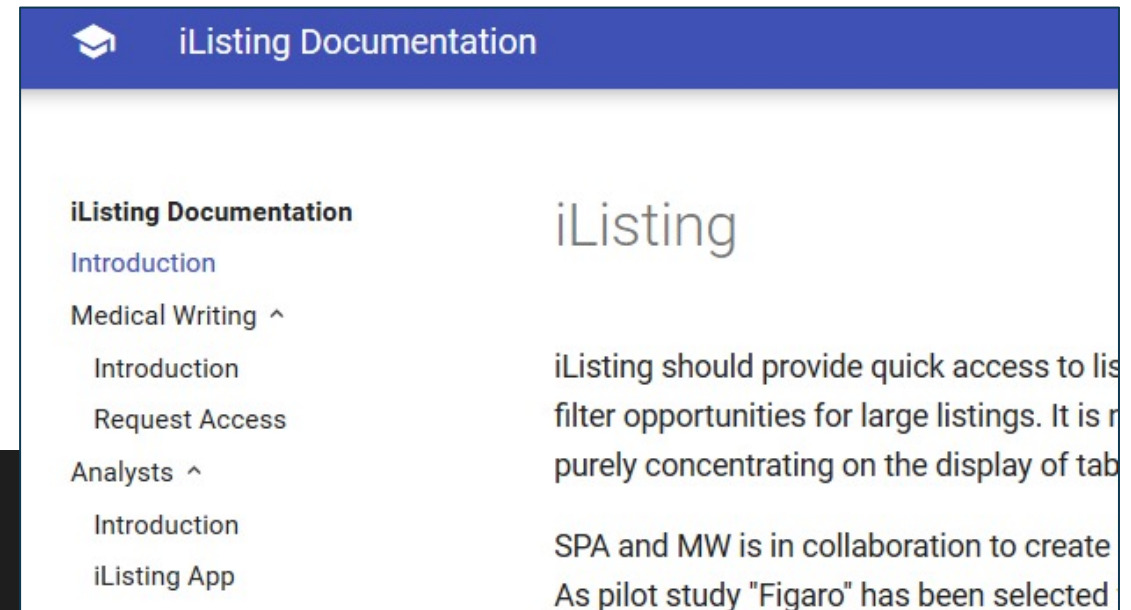


DevOps - Documentation

GitLab Pages and MKDocs (Documentation Webpage)

- ✓ Documentation
- ✓ Use MKDocs for documentation
 - ✓ Markdown content
 - ✓ Compilation to Website
- ✓ Release of website with GitLab Pages

```
33 # Page tree
34 nav:
35   - Introduction: index.md
36   - Medical Writing:
37     - Introduction: mw_introduction.md
38     - Request Access: mw_ro_instructions.md
39   - Analysts:
40     - Introduction: spa_introduction.md
```

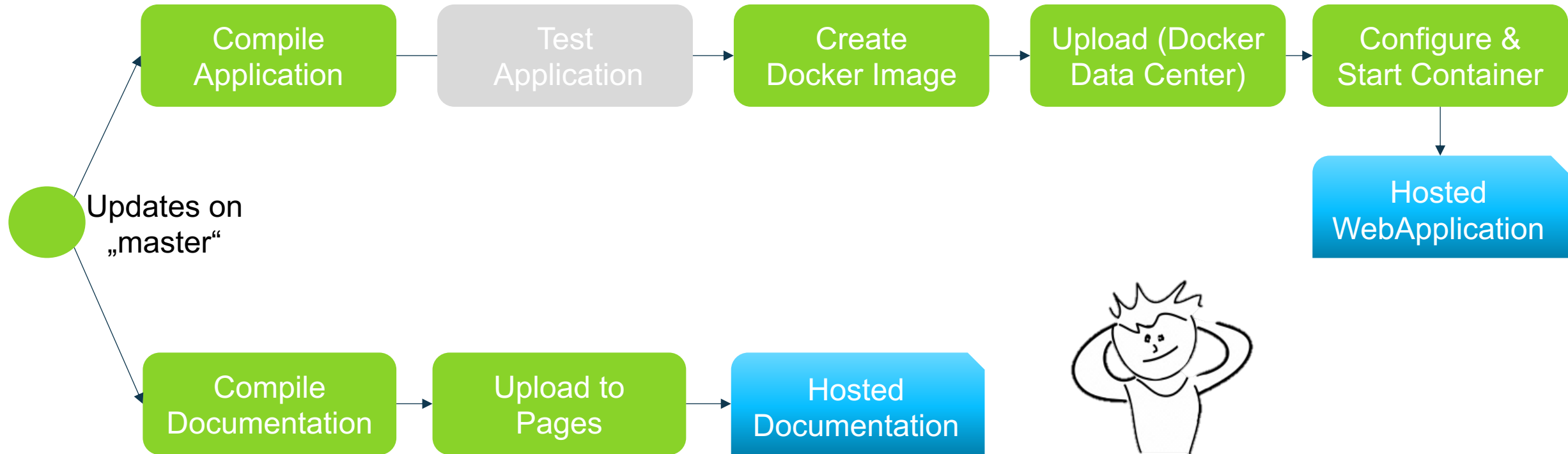


DevOps – Package & Release

GitLab Pipelines



- ✓ Run tasks one after the other with conditions
- ✓ Workflow support defined through “.gitlab_ci.yml”





DevOps – GxP Validation

Plans for GxP validation

- SAS backend, specific SOP for macros
- Frontend and API
 - Bayer tools & guides for agile GxP validation
 - Jira and GitLab (currently)
 - Transition phase to Azure DevOps and GitHub
- Risk assessment, user acceptance testing, user stories, tracking ...





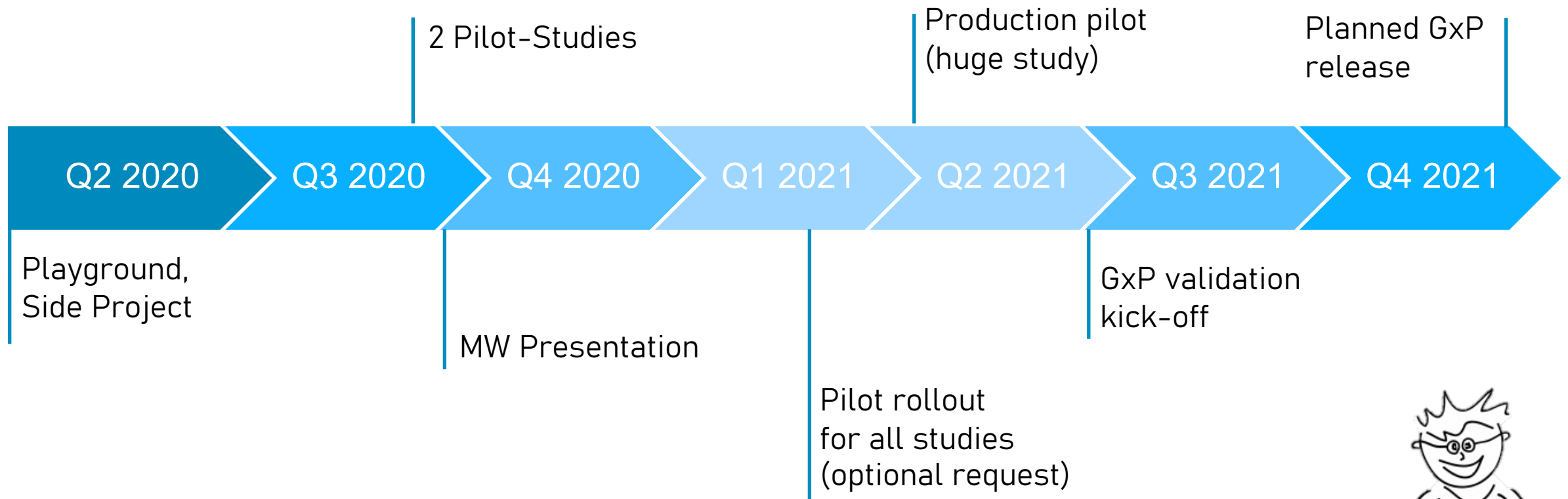
Timeline & Status

Project Progress



Project Progress

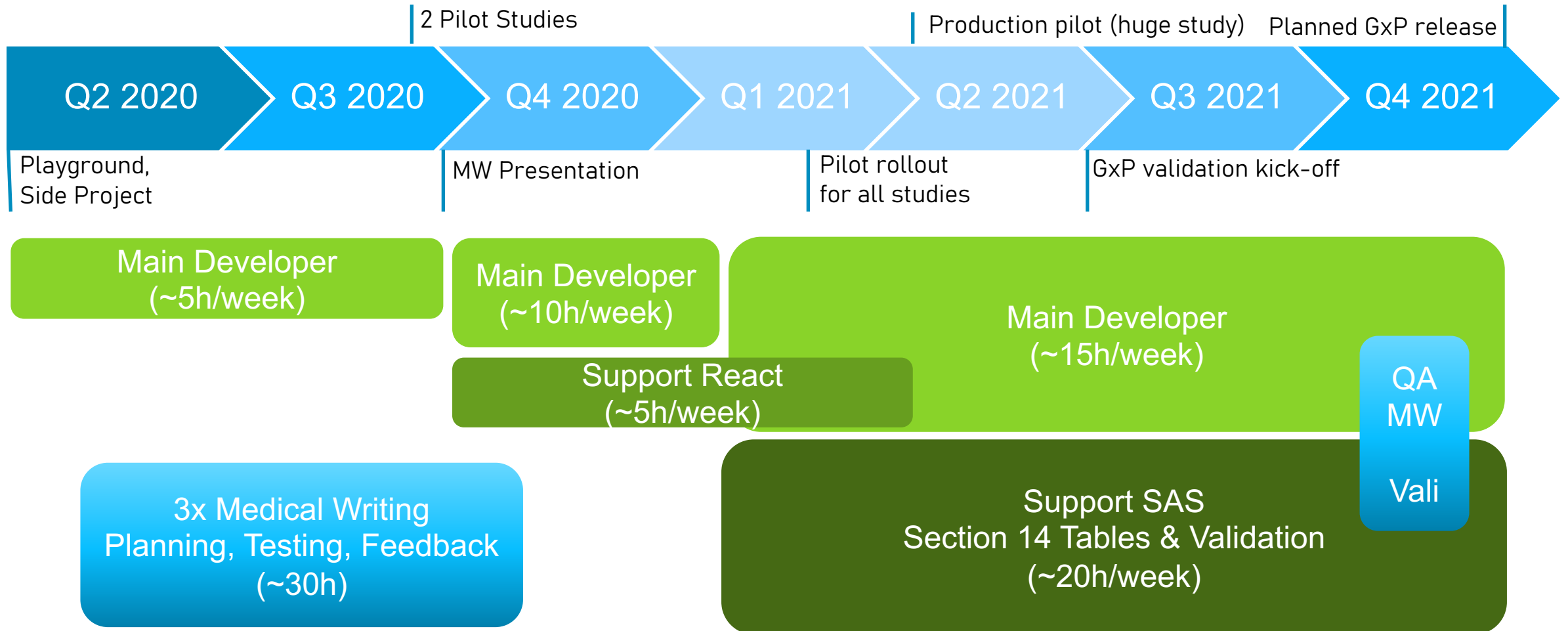
Timeline





Project Progress

Resources





Project Progress

Challenges

- Programming: performance
- Security: no separate storage
- Architecture: new read-only access for Medical Writing in clinical environment
- GxP validation:
 - Complex processes, require different departments (QA)





Summary

Summary

- Web technology provided fancy opportunities
 - Provide available outputs for better use
 - With little effort & flexible design -> huge benefit
 - DevOps with Pipelines quick update/test/release
-
- Small project to get happy Medical Writers





Thank you!



Bye-Bye

