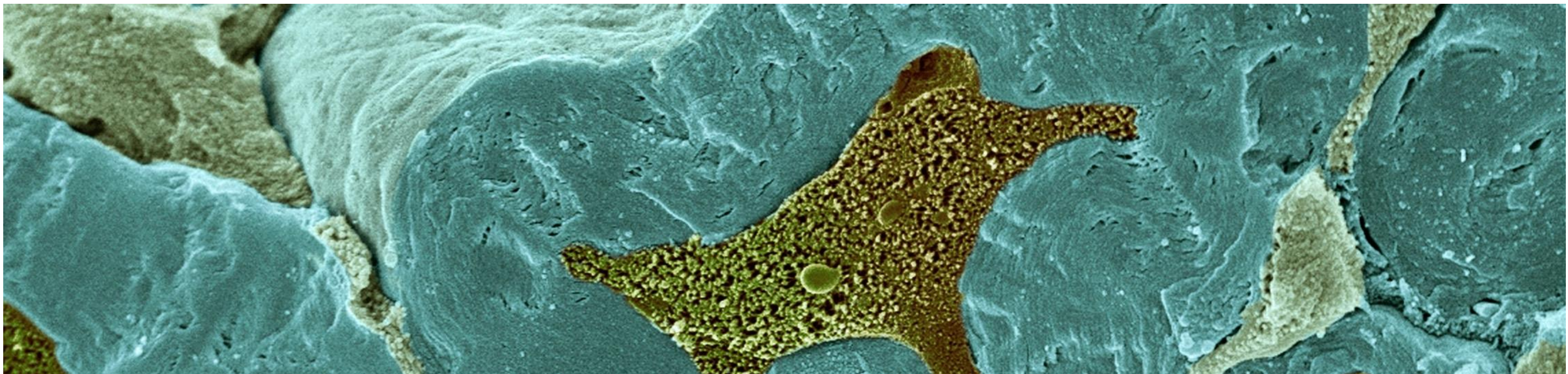


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Improving clinical operational insights delivery to different levels of leadership seniority using shiny-based automation

Paper AD21

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Nerve fibers

Janssen Research & Development, LLC
5-8 November, PHUSE EU Connect 2023

Agenda

- | | | |
|----------|--|-------------------------|
| 1 | Delivery of Clinical Operational Insights | Presenter Elena Núñez |
| 2 | Solution Requirements | Presenter Peyman Eshghi |
| 3 | Application And CI/CD Pipeline | |
| 4 | Limitations And Conclusions | |
| 5 | Q&A | |

***Have you ever been asked to
provide update slides on a
project status?***

Unmet Need

Delivery of Clinical Trial Operational Status Updates



Internal sharing of a snapshot of our territory's book of work

- Currently established process:

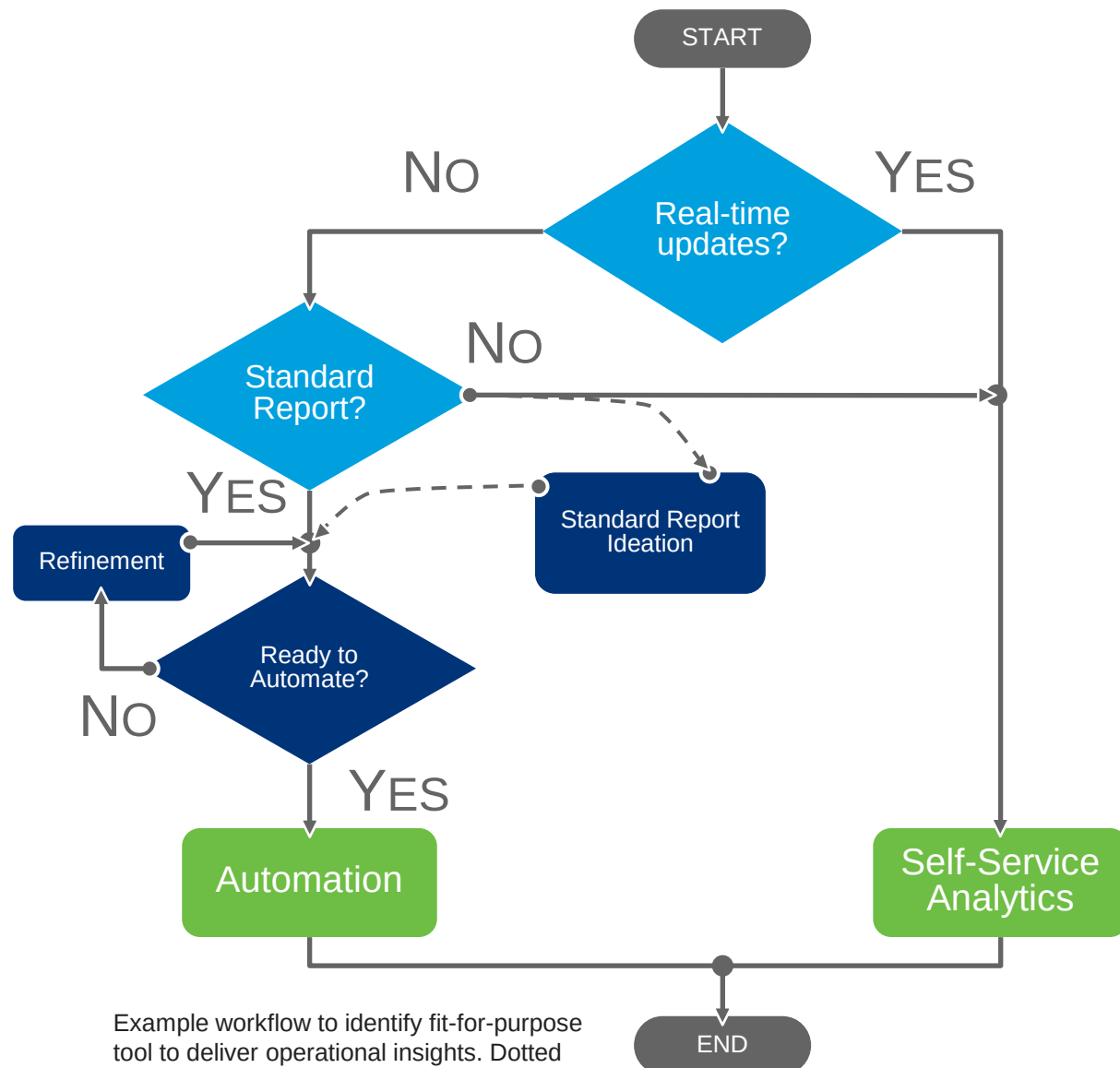
*"We deliver a **monthly, searchable, editable,** report on our ongoing clinical activities **per territory** for internal use."*

Are we ready to automate it?



Project Scope

A Minimal Viable Product (MVP) to Automate Reporting



Example workflow to identify fit-for-purpose tool to deliver operational insights. Dotted lines represent an alternative path.

- Create a **solution** that allows a standard report (slide deck) to be distributed monthly for internal use.
- Deliver the report via e-mail at the beginning of the month.
- Unburden clinical operations professionals.

Summary of Requirements

- Our solution should **automatically** provide monthly reports: **editable, searchable presentations** maintaining the pre-defined look and feel.
- Territory-level reporting should be obtained from established **dashboards** as provided by operational insights delivery team.
- Reports are **not for regulatory** use and should be **timely delivered** at the beginning of each month with an e-mail notification to users.

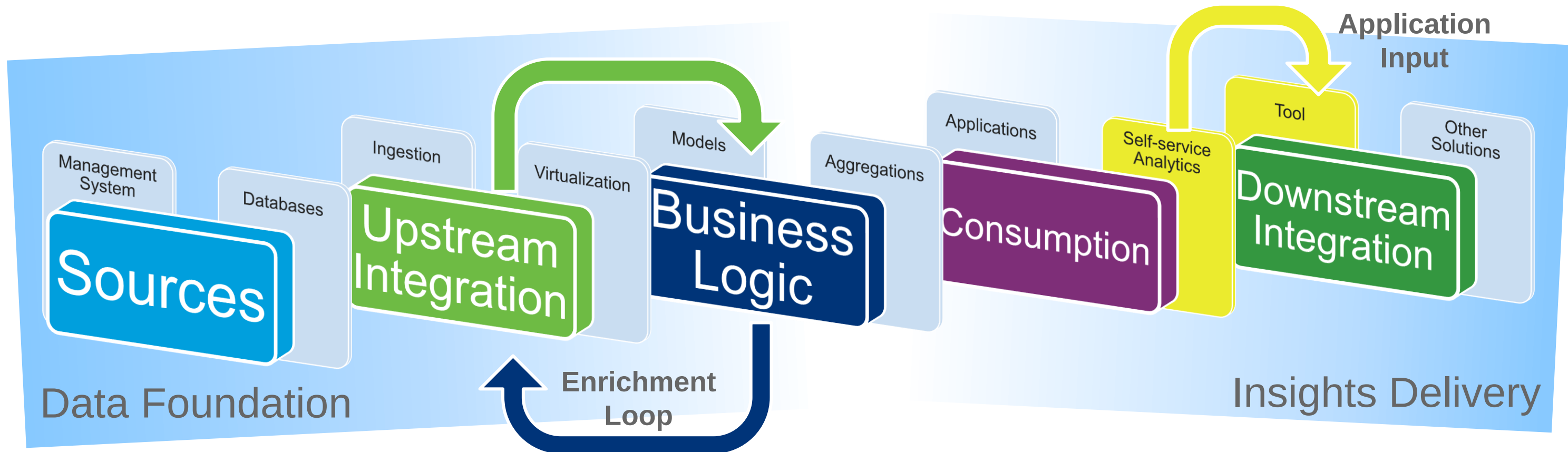
Solution

Skin cells at 20x magnification

Data Integration Overview

Our solution should be feed from a dashboard (self-service analytics)

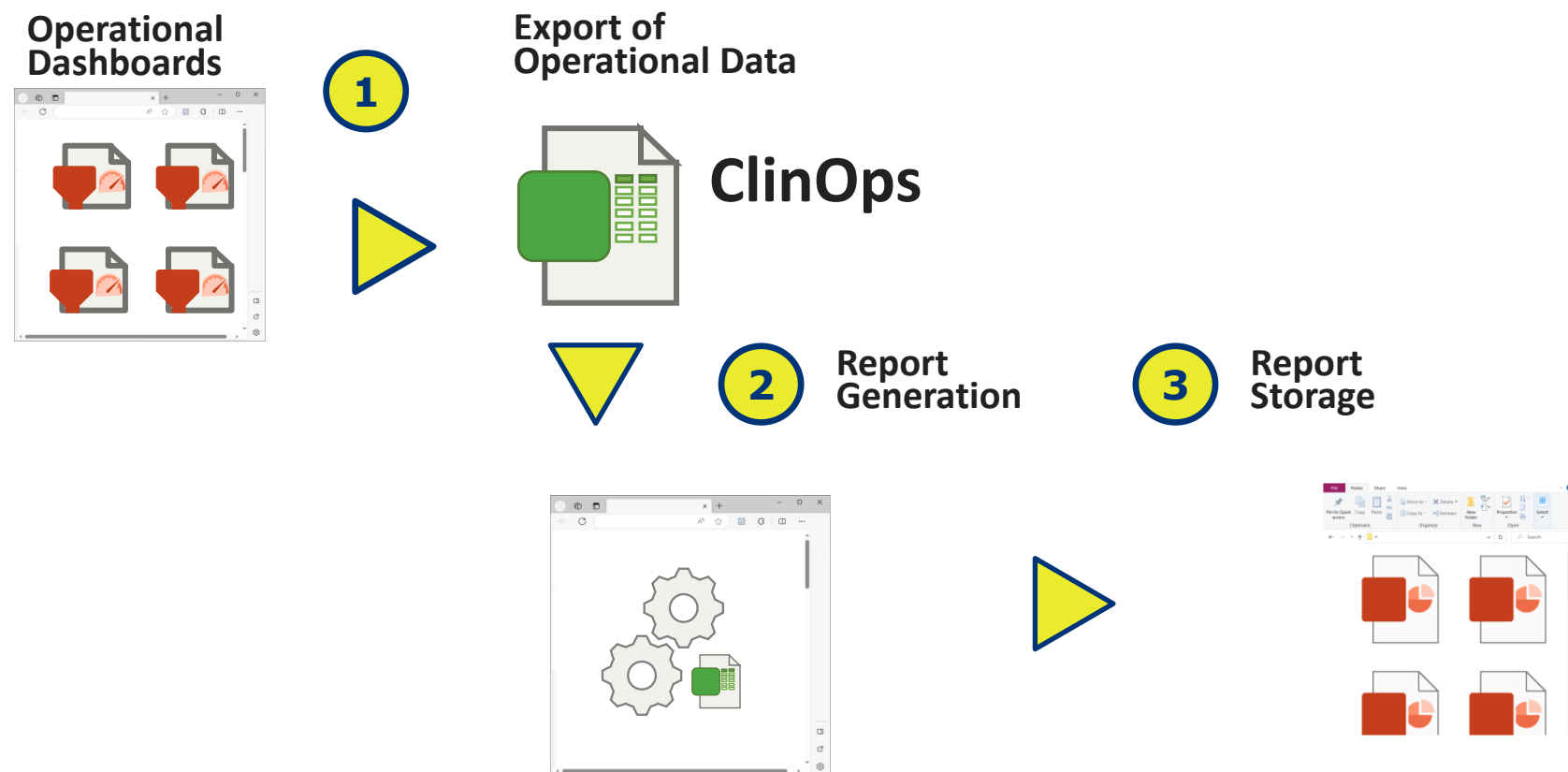
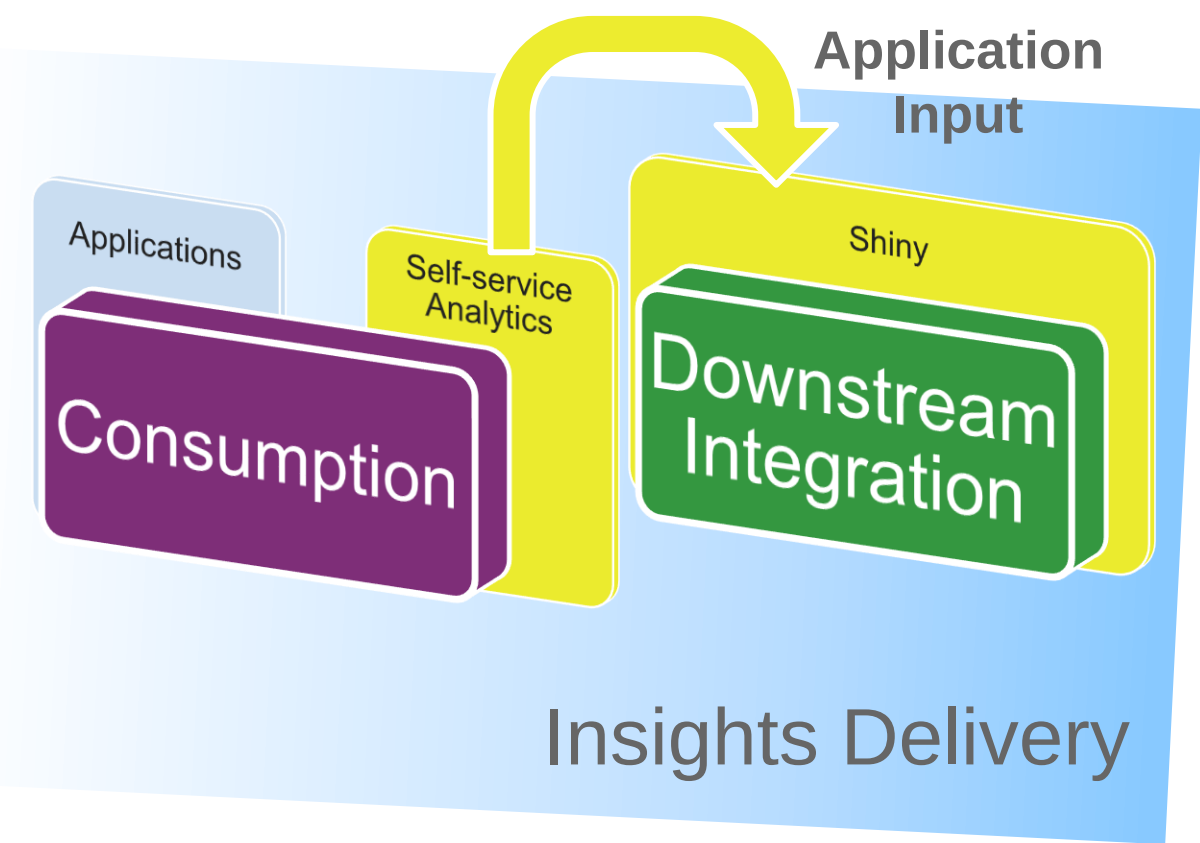
Data Workflow Layers With Examples From Sources to Insights



Application Functionality

Our solution should transform tabulated data into a slide deck

A single dashboard export can be used to generate several reports



Resulting Report And Storyline Breakdown

A territory-specific report is generated, and trials are grouped by area

1 Report Cover & Content



2 Section Dividers



3 One-Pagers: Project Info, Timeline, and List of Sites

Demo-Activity-Identifier-001

Project Information

Date: 01-Apr-2023

Title: Demo Title of Activity

Phase: 1

Status: Completed

Product: Demo Name 1

Type: Demo Type 1

Execution Timeline

Key Milestone

Plan Date

Actual Date

KM1

02-Jan-2020

02-Feb-2023

KM2

03-Jan-2020

03-Feb-2023

KM3

04-Jan-2020

04-Feb-2023

KM4

05-Jan-2020

05-Feb-2023

KM5

06-Jan-2020

06-Feb-2023

KM6

07-Jan-2020

07-Feb-2023

Site Status

Institution Name

Additional Info Demo 1

Milestone Demo 1

Milestone Demo 2

Milestone Demo 3

Milestone Demo 4

Summary Demo 1

Summary Demo 2

Summary Demo 3

InstitutionDemo 1

Additional Info Demo 1

01-Jan-2020

01-Jan-2021

02-Feb-2022

20-Feb-2023

1

0

1

Total

-

-

-

-

-

1

0

1

Built-in demo for informational purposes only using synthetic data examples

janssen

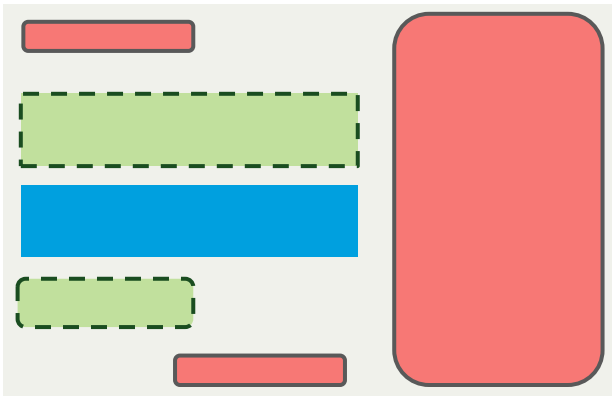
PHARMACEUTICAL COMPANIES OF

johnson-johnson

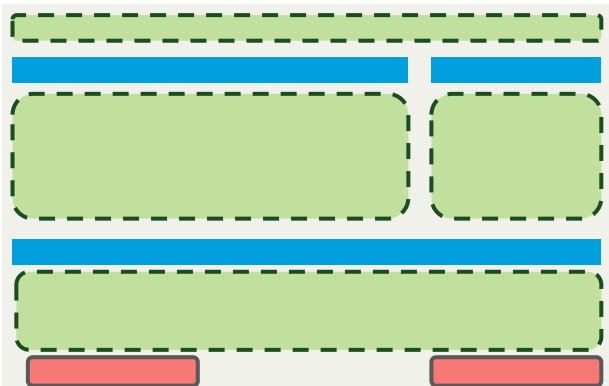
Application Design

Slide templates coupled with an extract-transform-load (ETL) module

- Cover example



- One-pager example

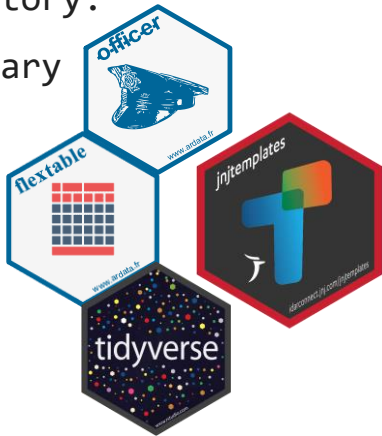


- Pre-requisites

-  Branding / Notes
-  Fixed Content
-  Placeholders

- ETL module

1. For each report, territory:
2. Create cover & summary
3. For each part, section, one-pager:
Map content to placeholders
4. Export presentation



- Deliverable

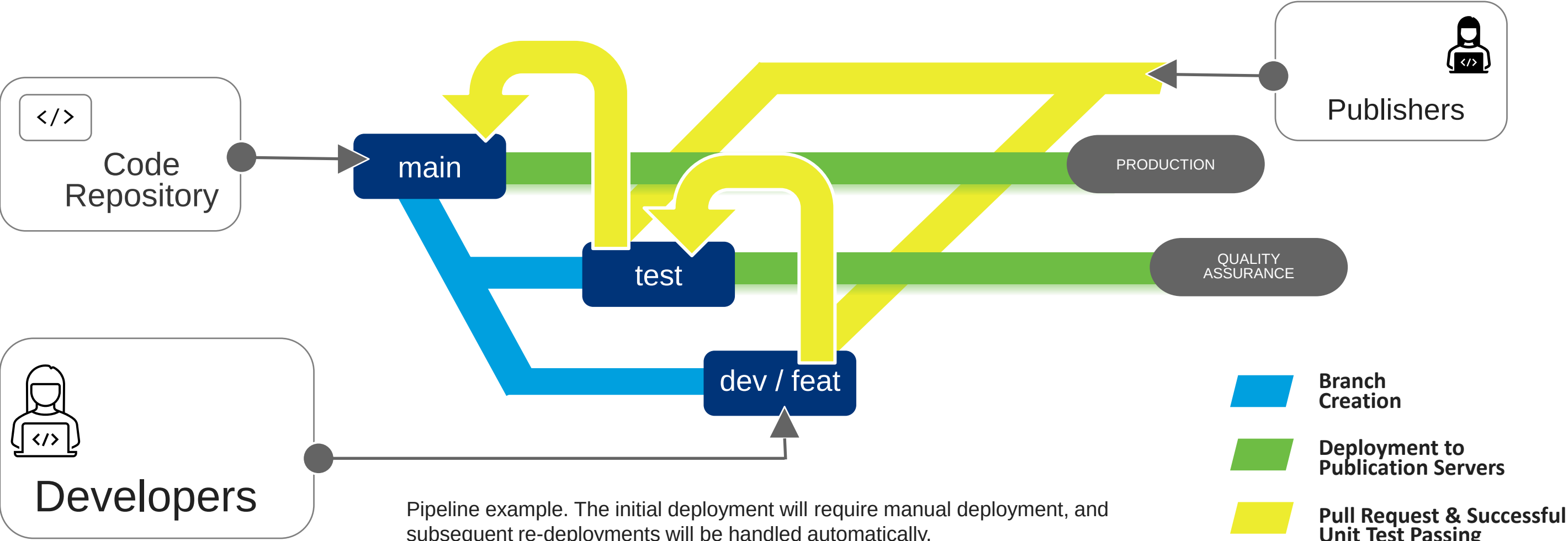


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jnjtemplates is a Janssen internal R package to facilitate Shiny application development. Also, officeverse (<https://ardata-fr.github.io/officeverse/>) and tidyverse (<https://www.tidyverse.org/>) package collections are used.

Continuous Deployment (CD) Pipeline

Push-based mechanism to continuous deployment



Risk: allowing non-publisher accounts to publish content.
Mitigation: enable a mechanism **to review/approve** merge requests to main or test branches.
Include **test automation** as part of CD pipeline.

Extended Scope and Broad Adoption

- **Minimal Viable Product:** We deliver a first version within 3 months over several cycles of process simplification and content refinement.
- **Global Adoption:** Reports are available monthly and are offered 'as-is' to different teams from countries across NA, EMEA, and APAC.

130

REPORTED STUDIES IN
AVERAGE PER
TERRITORY

43h

TIME SAVING (HOURS) IN
AVERAGE PER TERRITORY
EVERY MONTH

3

TIME (MONTHS) TO
FIRST RELEASE

20+

NUMBER OF
TERRITORIES
(COVERAGE)

“Automatic reports helped us to increase transparency on our clinical trial activity by communicating monthly updates in a timely manner”

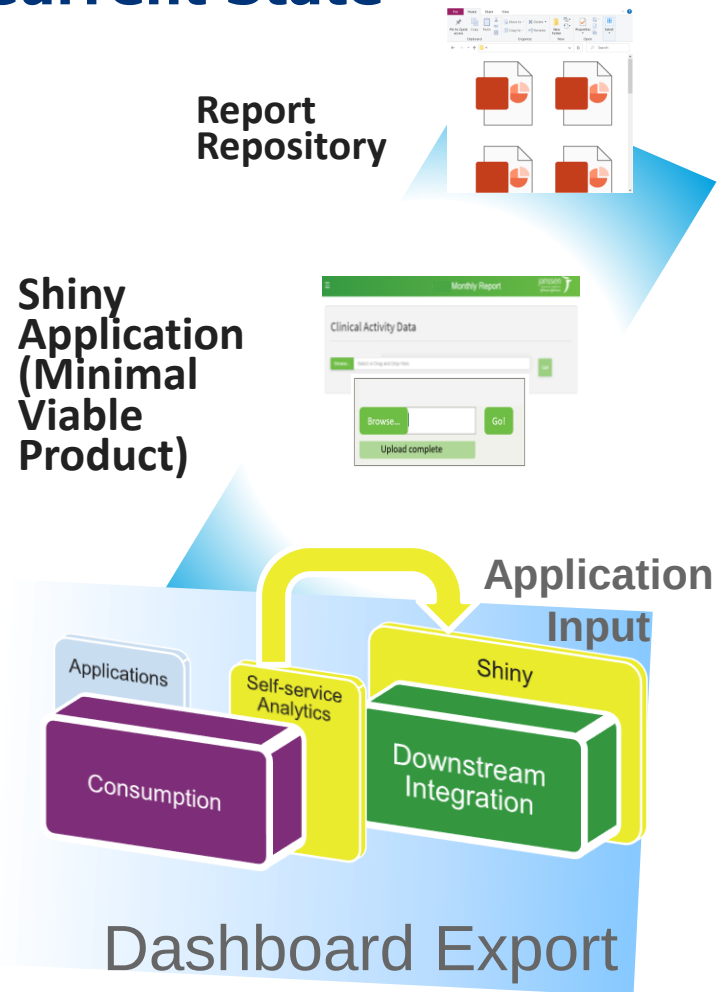
Territory Head testimonial

“Time-consuming manual preparations for monthly reports were eliminated for our whole team!”

Functional Manager testimonial

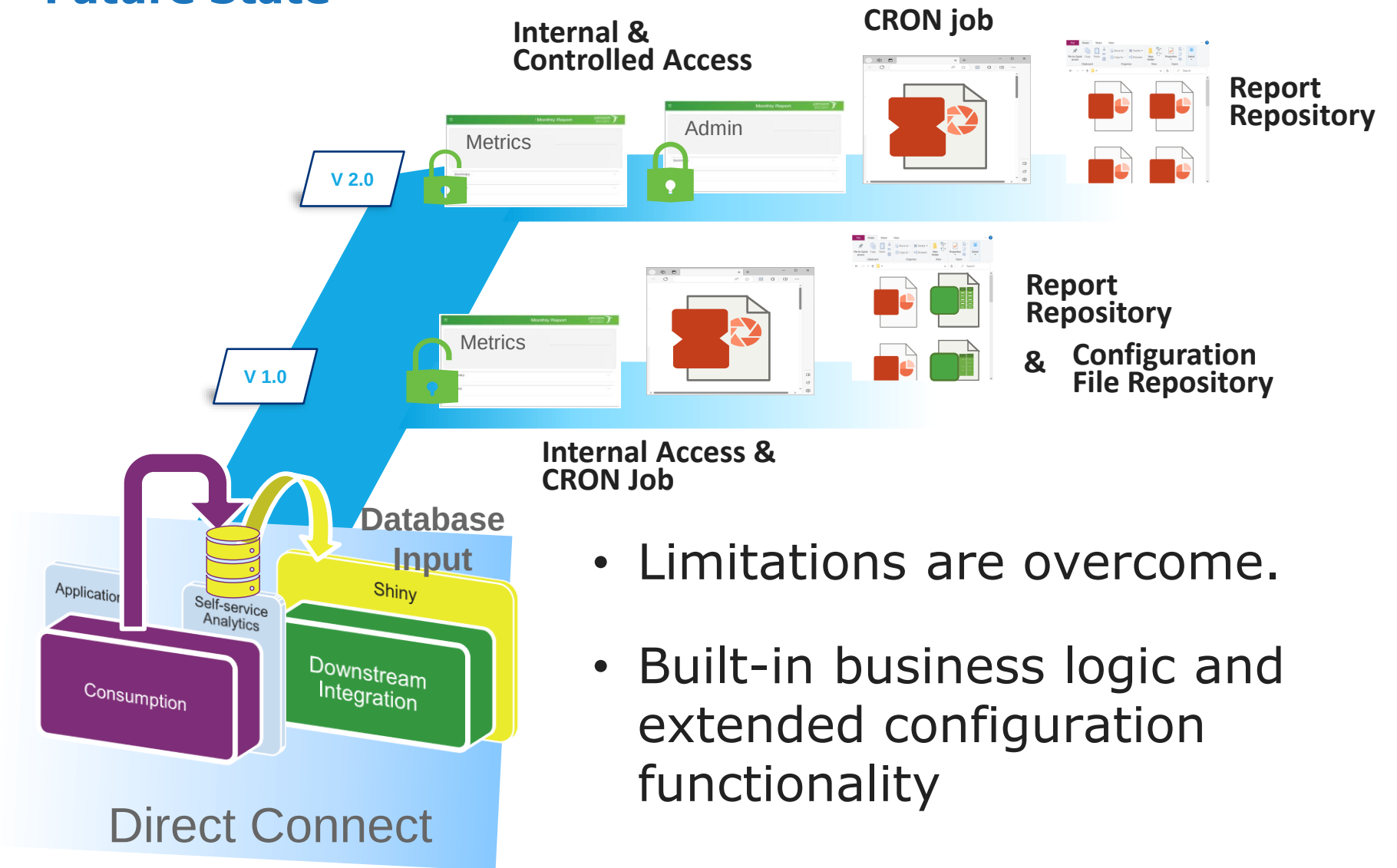
Main Limitations And Future Enhancements

Current State



- File size limitation & dashboard dependency

Future State



- Limitations are overcome.
- Built-in business logic and extended configuration functionality

Lessons Learned

Go simple, go visual. Incremental innovation for continued support.

1. **A simple solution.** We opted for a simple Shiny app which facilitated the CI/CD pipeline implementation.
2. **Visual familiarity.** Keeping the look and feel helped with user community adoption.
3. **Step-wise approach.** Our Minimal Viable Product focused on a single report for early adopters only.
4. **Design for success.** As much as possible feed your application from consumption layer to avoid re-implementation of business logic and establish a robust liaison with source data (for instance, a database connection).
5. **Open to feedback.** Automation may uncover errors alien to the application, familiarity with data uptake at the source level could help support activities. Keep track of Frequently Asked Questions to plan for new features (for admin roles).

Final Remarks

Effective elimination of communication bottlenecks



We facilitated globally adopted **recurrent communications** (status reports, newsletters, business meetings) by providing automated reports using slide decks.



Our solution has a **cost-avoidance value**, and we use available tools and in-house infrastructure and continuous practices to **minimize development cost and burden**.



Some use cases are better supported by dashboards and others may benefit more from a summary presentation. This experience can help us to delineate the boundaries between those use cases and **provide guidance for novel initiatives**.

Acknowledgments

Our team and collaborators span across several communities

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Data Integration



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James Gallagher
Clinical Innovation

Steering Committee



Dante Di Tommaso
Tech Solutions



Peyman Eshghi
Tech Solutions



Disa Lee Choun
Operational Insights



Elena Núñez
Operational Insights

Communities

- R Development & IT Support
- Clinical Operations
- Operational Insights
- Innovation & Communication

Q&A

Thank you for your
attention!

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