

# HSRAA24 CONFERENCE

24-26 SEPTEMBER | EDINBURGH



Arkivum

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## WORKSHOP

### DATA DYNAMICS: MASTERING GXP MIGRATION IN THE PHARMA INDUSTRY

PRESENTED BY:

FREDERIK SØRENSEN & PAWEL RUCKI

BASE LIFE SCIENCE



# Agenda

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13.00-13.45 **Introduction to Migrations**

13.45-14.00 Coffee Break

14.00-15.00 **Breakout Session (3 groups)**

- Migration Resources: 10 min group work / 10 min discussion
- Data Quality Assessment: 10 min group work / 10 min discussion
- What does good look like: 10 min group work / 10 min discussion

15.00-15.45 **Focus session: Migration Implementation & Execution**

- IT issues and how to avoid them
- Enrichment and cleaning strategies
- Go-live strategies
- Post-migration issues / workload

15.45-16.00 Coffee Break

16.00-16.40 **Breakout Session**

- What would you ask your migration vendor(s) in an RfP process? 10 min group work / 10 min discussion
- What should you (as a company) supply to the potential migration vendors during an RfP process? 10 min group work / 10 min discussion

16.40-17.00 **Wrap-Up**

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# Who we are

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Frederik, with a DPhil in Statistics from Oxford, has led complex GxP migration projects. At Base life science, he was in charge of Migration Delivery Excellence before becoming Head of AI and Automation.



Pawel brings a robust 15-year background in clinical operations to the table, with a specialized focus on Trial Master File (TMF) systems over the past 7 years. His expertise includes facilitating multiple migrations from a business perspective. Currently, at Base life science, Pawel leads the GxP Records Management Excellence.

# Today's goals

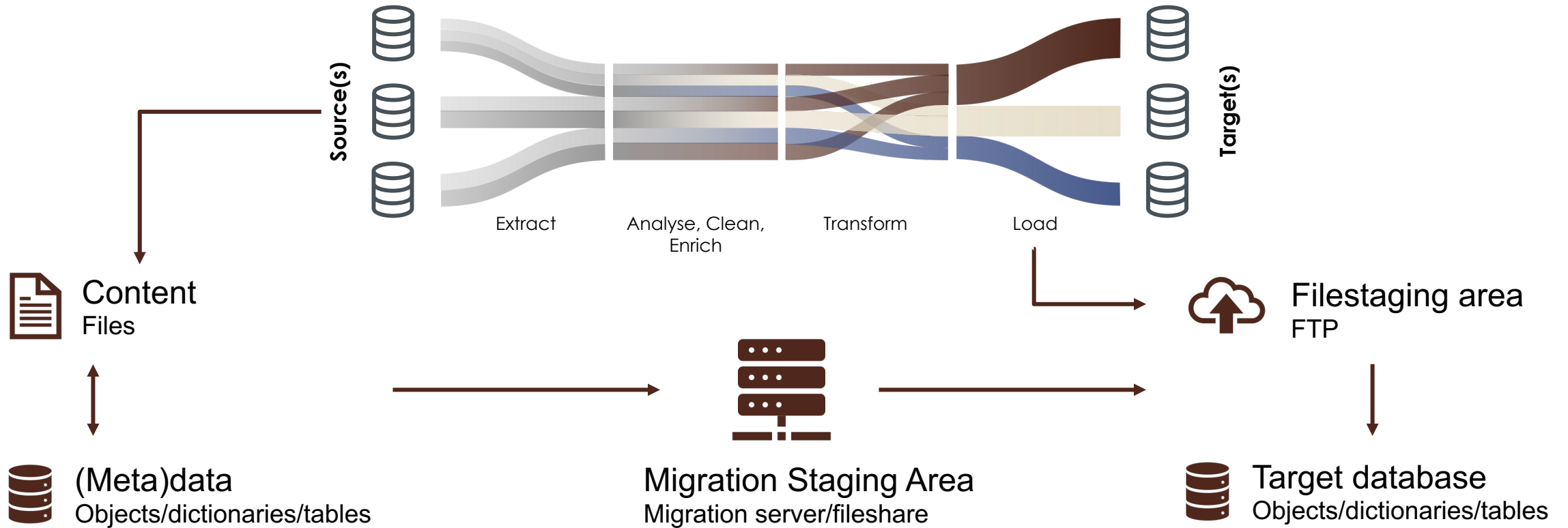
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1. To understand principles of migration
2. To be able to assess complexity of migration
3. To be able to structure a migration project
4. To be able to write and select migration vendor

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# INTRODUCTION TO MIGRATIONS

# Migration Process

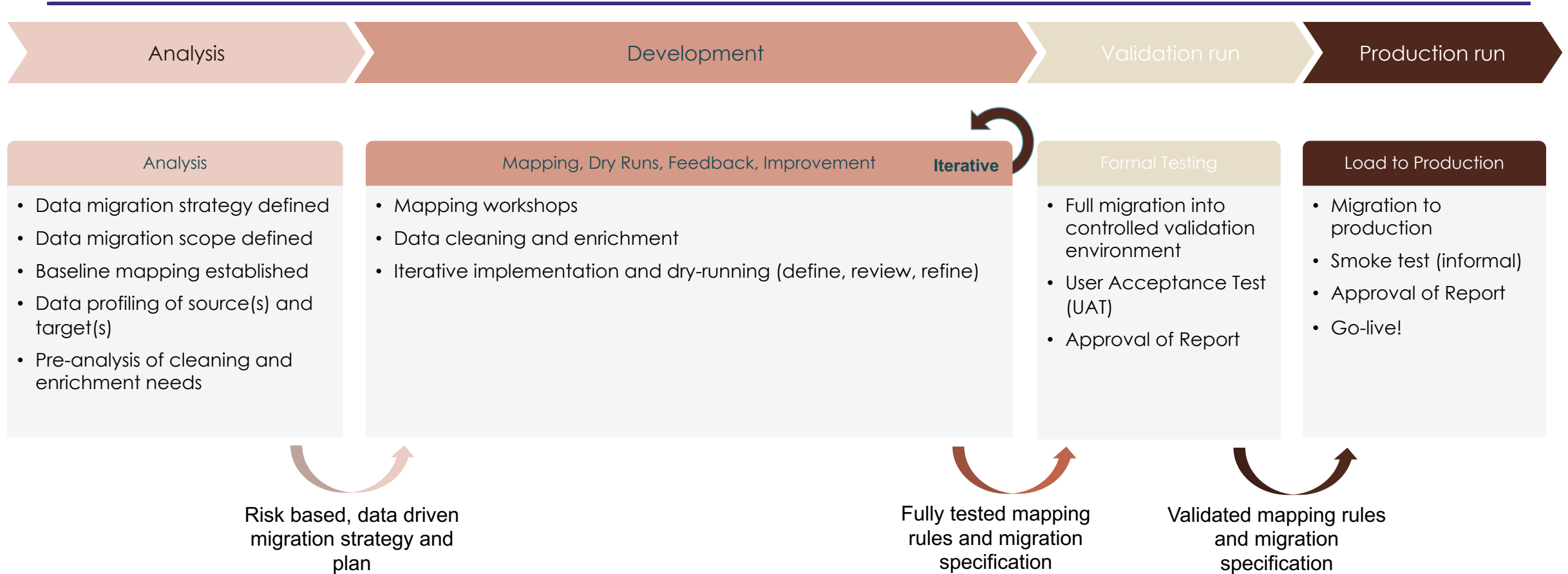


# Defining the Migration Scope

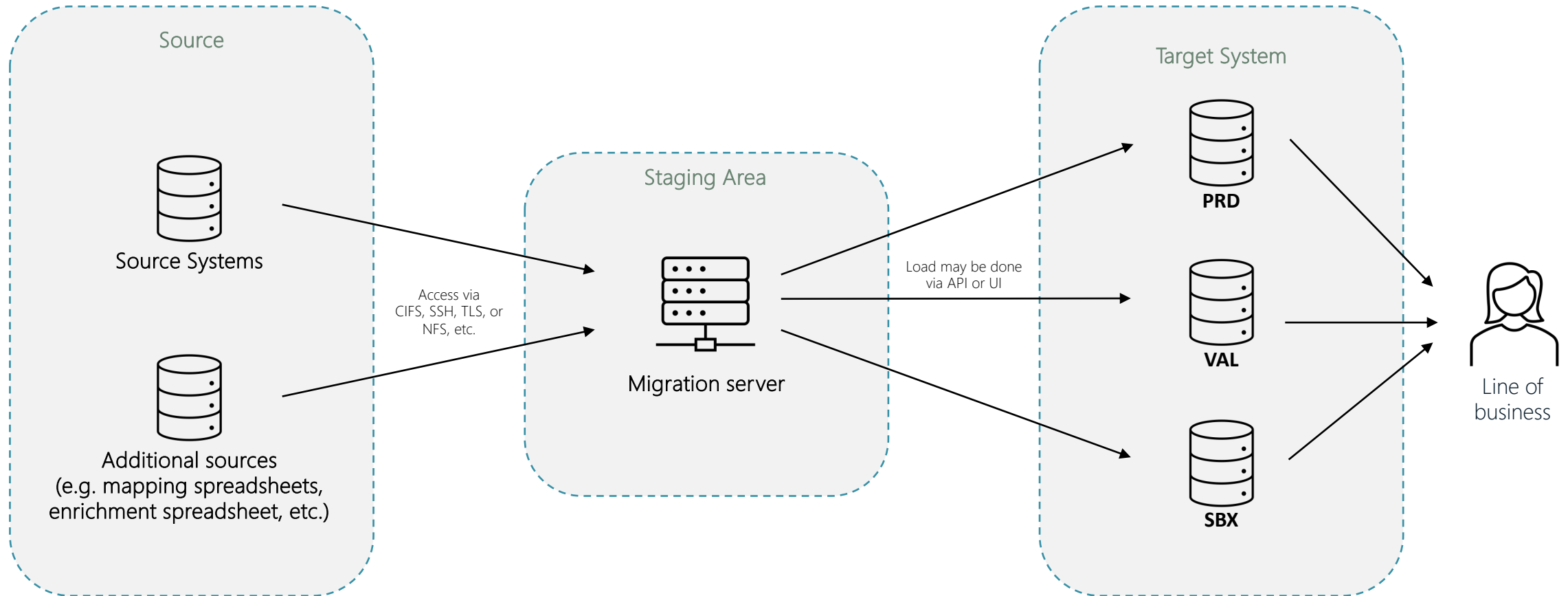
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- Documents
  - Content
  - Metadata
  - Renditions
  - References to other documents
- Meta(data)
  - Reference to other records
  - Attachments
- Users
- Audit Trail

# Migration Process – Vocabulary



# IT Infrastructure



# Migration Effort Drivers

## High effort drivers

These increase the migration workload for both LoB and BASE team significantly and should be clarified as early as possible



Data governance



Number of data sources



Source database structure



Unavailability of data



Number of object types



Source/target complexity gap

## Medium effort drivers

These are important and should be considered but only after analysis of high effort driver have been exhausted



Number of metadata fields



System usage variance

## Low effort drivers

These have very little impact on effort required for migration to be successful compared to other drivers

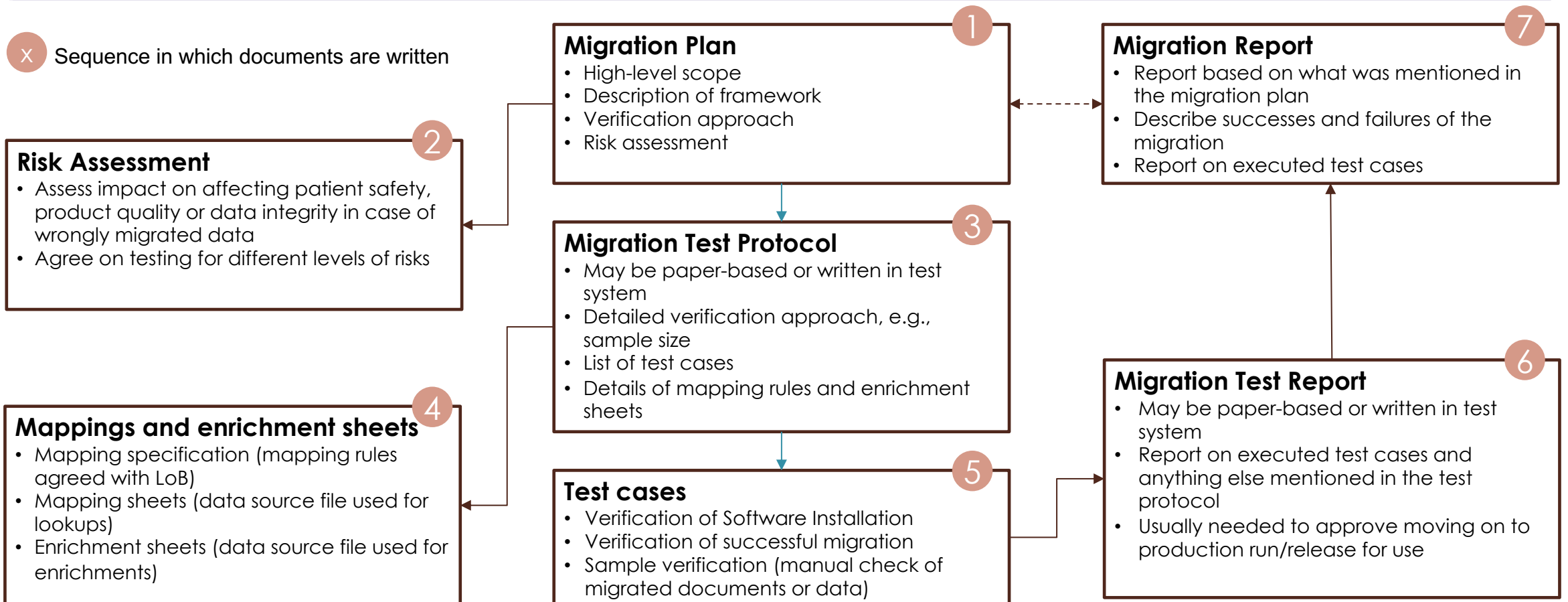


Number of object records



Number of documents

# Migration Documentation



13.45-14.00

# COFFEE BREAK

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Breakout Session

# GETTING STARTED

A background network diagram with blue and red nodes connected by thin lines, set against a light blue gradient.

Question – please discuss in groups (10 min)

# WHO SHOULD YOU INVOLVE IN MIGRATION?

# Who should you involve in migration?

## Business

- Defining requirements
- Validation and Testing
- Change Management
- Data Ownership and Quality
- Risk Mitigations

## IT

- Technical environment readiness
- Security and compliance
- Backup and Recovery
- Troubleshooting and Support
- Risk Mitigations

## Data Science

- Data Profiling and Assessment
- Mapping and Transformation
- Data Reconciliation
- Implement and execute Migration
- Risk Mitigations

## Validation & QA

- Requirements Verification
- Test Planning and Strategy
- Data Integrity and Accuracy Testing
- Functional Validation
- Defect Tracking and Resolution

# Why business user engagement?

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- **Ensures Data Accuracy and Relevance** - Business users know their data best, helping to identify critical elements, verify accuracy, and ensure only relevant data is migrated.
- **Aligns Migration with Business Needs** - Their involvement ensures the migration aligns with functional requirements, reducing workflow disruptions and better supporting operations.
- **Improves User Adoption** - Participation fosters ownership, making users more likely to adopt the new system smoothly and reducing resistance.
- **Identifies Data Dependencies and Relationships** - Business users understand how data is linked across processes, ensuring relationships between data sets are maintained during migration.
- **Reduces Errors and Misunderstandings** - Involving business users reduces errors from misinterpreting data or business rules, ensuring accuracy and avoiding incorrect assumptions.
- **Facilitates Better Testing and Validation** - Users help test migrated data in real scenarios, ensuring it functions correctly and improving the final product's quality.
- **Fosters Collaboration and Buy-in** - Involving business users fosters collaboration between IT and business teams, promoting shared responsibility and improving project success.
- **Improves Process Documentation and Knowledge Transfer** - Business users help document key processes, aiding in training and ensuring essential workflows are preserved post-migration.

Question – please discuss in groups (10 min)

# HOW TO ASSESS DATA QUALITY

# How to assess quality of data?

## Business Use Variation

- Engage with SMEs to understand how different units use the source system

## Completeness

- Check for missing values
- Distinguish between fields that are strictly mandatory and driven "business process" mandatory

## Consistency

- If information is registered on multiple "levels" with relationships – do they match?
- For picklists/dropdowns, are the end-user communities using different "types" of values

## Technical items

- Investigate system behaviour of deleted files, placeholders, etc.

## Validity

- Verify correct use of key fields
- Specific focus on dates, justifications, free-text fields used to capture structured data, etc.

## Variety

- For dropdown/picklist, inspect the unique values
- For date and numerical fields, use histograms or other visualisations (e.g., with groups)

Question – please discuss in groups (10 min)

# WHAT DOES GOOD LOOK LIKE

# What does good look like

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Focus Session

# IMPLEMENTATION & EXECUTION

# Which IT issues can appear during a migration?

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## Incorrect access privileges to source system can lead to wrong scoping

- Insufficient privileges to source database(s) can result in wrong scoping analysis (don't know what we cannot see) and can ultimately have a huge impact on migration budget, timeline or quality.

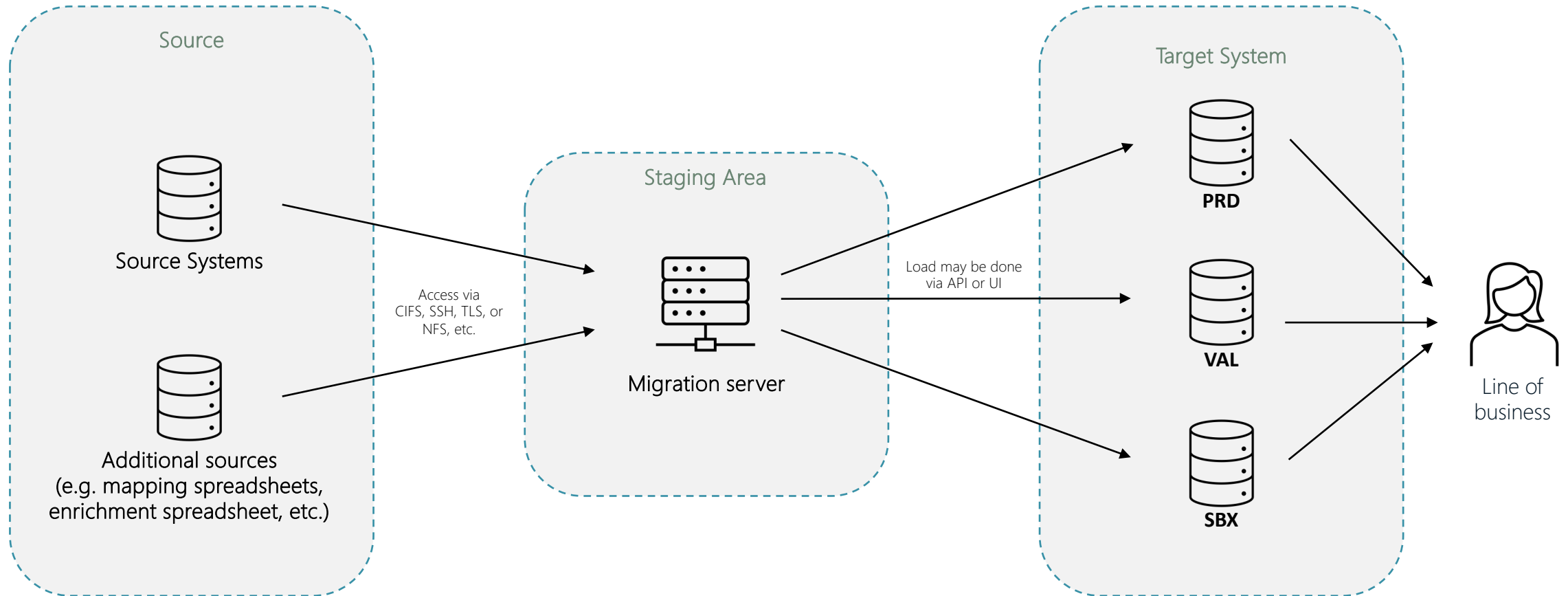
## Access issues can delay project initiation

- Direct access to content in source system(s) is difficult to obtain
- Firewall issues between migration server and source(s) and target

## Misalignment in the IT organisation can lead to critical disruptions

- IT Operations of migration staging area interfering with migration (updates, back-ups, change in protocols)
- Unscheduled maintenance of systems in critical time periods

# IT Infrastructure



# Enrichment and cleaning strategies

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- Balance between time, budget and (perceived) quality
- Set expectations with the business!!!
- Both cleaning and enriching can be done in-system, in-transit or post-migration
  - *Global* data cleaning or enrichment can typically be done more effectively and in a better way in-transit than in-system.
  - *Local* cleaning or enrichment needs (catering to e.g., a specific department) can better be done in-system.
- AI can be leveraged for data enrichment of e.g., document metadata if **incomplete data** is a big issues
  - **Important:** Use AI as input for the enrichment effort, and have the output verified and reviewed by an SME.

# Enrichment and cleaning strategies: Lift-and-shift

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## **Rationale**

- Lower implementation cost
- Less impact on key LoB



## **Project experience**

- LoB not heavily involved in project
- All document and records migrated successfully



## **Impact**

- Unharmonized business process
- LoB frustration post-migration
- New project for data remediation

25

# Enrichment and cleaning strategies: Everything is important

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## **Rationale**

- Ensure high data quality
- Avoid separate business process for migrated records & documents



## **Project experience**

- Extremely heavy for both migration team and LoB to enrich/clean metadata
- Timeline consistently not met due to data complexity live source data



## **Impact**

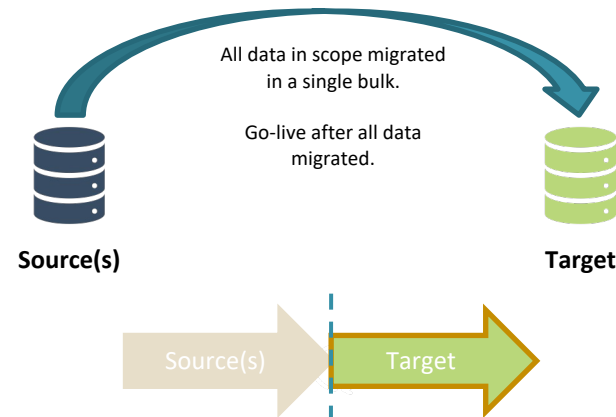
- Extended project budget & timeline
- Ultimately, delta was addresses by shift to “lift-and-shift”-strategy

26

# Migration go-live strategies

## Approach

### Big Bang



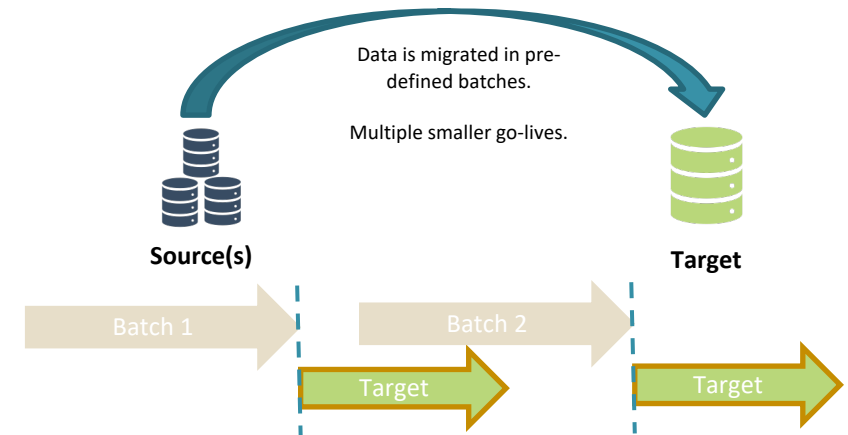
## Pros

Reduced overall implementation time  
"Clean" end-user experience

## Cons

Higher risk of error  
Long downtime during cutover\*  
Full testing in Dry Runs is time consuming and resource intensive

### Phased



Reduced risk of error  
Longer implementation time\*  
Allows more comprehensive testing  
Subsequent batches benefit from previous learnings

Increased scoping complexity  
Process required for dealing with overlapping records  
Reduced downtime during cutovers

# Typical post-migration issues

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- **Data Integrity and Accuracy Issues** - Business users may encounter missing, corrupted, or misformatted data post-migration.
- **Data Duplication or Redundancy** - Duplicate or redundant data can appear, cluttering the system and causing reporting errors.
- **Disrupted Workflows** - Workflows dependent on specific data structures may break if the migrated data isn't aligned correctly.
- **Incomplete Historical Data** - Some historical data may not be fully accessible after migration.
- **Data Access and Permissions Issues** - Users might face access issues or security risks if permissions and roles are not properly configured.
- **Reporting and Analytics Discrepancies** - Reports may not match legacy system outputs due to differences in data formats or calculations.
- **Performance Degradation** - Data retrieval or system performance may slow down if the new environment isn't optimized.
- **Learning Curve and Training Gaps** - Users may require additional training to efficiently use the new system.
- **Unfamiliar User Interfaces** - Users might struggle with a different interface, causing confusion and inefficiencies.
- **Business Rule Misalignment** - Incorrect business rules in the new system can lead to errors in data interpretation or processes.

# Typical post-migration workload

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## System Users (IT / Technical):

- **Data Enrichment and Transformation** - Enhance data by applying business rules, merging external datasets, or updating fields as needed.
- **Final Performance Tuning** - Optimize database and system configurations for efficient data retrieval in production.
- **Backup and Archiving Setup** - Implement automated backups and archive legacy data for compliance or future reference.
- **Monitoring and Alerts Configuration** - Set up real-time monitoring and alerts for system performance and potential issues.

## Business Users

- **Data Enrichment Validation** - Validate that enriched data meets business needs and is accurate.
- **Report Testing and Validation** - Run and verify business reports to ensure accuracy and completeness in the new system.
- **Business Process and Workflow Testing** - Test key workflows to confirm the migrated data supports normal operations.
- **Review Business Rules and Automation** - Ensure business rules and automated processes are functioning correctly post-migration.
- **Data Cleanup or manual enrichment (If Required)** - Perform final data cleanup to remove duplicates or errors in the production environment.

15.45-16.00

# COFFEE BREAK

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Discussion Session

# VENDOR SELECTION

Question – please discuss in groups (10 min)

# WHAT SHOULD YOU ASK THE VENDOR IN AN RFP?

# What would you ask vendor in the RfP

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- **Technical and Compliance Questions**
  - **Compliance:** How do you ensure compliance with GxP regulations during the migration process?
  - **Validation:** What is your approach to validation and qualification of the migration process?
  - **Data Integrity:** How do you ensure data integrity and security throughout the migration?
- **Process and Methodology**
  - **Migration Plan:** Can you provide a detailed step-by-step migration plan, including pre-migration assessment, data transfer, testing, validation, and post-migration support?
  - **Downtime Minimization:** What strategies do you use to minimize downtime and disruption to business operations during the migration?
- **Experience and References**
  - **Past Projects:** Can you provide case studies or references from similar GxP-compliant migration projects?
  - **Team Expertise:** What are the qualifications and experience of the team members who will be working on this project?
- **Risk Management**
  - **Risk Mitigation:** How do you identify and mitigate risks associated with the migration process?
  - **Contingency Plans:** What contingency plans do you have in place in case of unexpected issues?
- **Support and Training**
  - **Post-Migration Support:** What kind of post-migration support do you offer?
  - **Training:** Do you provide training for our staff to ensure smooth operation post-migration?
- **Cost and Timeline**
  - **Cost Breakdown:** Can you provide a detailed cost breakdown for the entire migration process?
  - **Timeline:** What is the estimated timeline for the completion of the migration?

Question – please discuss in groups (10 min)

# WHAT INFORMATION SHOULD YOU PROVIDE TO VENDOR?

# What information should you provide to a Vendor

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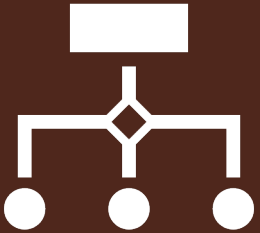
- **Project Overview:**
  - Brief description of the migration project and its objectives.
  - Who are the stakeholders involved in the migration?
  - Who will be responsible for extracting data?
- **Data Volume and Types:**
  - Total data size and number of records.
  - File types (extensions)
  - Do you want to include minor versions, drafts, audit trail
  - Types of data to be migrated (structured, unstructured, etc.).
- **Current Environment (Source):**
  - Description of the existing data sources and systems (including versions and configurations).
  - Any relevant architecture diagrams.
- **Target Environment:**
  - Specifications of the target system (cloud, on-premises, or hybrid).
  - Requirements for the target architecture.
- **Migration Scope:**
  - Specific datasets or applications to be migrated.
  - Any data transformations (enrichment) or integrations needed.
- **Data Quality Considerations:**
  - Current state of data quality and any necessary cleansing or validation steps.
- **Regulatory Compliance:**
  - Any compliance requirements that need to be addressed (e.g., GDPR, HIPAA).

# What information should you provide to a Vendor

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- **Timeline and Milestones:**
  - Desired start and end dates for the migration.
  - Key milestones and deadlines.
- **Budget Constraints:**
  - Any budget limitations or expected cost range.
- **Stakeholders and Communication:**
  - Key stakeholders involved in the project.
  - Preferred methods of communication and reporting.
- **Testing and Validation:**
  - Expectations for testing the migrated data.
  - User acceptance testing (UAT) requirements.
- **Support and Training:**
  - Requirements for post-migration support and training for staff.
- **Additional Requirements:**
  - Any other specific needs or expectations you have for the vendor.
- **Anything else?**
  - ...
  - ...
  - ...

# Migration Program: Critical factors for success



## Migration Program Management

For a migration program of this magnitude, it is vital to have dedicated migration program management with a solid understanding of the migration approach.

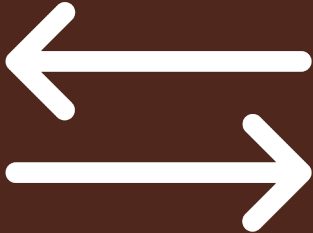
This can not only reduce cost, but also ensure streamlined reporting, planning and communication.



## Data-driven migration strategy

A big risk for migration programs is building a strategy based on too many assumptions. When these are violated, it severely impacts both budget and timelines.

With a thorough Phase 0 we ensure that the migration strategy is data driven, and key issues, interdependencies and risks are mapped out up-front.



## Change Management

Change management plans and communication that are specific to the different (groups of) source systems can greatly improve the adaption of the to-be process in Veeva Vault Quality.

Our Change Management Consultants understands both Veeva and our migration approach and can provide the necessary support.



## Streamlined validation approach

When migrating multiple systems, it is important to streamline the validation approach and documentation.

This is only beneficial in case of an audit, but also if decisions made as part of the migration needs to be revisited later on.