



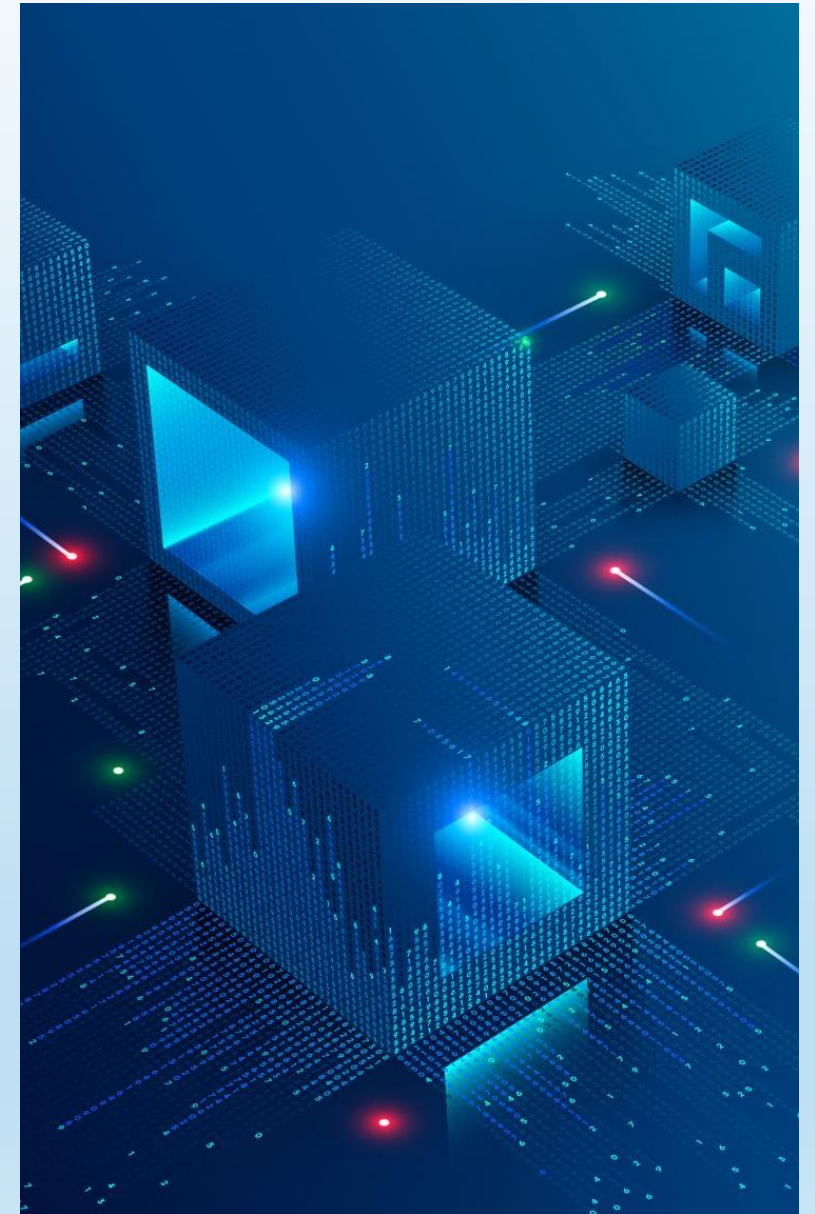
## **Veterinary Medicine Certification and Regulatory Information System**

SECURE, WEBBASE CLOUD NO CODE/LOW CODE SOLUTION



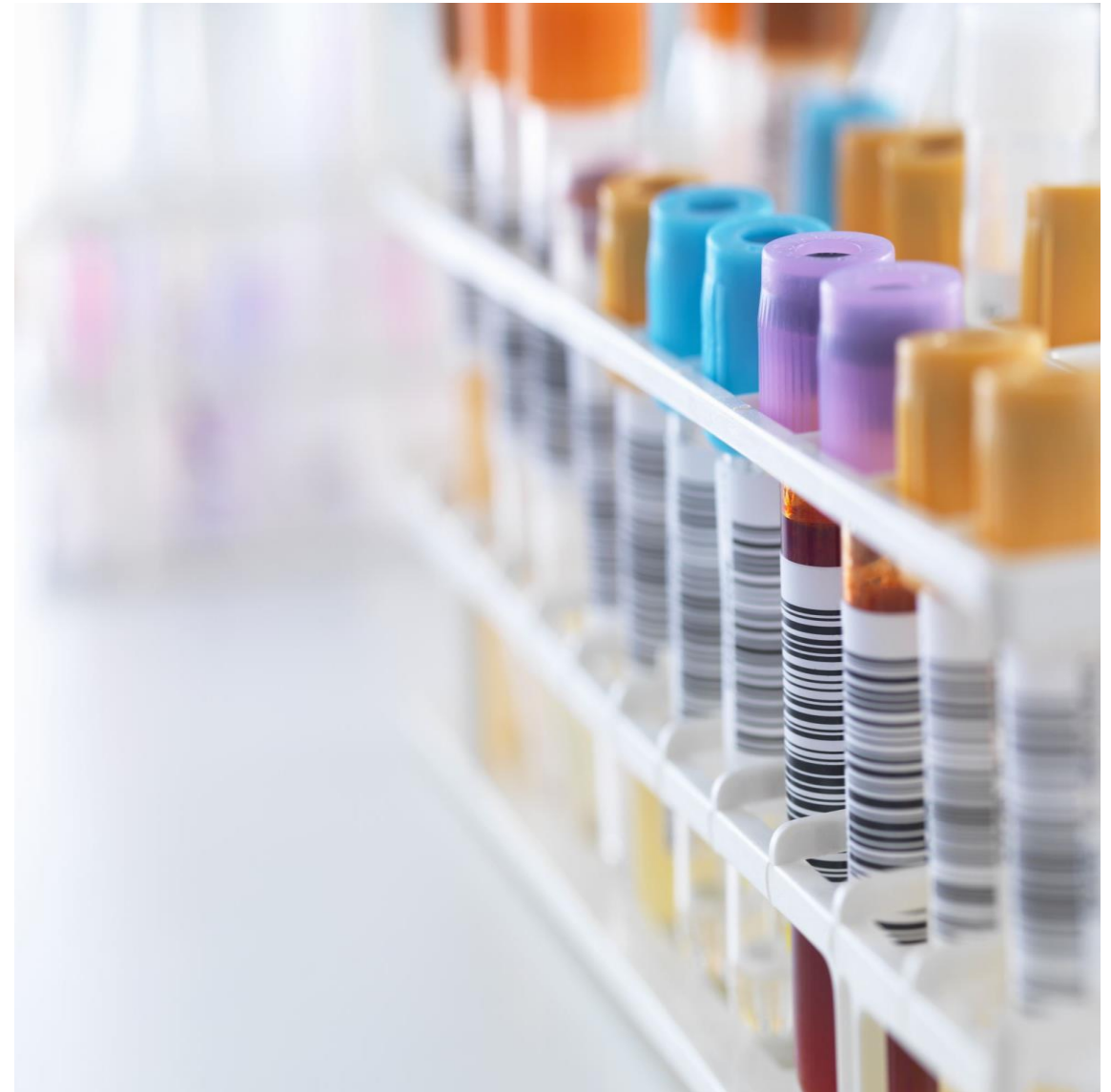
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## INTRODUCTION

**VEMCRIS** is a secure web-based, cloud, and low code/no-code platform designed to enable national regulatory agencies to ensure the safety and efficacy of veterinary medicines, a pivotal element in safeguarding animal health, public health, and environmental well-being. Through a comprehensive licensing process, the system enables scrutiny and approval of veterinary products, guaranteeing that they meet standards for safety and effectiveness.





## PROBLEM STATEMENT



Lack of automation and digitization in the veterinary medicine approval process



Lack of effective monitoring and surveillance leading to unapproved, counterfeit veterinary medicines in the market



Poor regulatory framework for veterinary medicinal products hence impact on livelihood for farming communities in sub-Saharan Africa



Lack of collaboration platform on the approval of veterinary products in the region



Inadequate ICT infrastructure and data security concerns



## BENEFITS OF THE SOLUTION

Better user experience - Dossier Chunking

Accessibility & Compatibility

Scalability & Flexibility

Efficiency and Reliability

Security and Maintenance

Ease of Deployment

Serverless Architecture

Low code/No code Solution

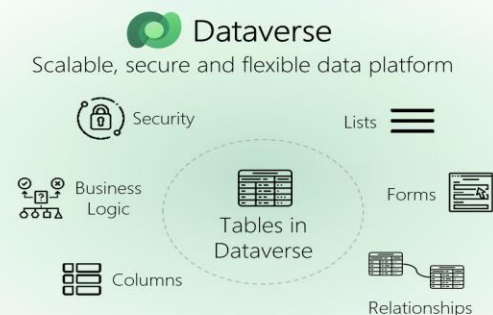
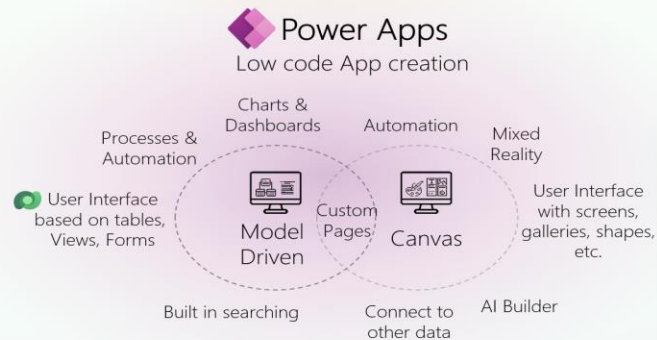
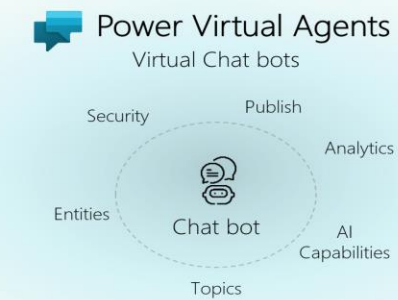
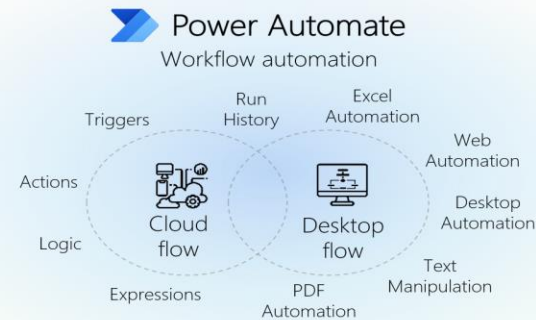
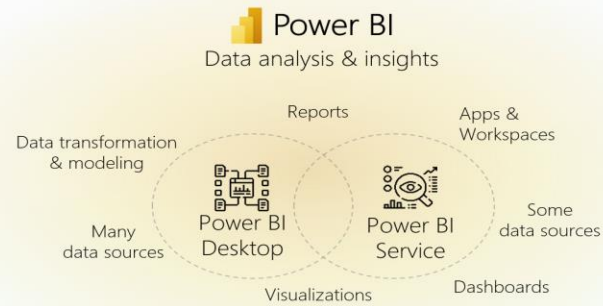


# TECHNICAL ARCHITECTURE

Dynamics 365 extension and customization

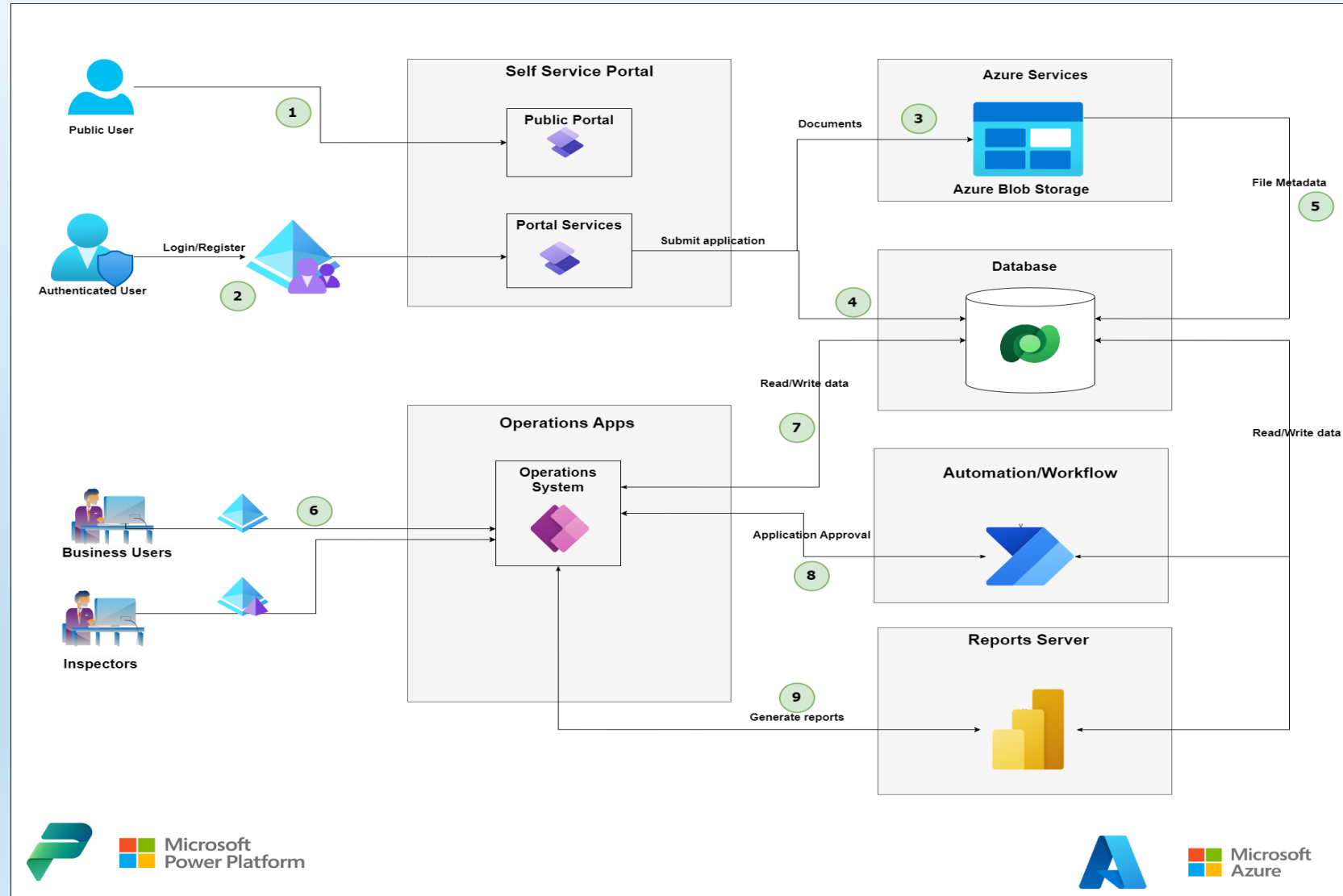
Microsoft 365 native integration

## Microsoft Power Platform





# HIGH-LEVEL BUSINESS ARCHITECTURE



1 - The public portal is available to anonymous users and has access to basic information(view registered veterinary products).

2 - Access to services and submission of applications is available to authenticated users using Azure AD B2C through self-registration and their accounts approved from the operations system.

3 - Authenticated external users with an interface to submit application forms, and upload dossiers and documents which are securely stored in Azure Blob Storage.










4, 5 - Application Data and Documents Metadata are stored securely in Dataverse

6,7 - Business users and external assessors/Inspectors have access to operations apps that provide internal processes and insights according to the role they play in the system.

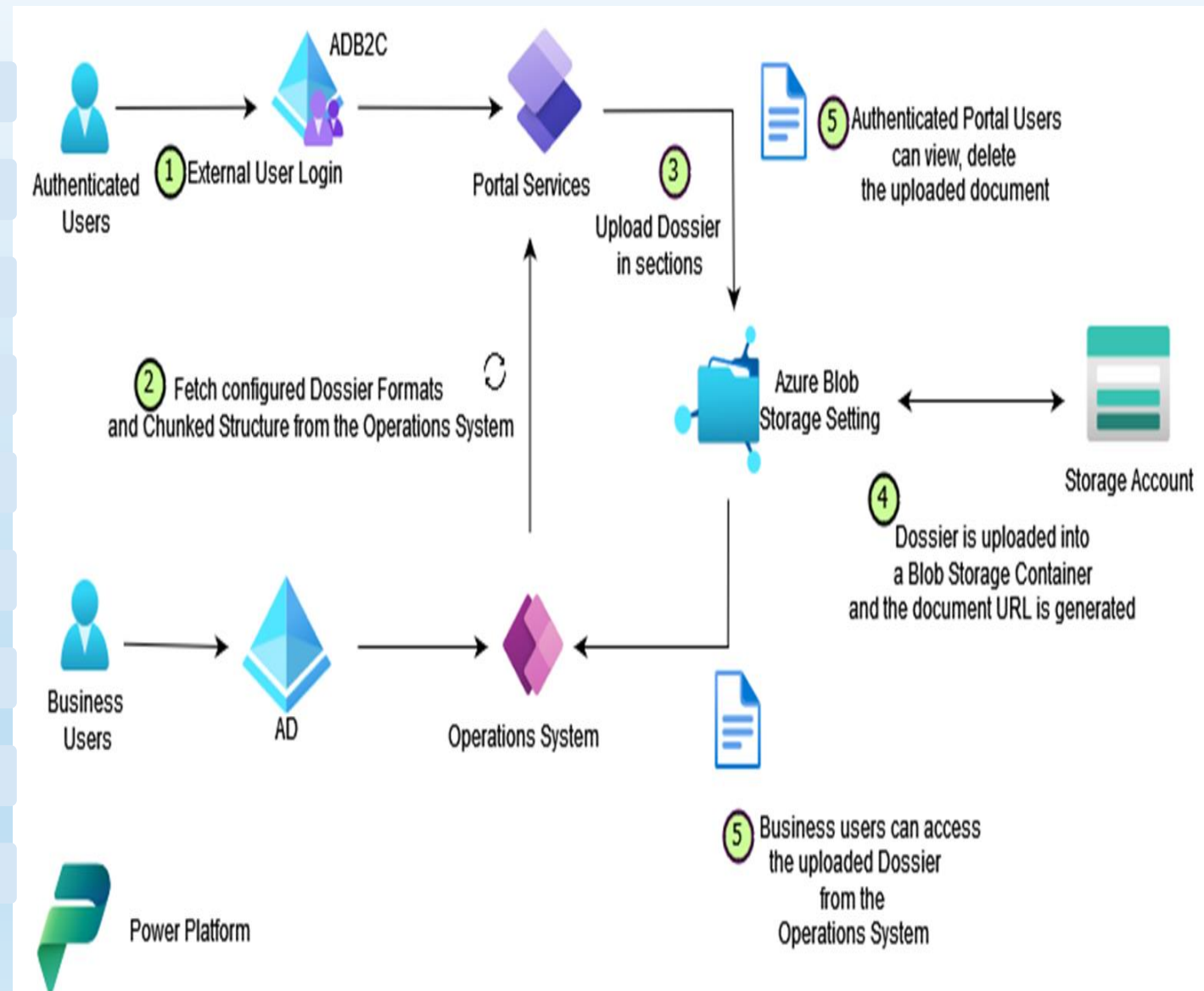
8 - The received applications are processed using the configured business process/ cloud flows for approval, While processing the self-service portal is updated on each stage of processing and applicants can monitor.

9 - On approvals the business process generates output/certificate which authenticated portal users can view and download.

# DOSSIER UPLOADS

-  Dossier chunking in a configurable format i.e., VNeS, NeS
-  Pause/resume file uploads.
-  Automatically pause/resume file uploads on power loss, network failure, or device shutdown.
-  Capability to upload with slow internet speeds.
-  Automatically chunk files based on file size. i.e., possible to upload files even above 10GB
-  Configurable allowable file extension types. i.e., pdf, doc, ppt
-  The files are uploaded in a temporary directory where they are scanned for malware before uploaded to the repository.
-  Modify document versions for duplicate versions.
-  File upload is accessible in all modern browsers i.e. *Firefox, Chrome, Edge, Safari*

## Architecture





# DOSSIER DOWNLOAD



Dossier uploads are done in chunked sections and stored in azure storage.



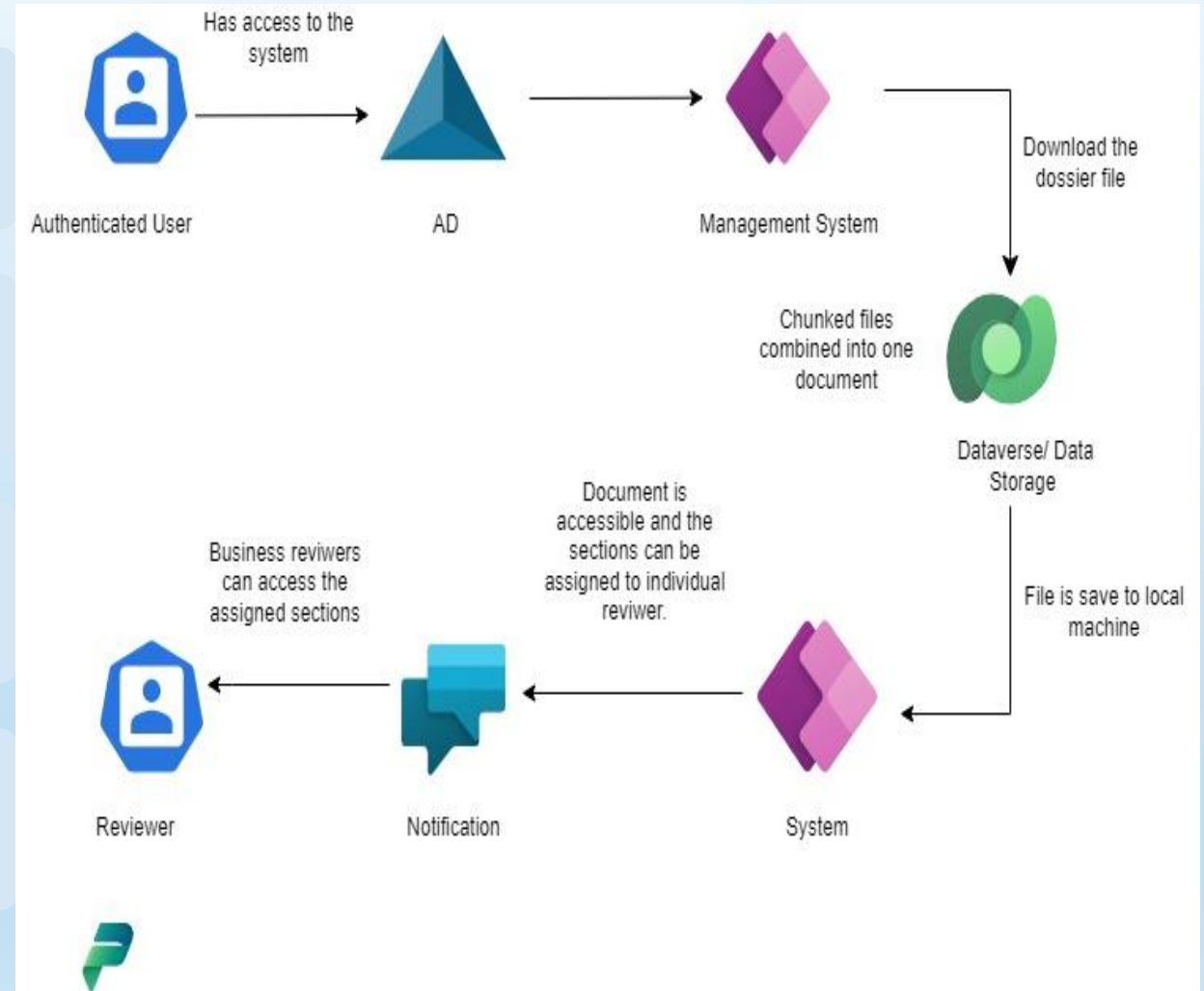
Power Apps interface allowing of initiating and managing of file download.



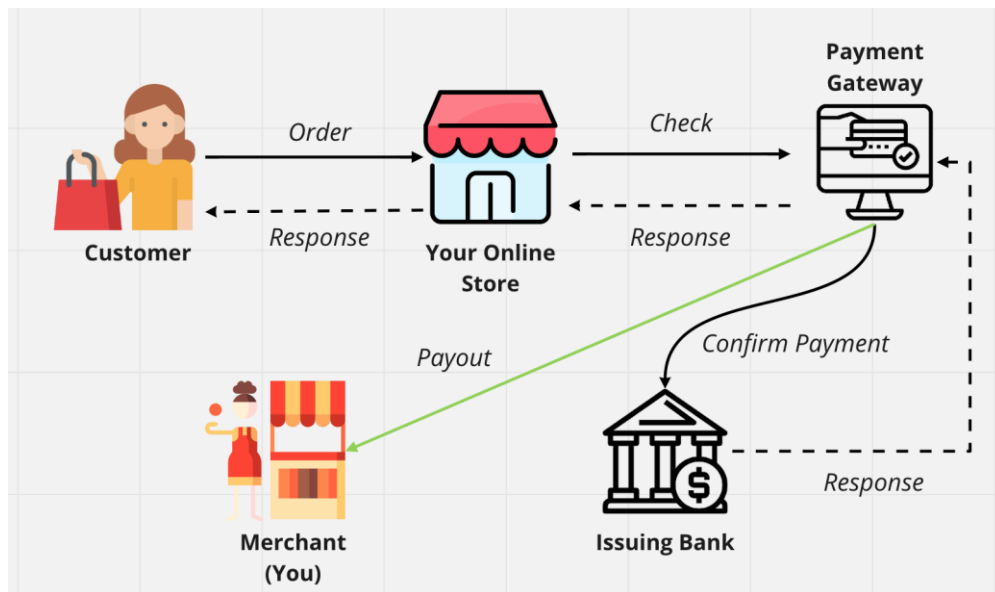
Retrieving of the chunked files into a single document.



Integrating with azure blob storage API for faster download and seamless integration.



# PAYMENT INTEGRATION



- The modern payment system allows ease of making secure transactions.
- Automated Billing/Quotation and invoicing reduces the burden of administrators managing the important payment information.
- Enhanced tracking and managing and reporting of financial insights.
- With PayPal payment system, allows using of multiple means of payment, from Visa to Mastercard to PayPal account, giving the user more "freedom of choice" to make payments.

## COLLABORATION (MULTITENANCY APPROACH)



Integration of collaborative features such as shared documents, dossier and sample repositories and communication tools facilitates better collaboration.



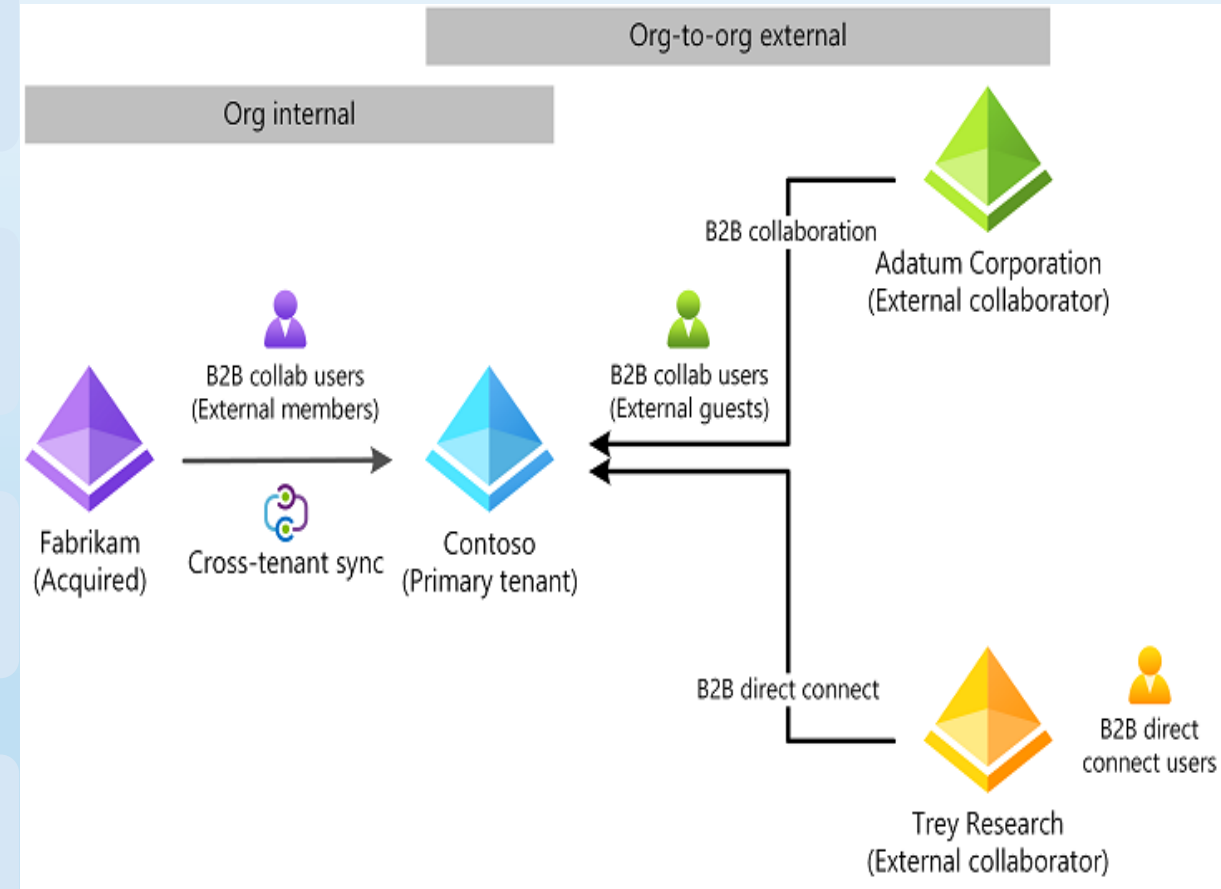
Allowing for dossier sections to be accessed indifferently by different personnel with accessed control to make reviewing easier and timely.



Each tenant data is isolated and cannot be accessed by other reviewers/tenants unless given access to the data. This is achieved through access control and row data security.



Timeline and use of interface that clearly indicates when a user accessed the data and the time and **duration of** what was accessed.





# PROTOTYPE FEATURES

## 1. Market Authorization Management

- New Market Authorization for Veterinary Products.

## 2. Premise Licensing

- New Facility Licensing

## 3. GMP Inspections

- New GMP inspections (Local and Foreign Manufacturers)

## 4. Dossier Management

- Standardization of Dossier Formats
- Dossier Chunking
- Resumable File Uploads/Downloads
- Version Control
- File Storage Features e.g., Malware Scanning for File Uploads
- Configurable Allowable File Extensions

## 5. Payment Integration

- Secure Transactions
- Automated Billing and Quotation

## 6. Collaboration/Multitenancy

- Document Collaboration
- Fine Grained Access to Dossier Sections
- Tenant Data Isolation

## 7. Workflows

- Automated processes
- Configurable workflows

## 8. Business Intelligence, Reports & Analytics

- Product Register
- Financial Reports
- Certificates/Approval Reports
- Business User Dashboards
- External User Dashboards
- Customer Dashboards

## 9. Digital Signing

## 10. Sample Management

# FEATURE ROADMAP

## 1. Market Authorization Management

- New Market Authorization for Veterinary Products.
- Exemption permit application (To facilitate importation of unregistered veterinary products).
- Variation/alteration/amendments of market Authorization.
- Renewal of market Authorization certificates
- Withdrawal and Suspension of veterinary product market Authorization.
- Veterinary Product retention process.
- Submission of PSUR and PBRER reports on Authorized products.
- Laboratory Sample test analysis request management

## 2. Premise Licensing

- New Facility Licensing
- Renewal of facility Licenses
- Variation of Licenses for Facilities.
- Withdrawal / Suspension of facility licenses.
- Facility Post Licensing Inspections (Routine Inspections and Spot Inspections)

## 3. GMP Inspections

- New GMP inspections (Local and Foreign Manufacturers)
- Renewal of GMP certificates
- Variation of GMP certificates
- Withdrawal of GMP certificates

## 4. Import Export

- Application for new Import/Export Permit
- Variation of Issued import/Export Permits
- Transits permit issuance for veterinary products.
- Permit Cancellation management.
- Issuance of permits for any controlled Veterinary Products.
- Port of entry and exit inspections (POE)
  - For utilization of issued permits
  - For recording entry of personal consumption veterinary products. (without permit based on quantity)
  - For illegal consignment management

## 5. Post Marketing Surveillance Management

- Planning & Scheduling Process Management
- PMS execution process (including sample collection)
- Result analysis and Reporting process for action items.

## 6. Field Trials Management

- New Trial Approval Management.
- Clinical Trials Renewals.
- Submission of Serious Adverse Events on Ongoing Trials.
- Submission of Report (Progress and Closeout) on Approved Trials.

## 7. Law Enforcement Management for illegal practices related to veterinary products

- New report receiving and evaluation (from internal/external source as a known or anonymous source)
- Case Investigation Process management
- Seizure and Destruction processes
- Monitoring and compliance management.

## 8. Financial Management

## 9. Promotion and Advertisement

## 10. Disposal Management

## 11. Medicine information center

## 12. Adverse event reporting

## 13. Record management

## 14. Electronic Document Management

## 15. Integration Management

- Laboratory system integration
- Financial Systems Integration
- Notification systems
- Regional collaboration systems



SECURE, SCALABLE AND FLEXIBLE IT SOLUTIONS

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**THANK YOU**