AMPLEXOR
LIFE SCIENCES

2023

Be The Expert

EMPOWERING EFFICIENCY

Applying AI To eTMF

Presented by: Anthony Vigliotti

Applying AI to eTMF

01 **AMPLEXOR - ADLIB RELATIONSHIP**
An Introduction

02 **ADLIB HERITAGE**
Managing Unstructured Data

03 **APPLYING AI**
Architecture & Rationale

04 **COMPLEXITY OF TMF**
Problem Definition

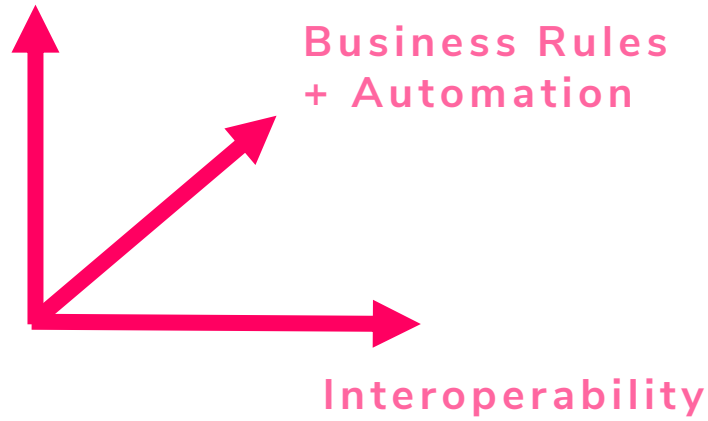
05 **AI & TMF Demonstration**
Scope, Method, Results

06 **REGULATORY IMPACT**
Projected Efficiencies

The Amplexor / Adlib Relationship

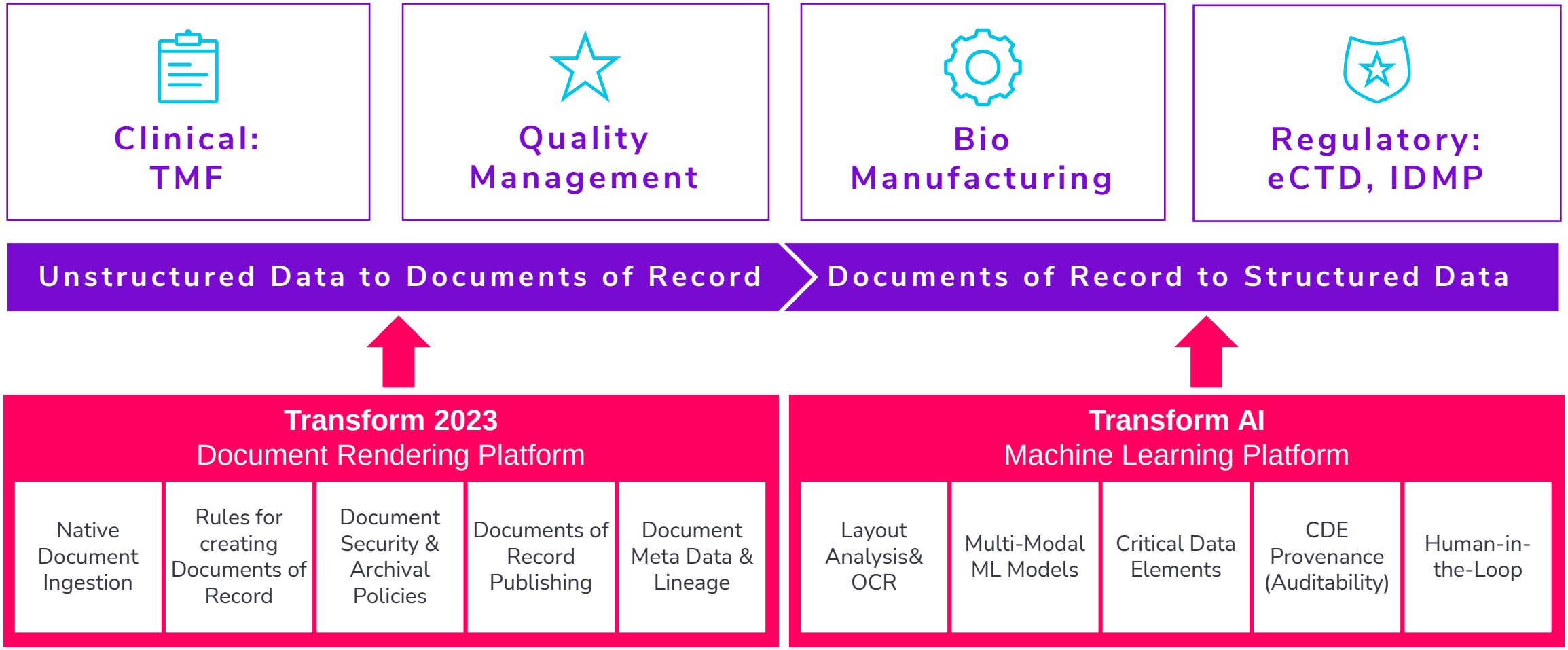
LONG TERM PARTNERSHIP DELIVERING SUCCESSFUL IMPLEMENTATIONS FOR THE LIFE SCIENCES INDUSTRY

Enabling “Readable – Searchable” Documents of Record From Unstructured Data at Scale to Manage Regulatory, Compliance & Audit Requirements



Business Outcomes For Document Heavy Processes

ARCHITECTURE & RATIONALE TO DELIVER STRUCTURED OUTCOMES



Trial Management By The Numbers

5-10

Trials Per CRA

UP TO 150

Sites Per Trial

! Site based documents need the most triage

1000-1500

Documents Per Trial

! Email and correspondence is hardest to identify

- Trial or Site level
- Multiple site level locations

Complexity Of TMF

THE CHALLENGE IS TO CLASSIFY TRIAL DOCUMENTS PER TMF SCHEMA ON A “CONTINUAL BASIS”

Challenge 1:

Site data comes from a variety of sources

- Email
- Portals
- Shared network folders
- Faxes
- Printers & Multifunction devices
- Document Repositories

Lack of an automated approach to capturing data

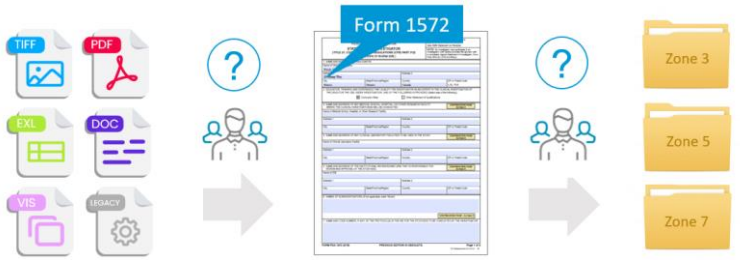
Challenge 2:

Clinical trial data is unstructured, voluminous and inconsistent

Lack of a standard format to simplify document processing

Challenge 3:

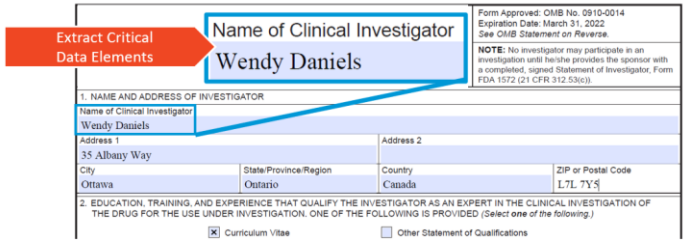
Classifying trial data into eTMF is manually intensive



Inability to categorize data with accuracy & speed

Challenge 4:

Extracting metadata from eTMF document types is difficult



Inability to easily unlock data to automate trial process

PRODUCT DEMONSTRATION

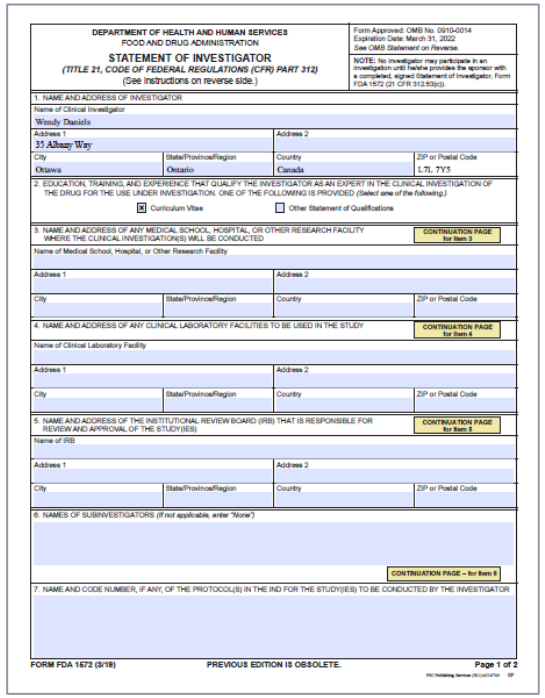
Adlib's eTMF Autoclassification

Demonstration #1 – AI based Classification

Demonstration #2 – Human in the Loop Validation

AI & eTMF: What We Learned

INCREASED VOLUMES OF DOCUMENTS CONTINUOUSLY IMPROVED THE ACCURACY OF AUTOCLASSIFICATION



DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

STATEMENT OF INVESTIGATOR
(TITLE 21, CODE OF FEDERAL REGULATIONS (CFR) PART 312)
(See instructions on reverse side.)

Form Approved: OMB No. 0910-0014
Expiration Date: March 31, 2022
See OMB Statement on Reverse.

NOTE: No investigator may participate in an investigation until he/she provides the sponsor with a completed, signed Statement of Investigator, Form FDA 1572 (21 CFR 312.53(c)).

1. NAME AND ADDRESS OF INVESTIGATOR

Name of Clinical Investigator			
Wendy Daniels			
Address 1		Address 2	
35 Albany Way			
City	State/Province/Region	Country	ZIP or Postal Code
Ottawa	Ontario	Canada	L7L 7Y5

2. EDUCATION, TRAINING, AND EXPERIENCE THAT QUALIFY THE INVESTIGATOR AS AN EXPERT IN THE CLINICAL INVESTIGATION OF THE DRUG FOR THE USE UNDER INVESTIGATION. ONE OF THE FOLLOWING IS PROVIDED *(Select one of the following.)*

☒ Curriculum Vitae ☐ Other Statement of Qualifications

3. NAME AND ADDRESS OF ANY MEDICAL SCHOOL, HOSPITAL, OR OTHER RESEARCH FACILITY WHERE THE CLINICAL INVESTIGATION(S) WILL BE CONDUCTED — CONTINUATION PAGE for Item 3

Name of Medical School, Hospital, or Other Research Facility			
Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

4. NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY — CONTINUATION PAGE for Item 4

Name of Clinical Laboratory Facility			
Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

5. NAME AND ADDRESS OF THE INSTITUTIONAL REVIEW BOARD (IRB) THAT IS RESPONSIBLE FOR REVIEW AND APPROVAL OF THE STUDY(IES) — CONTINUATION PAGE for Item 5

Name of IRB			
Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

6. NAMES OF SUBINVESTIGATORS *(If not applicable, enter "None")*

CONTINUATION PAGE – for Item 6

7. NAME AND CODE NUMBER, IF ANY, OF THE PROTOCOL(S) IN THE IND FOR THE STUDY(IES) TO BE CONDUCTED BY THE INVESTIGATOR

FORM FDA 1572 (3/19) PREVIOUS EDITION IS OBSOLETE. Page 1 of 2

Transform AI
Machine Learning Platform

OUTCOMES:

- **High Confidence Level: Files Classified**
- **Low Confidence Level: Files not Classified**
- **Enables Human in the loop efficiency**

Business & Regulatory Impact

INTEGRATING ADLIB AI INTO A RIM PLATFORM

UP TO

75%

Increase in Clinical Ops efficiency

UP TO

50%

Faster Regulatory submission prep

UP TO

12 Months

Faster product launch to market

Reduced 30-day manual report assembly to a 2-hour review

More than 1000% EFFICIENCY BOOST

Anthony Vigliotti

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Twitter

Anthony has 20+ years of experience in Business Workflow and Intelligent Document Processing segment with prior roles at Kofax, Nuance, Notable Solutions (NSi), and Xerox. Anthony brings a well-rounded set of experiences with solution-related roles in Product Management, Alliance and Partner Management, and Product Development. He holds a bachelor's degree in Mechanical Engineering and a Master's Degree in Information Technology, both from the Rochester Institute of Technology.