Approaches to a Digital Transformation of Imaging Management for Biopharmaceutical Research

RESULTWORKS
An astrix Business

Introduction

Across the research, product development, and clinical sectors, organizations are working to improve their operations by harmonizing imaging systems. The goals are typically focused on achieving:

- more consistent collection, storage,
- broader accessibility of images and
- easier access to image data across functions (e.g., metadata, analysis).

The challenges to creating a solution for enterprise-wide image management may be numerous but they are not insurmountable, as this eBook illustrates. The key to easily overcome the challenges is to create a coherent roadmap with the participation of stakeholders as well as system architects and administrators. The real challenge, then, entails envisioning a comprehensive solution for the entire organization. The hallmark of a solution's effectiveness is that all modalities' unique requirements have been identified, documented, examined, understood and used as a basis for addressing the common and unique needs of each modality.

The guiding question to be employed by the planning team is:

What is the appropriate process, and which approach is best, for the unique requirements of the organization?

It is imperative to understand the current situation across all modalities, their needs, priorities, and uses of images and image data. As this is being collected, it is essential to identify the technology and workflows unique to each group. In this eBook we discuss:

- How to Understand the Current State Before Embarking on a Digital Transformation
- How to Consider Imaging Management Approaches to Develop a Coherent Roadmap
- How Understanding Emerging Imaging Technology Trends May Impact—or Govern—Solution Selection
- 6 Key Steps to Generate a Successful Transformation Plan for Digital Image Management
- How to Bring an Initiative Together to Ensure Success

Understanding the Current State Before Embarking on a Digital Transformation

Key Aspects to Consider before a Digital Transformation

Modality Differences	Stakeholder Requirements	Unique vs. Common Capabilities	Understanding Image and Image Data Volumes
Across the R&D landscape, groups are tasked with managing images within their modality that can differ from others in the same organization. These differences need to be identified as part of the process of understanding each group's workflows and data needs.	All imaging stakeholders needs should be understood because they can vary by their purpose and their use of the images and image data. There may be many stakeholder departments involved including Pathology, Radiology, and Biologics, among others unique to each organization.	In many organizations, imaging solutions were originally decentralized to meet the needs of individual groups. To ensure digital transformation can succeed, a harmonized solution requires considering the needs of each of the groups that are involved and impacted.	Differences in image data volume requirements will be key to the success of a digital transformation. Some groups may have event-driven image collection analysis, while others require high volume image processing (e.g. High Content Screening).

Approaches to Consider When Developing a Coherent Imaging Management Roadmap

There are several potential approaches for harmonizing the imaging systems across the modalities so that there is a consistent collection, storage, and accessibility process across R&D. The choice of options will depend heavily on the business' modalities requirements. Prior to launching a search for a new solution, it is imperative to understand the current requirements and technology in use among stakeholder groups as well as the emerging technology landscape. The following approaches are not mutually exclusive, and may be useful to leverage several to optimize R&D's imaging infrastructure.

- **Implement a Single Commercial Solution Across All Modalities**

  It would be desirable to have a single commercial solution that can satisfy the variety of image and image data management needs of the various domains in research and development. However, our investigation has found that there is no one size fits all solution given the requirements and complexity of the imaging modalities across Life Sciences R&D.

- **Extend Existing Application(s) to Cover Additional Domains**

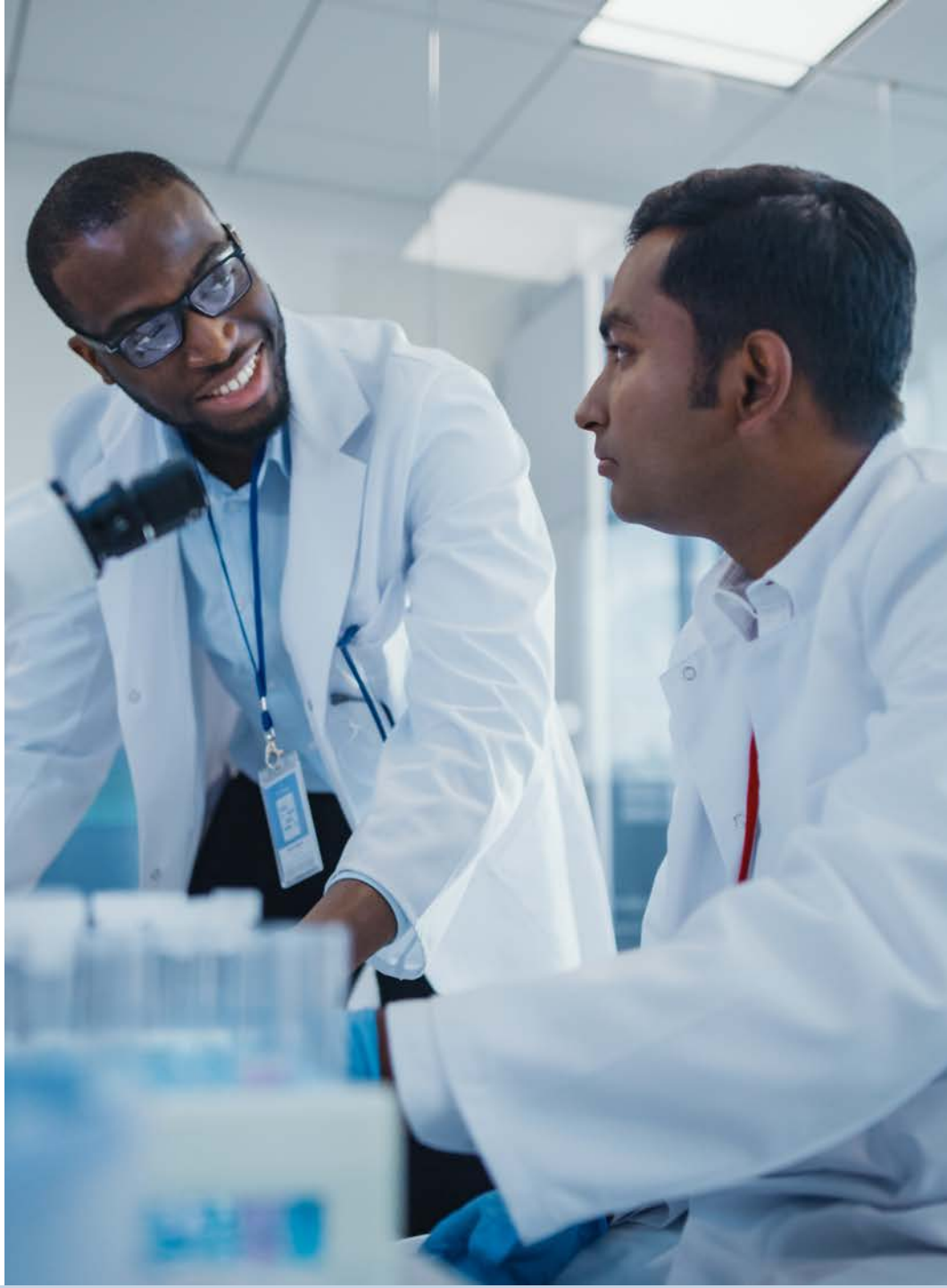
  Extending an existing solution within the organization to other areas of the business may be worth considering if enough commonalities exist across the modalities. This approach may present challenges, however, since an existing application would need to have the flexibility to handle requirements unique to one or more of the other groups.

- **Common Shared Supporting Technical Foundations and Services**

  Conducting a survey of the technology requirements of the modality can provide insight into how the organization can leverage common needs such as metadata, digitized images, analysis tools, storage, libraries, and viewing tools. This survey can identify how various modalities could leverage a common technology foundation, and services, across several user and stakeholder groups.

- **Separate Functional and/or Site-Specific Optimized Solutions**

  Geographic needs, as well as workflows, based on unique work performed in various modalities need to be assessed so that they can be adequately addressed during subsequent design and implementation phases.



Understanding Emerging Imaging Technology Trends

An examination of emerging technologies would be helpful to determine if available technologies might be leveraged across one or more of the imaging modalities. Examining existing market technologies involves understanding the various technologies' abilities and current use in imaging areas. If they are not currently being used in an R&D settings, it will be essential to assess the applicability for the imaging modalities of the biopharmaceutical R&D groups.

The following are some of the categories of emerging imaging technologies that could be considered. All of these technologies may have applicability in R&D imaging in the near future.

Integrity, Authenticity & Confidentiality
In the life sciences industry it is imperative to ensure the security and confidentiality of any image and the metadata surrounding that image.

- **Medical image watermarking** - Watermark graphic or text indicates ownership or copyright of an image. This technology makes it difficult for someone to use the image without permission or claim ownership of the original.

- **Blockchain** - For secure sharing of medical images blockchain allows users (i.e., patients, physicians, radiologists and scientists) to control how and by whom healthcare data are used.

Image analysis
The main goal of image analysis is to help address and solve scientific questions by leveraging state of the art image analysis technology to find ways to harvest information from those images.

- **Reproducible image analysis** – Is a set of resources that allow any person to replicate the process of image handling and analysis. The aim is to derive the same results as the authors presented.

- **Container - based image analysis** – containers support the ability to deploy analysis code along with versioned run time elements across different infrastructures regardless of the host environment. Resources, libraries, and tools are shared in real time and only for the analysis needed . This provides for reproducible and repeatable image analyses. Technology providers include Docker, Singularity, Amazon Machine Images, Amazon Fargate.

- **AI/ML Deep Learning** – AI has been deployed significantly in image analysis especially in cellular image analysis and high content analysis. There are solutions that utilize machine learning classification algorithms to evaluate multiple measures simultaneously to automatically identify classes within the data and reveal deeper information than can be discovered with manual classification in more biophysical approaches. As of today, AI uses have been limited to improving peak detection in NMR or mass spec or diagnosing potential sample related problems. Other applications are focused more on the use of AI for the curation of large structural data sets for further analysis.

Augmented Reality / Virtual Reality
Augmented reality augments your surroundings by adding digital elements to a live view, often by using the camera on a smartphone while virtual reality (VR) is a completely immersive experience that replaces a real-life environment with a simulated one.

Given the 3D structure of our cognitive and visual processes, an intuitive 3D visualization and computational tool is more than a step forward - it's the inevitable progression of research ranging from 3D genetic analysis to 3D data visualization. When we reduce a 3D object to a 2D medium, our cognitive system has to work extra hard to comprehend the information. We can undertake scientific research more efficiently by using spatial computing to view massive data sets and analyze test findings of 3D objects.

Semantic Image Annotation (SIA) & Ontologies
The process of assigning a class or description to an unknown image is known as image annotation. The goal of automatic picture annotation, in particular, is to provide coherent visual descriptions that are as excellent as those written by humans. This will not only allow for a more rapid and thorough knowledge of the contents of image collections, but it may also be used to improve the performance of image retrievals by content. SIA is a framework for automatically annotating photos with ontologies.

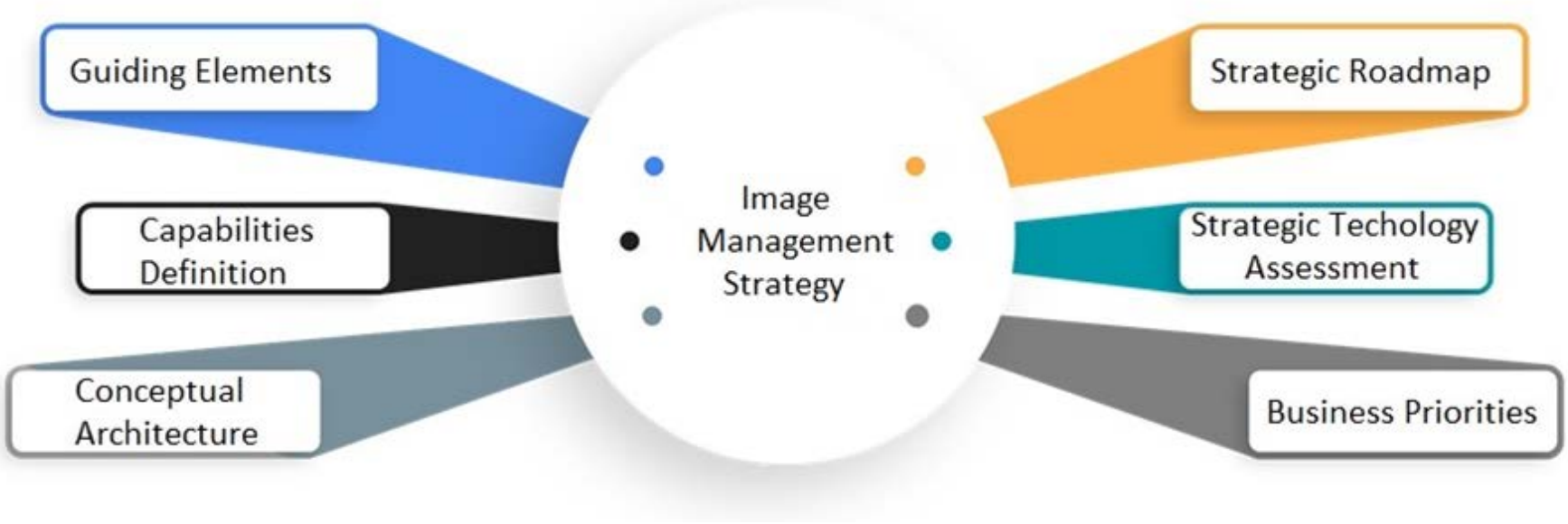
Image Management & Viewing
Intended to provide access to images for viewing in various ways.

- **Zero-footprint image viewing** - A zero footprint viewer requires no client-side installation or download, allowing users to read documents and images in their native web browser while taking advantage of the browser's full capabilities, built-in plugins, and interactions with the device.

- **Content-based image retrieval** – this is the application of computer vision techniques to the image retrieval problem. It solves the issue of searching for digital images in vast databases.

- **Multi-modality enterprise Vendor Neutral Archive(VNA**) – healthcare organizations are moving to VNA to manage images regardless of source or format. VNAs are intended to manage images in their native format and can be implemented alongside an existing PACS. Supports DICOM and non-DICOM images, but extent of native image format support can vary.

6 Key Steps in Building Digital Transformation for Image Management



To successfully perform a transformation of the Imaging Management area of the business to improve efficiency and effectiveness, there needs to be both a business and technology strategy that enables the process. There are six important steps that ResultWorks, an Astrix Business, follows in order to ensure our client's success.

1. Guiding Elements

First, we facilitate the definition of guiding elements to inform the strategic direction. Guiding elements incorporate the leadership vision, key business imperatives. as well as the critical issues that are being faced by the organization to ensure that they are addressed through the strategy setting. Aligning on these elements upfront helps to guide how we define and view the architecture, the data or information, and how the organization wants to deliver the user's experience. These guiding elements clarify and drive the decisions regarding the strategy.

2. Capabilities Definition

Identifying and capturing the business and technical capabilities in each of the imaging modalities is the next step in the process. In this phase the core business workflows for each function and the cross-cutting capabilities needed across functions are evaluated through our framework to uncover needed capabilities. This is assessed operationally as well as from a data

and an analytics perspective. Mindful of imaging trends and relevant emerging technologies, more aspirational capabilities can also be captured. Once compiled, these capabilities can be viewed through the lens of different processes, the needs of different functional areas, and the needs dictated by each imaging modality.

3. Conceptual Architecture

Using the capabilities as a basis, the conceptual technical architecture is developed. Capabilities are organized into platforms to support both foundational and aspirational needs. The more transactional business platforms provide more specific business capabilities to meet the needs of a certain functions or modalities.

Cross-cutting capabilities are also molded into platforms that span needs across multiple areas of the business. For example, analytics capabilities can be structured into cross-cutting analytics platform that can be used across the modalities. In this scenario all those groups are then able to access and use the common analytics platform rather than buying, building or maintaining their own tools.

4. Business Prioritization

Once the desired capabilities and platforms have been defined, the business needs to prioritize the implementation and timing of those capabilities. Not everything can be constructed on day one and all organizations will have gated investment decisions to make.

Capabilities can be built in an extensible way where you start small and build out according to an agreed plan. For some areas, there may be sufficient capabilities for the short term allowing us to focus on other areas that may be more urgent and impactful where there is no solution currently in place. This prioritization process addresses the business priorities, the urgency from a technology perspective, and the logical progression in building out the solution to realize the strategy.

5. Strategic Technology Assessment

As is the case with most organizations, there are existing solutions in place. Therefore, in parallel to performing the capabilities determination, an assessment of the organization's current imaging systems is performed. This requires a rationalization of the existing technologies compared with the defined and agreed capabilities. A determination needs to be made whether the organization will continue to use and invest in certain technologies, that is the technologies still meet the needs of the organization. Alternatively, it may be advantageous to search for another solution that may better address not only today's needs but also the aspirational needs of the organization going forward.

The final aspect regarding a technology assessment is understanding the vendor solution landscape. To address where technology needs to be replaced or where new technology is needed, vendor solutions need to be measured against the agreed and prioritized business and technical capabilities. Those solutions need to be viewed based on vendor functionality as it exists today with some allowance for product plans that map to the time horizon of the strategy.

6. Strategic Roadmap

All of these steps culminate in the development of a high level strategic roadmap. Typically, the roadmap is broken down into three primary areas. A high level roadmap summary typically captures the key program workstreams. These workstreams can tie to a variety of different mechanisms that can be either organizational, based on product lines if the organization has product line set up, or based on business outcomes the organization wants to achieve. The workstreams defined in the high level roadmap identify further levels of detail in the projects needed to execute the workstream. This is further supported with detailed work descriptions that may serve as a preliminary charter for the project to help spin up initiatives within the right timeframe without losing strategic intent.

The roadmaps are built to be living documents that evolve overtime as progress is made and as technology continues to change. By using a platform-based model as the basis of the strategy and the future technology ecosystem, it facilitates versatility to incorporate new technologies while enabling the organization to deliver expanded business capabilities.

Transformation Requires Alignment

To ensure a successful image management program, organizations need to have the key constituents involved throughout the project. It is important to secure and maintain alignment along the way. The leadership of the organization sets the tone, drives through the business imperatives, and participates in key decisions to be made throughout the effort. Also critical is communicating decisions, intent and tradeoffs along the way.

On the other hand, the organization must ensure that stakeholder's voices are heard and accounted for throughout the journey. Decision making, prioritization, and the development of the strategic roadmap need to tie back to the stakeholder input so that it is clear how the business needs are being addressed by the strategy. To be successful everyone needs to be part of the process and aligned to support the strategy. This alignment needs to continue throughout the implementation and as the strategy evolves.

How to Bring an Initiative Together to Ensure Success

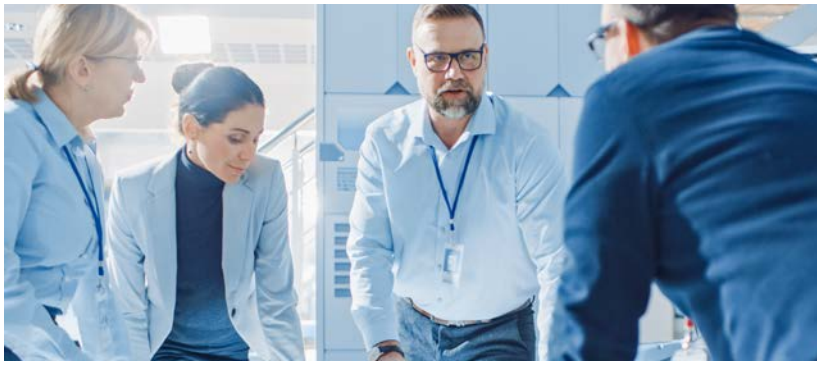
The digital transformation of the imaging area can be a challenging endeavor. This is largely due to the complexities associated with the various imaging modalities. There are unique needs associated with each modality and unfortunately, there is no one size that fits all solution. As our research showed, while there are numerous emerging technologies to keep an eye on, there are no unicorns in other industries that can be readily applied to Life Science imaging and image data management needs, today.

Before proceeding forward the organization needs to first understand the commonalities and differences of the various modalities and business functions to understand what imaging technology and infrastructure can be leveraged. Fundamental areas that can and should be leveraged include image ingestion, metadata, digitization of images, analysis tools, storage, libraries, and viewing tools to name a few.

In the end, a reasonable objective of an image and image data management program should be to realize a consistent collection, storage, and accessibility of images and image data across R&D.

To recap, the key things to consider when embarking on an image and image data management program include:

- Define key image management capabilities needed across modalities and business functions that the strategy needed to address
- Ensure alignment on an image management strategy leveraging a common technical environment to support modality-specific technology and workflows.
- Prioritize the strategy roadmap to meet the needs of the business
- Once a solution has been selected and the company is moving through implementation across the sites and functions, ensure that the organization is leveraging existing technical infrastructure and tools where applicable.
- Ensure leadership is involved and committed to the success of the project.



About Astrix and ResultWorks

For over 25 years, Astrix has been a market-leader in delivering innovative solutions through world class people, process, and technology that fundamentally improves scientific outcomes and quality of life everywhere. Founded by scientists to solve the unique challenges life sciences and other science-based business face, Astrix offers a growing array of strategic, technical, and staffing services designed to deliver value to clients across their organizations.

ResultWorks, an Astrix business, achieves success for our clients through skilled facilitation and exceptional management leadership across Life Science domains from Research, Non-Clinical & Clinical Development, Regulatory Affairs, to Safety, Manufacturing, and Pharmacovigilance. To learn more about how ResultWorks enables biopharmaceutical leaders' success, visit www.resultworksllc.com.

To learn the latest about how Astrix is transforming the way science-based business succeed today, visit www.astrixinc.com.