Maturity Level Characterization of Artificial Intelligence Capabilities for Self-Assessment

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XAVIER HEALTH

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ABOUT XAVIER HEALTH

Xavier Health is more than an organization. It is a community of hundreds of FDA, industry experts, thought leaders and academics. Xavier Health was formed in 2008 as an outreach of Xavier University charged with making a difference in the pharmaceutical, medical device, and combination products industries. Our mission is inspiring collaboration, leading innovation, and making a difference in all that we do.

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May this work provide you with inspiration and insight as you navigate the AI landscape.

Cynthia A. Ipach, Compliance Insight, Inc., Co-Leader & Principal Author

Kip Wolf, X-Vax Technology, Inc., Co-Leader & Principal Author

Bill Whitford, DPS Group, Principal Author

[1]The opinions and viewpoints expressed by the contributors are their own and do not necessarily reflect the opinions and viewpoints of their respective organizations or employers.

INTRODUCTION

Artificial Intelligence (AI) has been around for a long time, but it has only recently become sophisticated enough to tackle challenges such as identifying diseased cells in images and recognizing mental illness in human speech patterns. It is easy to see how the value of this technology will continue to be realized in industries such as pharmaceuticals and medical devices, given its ability to analyze huge amounts of complex data quickly and accurately. The use of artificial intelligence in pharmaceutical and medical device manufacturing is one of the most promising areas of innovation. It can help find and fix problems before they arise, automate routine tasks, and even predict future outcomes based on past data. But it is not always easy to know where or how to start.

The simultaneous rise of computational power, cloud-based storage, and increasing sophistication of AI algorithms has enabled the evolution of dynamic and intelligent AI, which is in contrast to the classical, yet sometimes less nuanced capabilities of statistical modeling and brute-force based tools. Although the abilities of artificial intelligence have evolved, the data needed to feed the algorithms often remain locked in archaic and often siloed IT systems throughout the organization. Once accessible, the onerous process of standardizing and normalizing large datasets through manual analysis can prevent the ability of an organization to move forward.

Despite the many challenges of evolving from manual analytics to artificial intelligence solutions, the medical device and pharmaceutical industries are making advances. However, these advances must be met responsibly with the question: “Is my organization ready for artificial intelligence”? Fortunately, the discernment and assessment of organizational readiness and ability to build/implement AI tools is made possible through the AI Maturity Level Characterization Matrix.

AI MATURITY LEVEL CHARACTERIZATION

The AI Maturity Level Characterization Model enables the assessment and measurement of (1) the functional AI capability of an organization in defined operations or categories, as well as (2) the current capability to improve in these areas over time. With a few exceptions[1], the organization is able to assess the practical ability of the human resources, departments, and culture to understand, implement, and operate applied AI tools or instrumentation. To be clear, rather than assessing the capability to create or maintain integral AI algorithms, the maturity model qualitatively measures the functional capabilities of an organization to work with AI empowered tools, processes, and structures.

[1] Reasons an organization may not be able to apply AI tools at this point include limitations in the financial and personnel resources available, concern for the legal or regulatory acceptance of its effect upon process, and immediate corporate goals that diverge from this initiative.

STANDARD PROCESS FOR IMPLEMENTATION OF AN AI SOLUTION

Prior to development of the AI Maturity Level Characterization Model, the Roadmap for AI Implementation Sub-Team considered the AI algorithm development workflow at a high level, starting from research and data analysis to validating the code required for that task. The algorithm development workflow typically occurs sequentially as follows:

1. Acquiring information about problems in need of solving
2. Defining relevant tasks and required input
3. Evaluating solutions through design iterations
4. Qualifying the model
5. Validating the problem-solving results

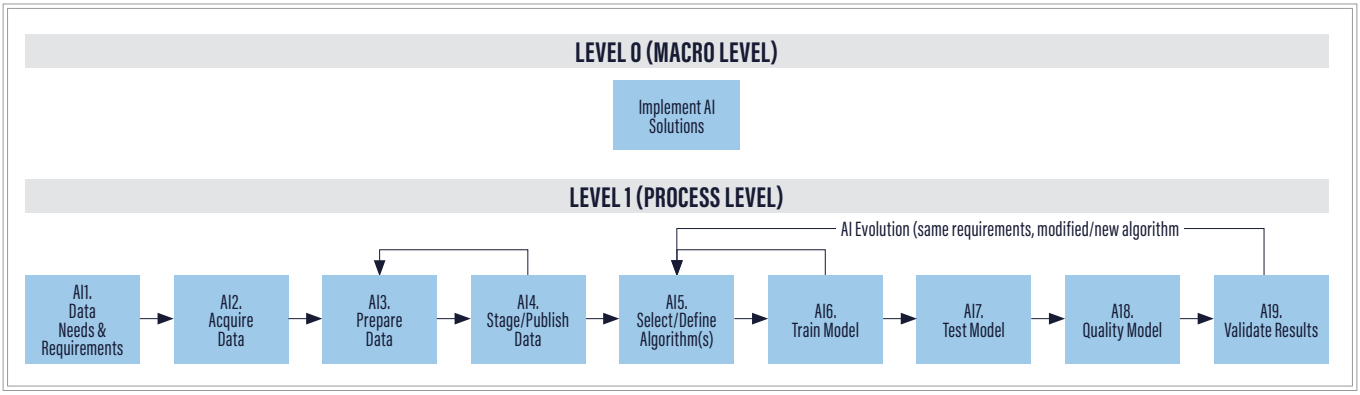

Figure 1: Detailed steps in a standard process for implementation of an AI solution.

Note the loops in the AI Algorithm development workflow cycle. The processes may be repeated when an AI algorithm update/modification is needed, as well as when new algorithms are generated. Such iterations can also be noted in movement through the AI Maturity Characterization Matrix for the same reasons. For example, consider the category "Culture" in the AI Maturity Level Characterization Matrix. An organization that initially assesses themselves as a "2" (Random or ad hoc communications…) in the Maturity Area "Communications" may take measures to improve, and then return to re-assess themselves as a "4" (Coordinated communications…).

The AI Maturity Level Characterization Model – Getting Started

In order to ensure that a holistic view of the organization is included during the assessment, a diverse team of representatives from across the organization should be assembled ("Assessment Team") to evaluate the four categories of capability. Examples of team diversity includes representatives from: (1) key departments across the organization, (2) varying levels of leadership, (3) varying levels of experience, (4) varying plant sites, (5) varying countries, etc. A diverse team can help ensure the

needs, requirements and preferences across the organization are balanced, and may help prevent functional bias, avoid overemphasis on a certain factor (e.g., cost or personal goals), as well as underrepresentation of critical success factors. It is important, for example, to include representatives from the areas that will be assessed (e.g., keep in mind that a multinational organization will need appropriate representation from cross-cultural leadership to completely evaluate the maturity levels).

The Assessment Team should first ensure that agreement is made on the scale of the assessment, such as determining if the evaluation will be conducted at a department level, facility/site level, or complete holistic organizational level. It is recommended that each assessment team start small for the first evaluation and expand scale and scope over time.

The use of the AI Maturity Level Characterization Model should not be an isolated activity, but rather, is intended to be repeated periodically as the organization grows and changes. It is useful to assess baseline measurements and to set target maturity goals by individual categories, maturity areas, or both.

Understanding Maturity Level Characterization

The maturity levels are intended to be a guide along the evolution of AI implementation and not a discrete measurement of AI success. Most organizations find that the level of maturity across the four categories are not identical. It is common to find high maturity in one category and great opportunities for improvement in another. The individual Maturity Areas for assessment are grouped into four common categories:

- Culture
- Governance and Organization
- Data Management
- Tools and Techniques

Each Maturity Area and related Maturity Factors are then rated across a five-point scale to indicate level of maturity.

Identifying low maturity (i.e., Level 1) does not indicate failure, but an opportunity to advance. Maturity may wax and wane during the life cycle of an organization as personnel change, processes become outdated, or technology becomes obsolete. Additionally, very few organizations can claim top maturity (i.e., Level 5) in any or all categories. Level 5 represents best practices and stretch goals for which organizations may strive. Understanding current maturity levels and future target maturity provides an organization with the necessary clarity to construct specific plans for transformational change.

Please note that maturity levels are meant to be directionally correct but not necessarily linear.

APPENDIX: MATURITY MATRIX BY CATEGORY

Culture

A company's culture around use of Artificial Intelligence grows much like any relationship. It starts with intrigue. What can it do for me? How does it work? Will my life be better? As the company learns, it is curious and tests AI. The culture can bloom from curiosity to dependence with more use cases and verification. At levels 4 and 5, a company trusts AI and it is integrated into everyday work to support the mission of the company and help inform the path forward. Keep in mind that this does not mean blind trust. In an FDA regulated environment, the company culture must include verification to ensure that the AI is operating on credible data, communicating properly with other systems, and adhering to relevant procedures.

MATURITY AREA	MATURITY FACTORS	MATURITY LEVEL CHARACTERIZATION				
		LEVEL 1	LEVEL 2	LEVEL 3	LEVEL 4	LEVEL 5
Communication	Established channels for communication with feedback mechanisms.	No communication.	Random or ad hoc communications, likely one-way (no feedback loop).	Random or ad hoc communications with feedback loop.	Coordinated communications with feedback loop.	Coordinated communications with integration to results from executing on feedback. Could include an internal website or internal social media applications.
Procedures	Established procedures defining key roles, responsibilities, activities and processes.	No established procedures for AI life cycle management.	Ad hoc processes and loosely defined procedures for AI life cycle management.	Some procedures for AI life cycle management, not covering the full life cycle or not complete.	Procedures for all areas of AI life cycle management and integrated into the broader QMS.	Procedures regularly updated by feedback mechanisms for continuous improvement.
AI Mode Awareness and Understanding	Evolving from lack of understanding to trust.	Mistrust, black box.	Interest in AI and research as to how it is being used by others. ID the issue to be addressed.	Build trust, select algorithm.	Build model, better decision-making capability	Assume AI use and value. Routine AI use in business and/or operational efficiencies attained
Technical Capability & Key Learning	Programs/initiatives to address culture issues related to AI.	No information shared.	Ad-hoc awareness program. More of a coding level.	Citizen data scientist—can ID opportunities for tools that do not require expertise.	Ability to discern if data from AI is correct/usable vs. what is not. Formal education system.	Continuous learning and benchmarking. Apply best practices.

Governance and Organization

This category is used to evaluate the governance and organization of personnel that allows for, and supports, responsible use of AI. The goal is to evaluate the structural integrity of the framework of the organization, practices, and processes by which a firm is directed in its use and application of AI.

MATURITY AREA	MATURITY FACTORS	MATURITY LEVEL CHARACTERIZATION				
		LEVEL 1	LEVEL 2	LEVEL 3	LEVEL 4	LEVEL 5
Executive analytics orientation (Chief Information Officer, Chief Data Officer, Chief Executive Officer, etc.)	How well the AI outputs influence executive insights and strategic direction.	Limited, if any, understanding of AI output (may be limited to classical statistic and not true AI).	AI is used as a prospect tool for non-critical tasks and using non-sensitive data. AI Teams are experimental task forces mainly formed by internships or non-experimented people.	Beginning to understand relationships between data sets and outputs. AI is starting to be used for several critical actions (e.g., manufacturing) but with no access to sensitive data (e.g., AI Vision). Strategic initiatives in place.	Roadmap for integration of data for reliability (I.e., plan for a plan). AI tasks and results are part of the critical processes and sensitive data is used for AI model creation. AI activity is lead at the management level.	Strategic integration of outputs for synthesis of insights that directly influence and reflect the business strategy. Used for decision making at the highest level. AI activity is lead at an enterprise level
Good Data Science practices/adoption	Available SOP. Consolidated structures. Organizational recognition and transversal support (SME).	Data scientists apply their own criteria, tools and data storage in order to get insights.	There are non-formal agreements regarding the AI tools (e.g., IDE and frameworks), data storage, and ways to present results.	There is a departmental strategy for AI tasks, mainly for the data, algorithm and model life cycle.	The AI practices are described in the Quality System framework.	The proposed AI practices have been followed for >1 cycle in the Quality System review and is integrated in the rest of global procedures.
Human Resource Structure and Technical Capabilities	How well the degree of technical capability & subject matter expertise aligns to organizational goals.	Hire/develop technical resources/ consultants. Data scientists workforce are based on internships and outsourcing.	Hire/develop data analysts. AI activities are only known from a reduced team limited to the AI resources, I.e., centralized model,	Hire/develop data engineer and specialized data scientists. They would likely operate under IT management structure.	Hire/develop data scientists/ Machine Learning Engineers + AI Manager. AI activity is known by collateral departments. More centralized model.	Establish AI team and along with CIO. AI is part of the cultural structure of the company managed as an asset. Analytically innovative at all levels, decentralized.
Competence of organization with AI-based tactics. Commoditization and democratization of AI and AI-based tools.	How well the rank and file understand, and are able to utilize AI-based tools and approaches.	Limited, if any, understanding of AI and tools based upon them. Find Excel stimulating.	Some individuals moderately proficient or many individuals generally aware.	Many beginning to understand and moderately capable with AI in functional applications. Can readily implement with some guidance. Same personnel using AI tools without interaction in daily work.	Many individuals can receive new AI tools and independently understand their application, power and operation. AI results used in critical processes.	Routine AI use in business andor operational efficiencies attained.

Data Management

AI is logical and operates on groups of data based upon the orderly observance of rules (via algorithm). The organization of input is equally important to the success of the process and the credibility of the output. Data maintenance is an integral part of the AI system integrity.

MATURITY AREA	MATURITY FACTORS	MATURITY LEVEL CHARACTERIZATION				
		LEVEL 1	LEVEL 2	LEVEL 3	LEVEL 4	LEVEL 5
Data acquisition	Data quality and volume for use by AI	Paper based, collected by humans, not real time. Prone to human error.	Systems in place for data collection. Dataset with missing, partial, low volume information.	Transformation required from raw data to final format. Human interaction to attain data.	Removal of data bias and sampling noise. Automated process to attain data.	Real time quality data. Fault is understood and immediately corrected. System is aware of accurate data.
Data source	Data source and structure	Spreadsheets are primary data source. Minimal standards for data format and structure.	Minimal level of data collected from many systems with little to no curation. Structured and unstructured data. Human-data interaction needed.	Data sources and data management are integrated accurately but not systematically or totally automated.	Most data are curated, organized and accurate. Management of the data lifecycle.	All data are curated and best practices are in place.
Data integrity/security	Traceability, accuracy and validity of data	Paper-based data with uncontrolled access.	Manage access to data, address content protection. Strong access control and password management.	Conform to ISO IEC standards. FAIR principles. ALCOA+. Fully encrypted data.	Full traceability for changes and model version. Continuously validated state.	Data security/integrity in place to deal with continuous learning model (self-improving). Detects tampering.
Data availability	Data accessibility	Paper-based data archived, accessible manually.	Centralized electronic repository for critical data.	Organized use of structured and unstructured data. Critical data is still in siloed systems although there are initial initiatives integrating non critical data systems.	Hybrid data management practice in place. Leverage both cloud and on-premises data. Data centricity in place.	Fully data-driven business. Access to all required data for AI implementation and operation.

Tools and Techniques

Adoption of AI and the advancement of technology maturity can stimulate and directly relate to holistic business maturity. Practical implications of AI utilization include realization of goals and development of new capabilities at a rapid pace. With AI as a tool, companies have the potential to achieve a remarkably favorable ROI, as decisions are much more informed than ever before.

MATURITY AREA	MATURITY FACTORS	MATURITY LEVEL CHARACTERIZATION				
		LEVEL 1	LEVEL 2	LEVEL 3	LEVEL 4	LEVEL 5
Depth of AI application in a company vs. breadth of application	Digitization level (across company: warehousing, R&D, manufacturing, quality, labs, etc.). For example, Product Development might be all over it, but the rest of the company still using clipboards. Or, the whole company might be employing some initial, basic steps.	General understanding of function but not the use of AI.	Operation of AI vs. understanding programming.	Elements of AI are present but it is not used broadly and comprehensively.	Degree of application to replace human actions. Models are dynamic vs. static. Models are implementation specific with updates from own measurements, self-calibrating.	Quantify the number of areas automated year over year. Use across multiple projects and departments within the company. Majority of personnel trained and using AI capability.
Analytics	Gartner's maturity model, bioforum maturity level, FDA maturity model Application of AI.	Basic descriptive analytics. Raw massaged data, not interpreted.	Advanced Descriptive analytics. (Hindsight) Interpreted data.	Diagnostic analytics. (Insight) First level interpretation.	Predictive analytics (Foresight) Know what the outcome is going to be with manual response to maintain controlled state.	Prescriptive analytics, Process control, Avoid failure, No need for human interaction for a controlled state.
IT	Proprietary software/ libraries. Open source platform libraries. Software installation. Limited computational capabilities.	$ Ad Hoc. Software platforms decided by each Data Scientist. Platforms and algorithms self-maintained. No organizational control on the applications nor hardware.	$$ Part of the functional budget. Investment in AI as a potential opportunity.	$$$ Dedicated, but limited budget. There is a non-dedicated budget for AI, although AI is included in the same bag with the rest of technologies.	$$$$ Dedicated, strategic budget. Strategic platform management via life cycle and quality system approach. Version evolution.	$$$ Enterprise budget as a corporate service. Enterprise level strategy and support alignment. ROI supports cost of on-going AI growth plans.

XAVIER AI WORKING TEAMS

Through the Xavier Artificial Intelligence Initiative, chartered working teams have been established during the face-to-face setting of the annual Xavier AI Summit. The teams that are currently formed are as follows, and are accepting new members:

AI in Operations (AIO) Team
The AIO Team is an organized, cross-industry discussion group of FDA officials and industry professionals working to increase the predictive assurance of product quality across all operations through the power of AI. →Learn more

Good Machine Learning Practices (GMLP) Team
The GMLP Team is bringing the world of AI activity into one place in order to increase the awareness of good work that has already been done and to collaboratively further solutions that address challenges related to AI implementation across the industry. →Learn more

AI at the Point of Care (AI@POC) Team
The AI@POC Team is designed for physicians and healthcare system members seeking to leverage augmented intelligence to improve patient care, clinical workflow and system operations. →Learn more

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