Predictive AI for CDS
A 7-Step Suitability Framework

Illustrated with a CGM based
Diabetes Early Detection AI Tool

1. Clinical Hypothesis
2. Labeled Data Availability
3. Data Structure and Preprocessing
4. Interpretability and Explainability
5. Financial Sustainability
6. Bias Mitigation
7. Data Acquisition

Darena Solutions | MeldRx

Executive Summary

Evidence-based medicine (EBM) has long been the gold standard for validating clinical interventions. By relying on prospective studies, most notably randomized controlled trials (RCTs), EBM aims to establish causal relationships under controlled conditions. These relationships inform the guidelines that have driven clinical decisions in medicine.

The past few years have seen a surge in the adoption of AI in healthcare, accelerated by rising awareness of AI's potential following the mainstream exposure of ChatGPT in late 2022. Predictive AI, a subset of artificial intelligence, offers data-driven insights that promise to transform clinical workflows and decision-making processes. Unlike EBM's prospective trial designs, Predictive AI can leverage both retrospective and, increasingly, real-time data sources to forecast events (e.g., hospital readmissions, sepsis onset) by identifying patterns and correlations in large datasets.

Despite differences in data collection and validation, EBM and AI share crucial principles. This white paper proposes a structured, hypothesis-driven framework to evaluate the suitability and develop Predictive AI for clinical decision support (CDS) tools with the same rigor we expect from EBM. This seven-step framework ensures that AI solutions are clinically valid, ethically sound, financially viable, and capable of providing personalized insights at the point of care and for population health.

Evidence-Based Medicine and Predictive AI

EBM and predictive AI differ in methodology, but their complementary strengths can drive innovation in clinical decision support. Both approaches begin with a hypothesis. EBM seeks to answer whether an intervention reduces risk through controlled trials, while predictive AI determines whether future risk can be forecasted using existing data.

EBM is "*Does X intervention reduce Y risk?"*

Predictive AI is "*Can we predict Y risk using X factors?"*

EBM's prospective trials establish causation, while predictive AI's real-world data analyses illuminate correlations.

🦋 Key Points

- **Validation Approach**: EBM relies on prospective trials under controlled conditions to establish causality, whereas predictive AI predominantly uses retrospective or near-real-time data to identify correlations in real-world settings.
- **Data Sources**: EBM draws from structured clinical trials, while predictive AI leverages heterogeneous data, including electronic health records (EHRs), wearable sensors, and imaging datasets.
- **Application Scope**: EBM provides standardized guidelines that inform medical practice, while predictive AI offers personalized insights by tailoring predictions to individual patients.

Table: Comparing EBM and Predictive AI Development

EBM	Predictive AI
Prospective RCTs	Retrospective or real-time data
Causal relationships	Correlation-based insights
Controlled conditions	Real-world data variability

We have explored the detailed comparisons between EBM and Predictive AI in a separate white paper titled “Embedding Predictive AI in Clinical Decision Support.” This paper focuses specifically on the suitability framework, demonstrating how AI-driven insights, when aligned with the rigor of EBM, can ensure both reliability and innovation in clinical decision-making.

The 7-Step Framework for AI Suitability

We propose a structured, hypothesis-driven approach to determine when Predictive AI is appropriate for clinical decision support. This framework is specifically designed for **supervised learning**, a widely used type of Predictive AI that relies on labeled data to train models for forecasting clinical outcomes. By following these seven steps, healthcare organizations and solution developers can ensure that predictive AI solutions are clinically relevant, ethically sound, and practically viable.

Each step is a critical checkpoint in assessing whether supervised learning-based Predictive AI solutions can effectively integrate into a healthcare setting. In the following sections, we will explore each step in detail, discussing its significance, challenges, and best practices for successful implementation. These seven steps are:

1. Clinical Hypothesis
2. Labeled Data Availability
3. Data Structure and Preprocessing
4. Interpretability and Explainability
5. Financial Sustainability
6. Bias Mitigation
7. Data Acquisition

1. Begin with a Clinical Hypothesis

- **Example**: “Can we predict sepsis onset 6 hours early using vital signs and lab results?”
- **Key AI Terms to Know**:
    - Label: The outcome to predict (e.g., sepsis diagnosis)
    - Features: Input variables (e.g., heart rate, lactate levels)

🦋 Why it Matters

AI can detect patterns in clinical data that may not be immediately obvious, helping improve risk prediction and early intervention. However, **the most effective Predictive AI solutions begin with a well-defined clinical question and outcome** rather than relying solely on automated pattern discovery.

Traditional machine learning models depend on carefully selected features (structured variables chosen by experts), while deep learning can automatically extract meaningful patterns from complex data sources, such as imaging or unstructured clinical notes. This makes deep learning particularly useful in cases where relationships between variables are less well understood. Still, even deep learning models benefit from a structured clinical hypothesis to guide their development and validation.

🦋 Key Action

Clearly define your **target outcome (label)** and the **relevant data points (features)** that may influence it. While AI can enhance discovery, a strong clinical hypothesis ensures the model is aligned with real-world decision-making and avoids generating spurious correlations. The best Predictive AI solutions balance AI-driven pattern detection with a structured clinical foundation. **Avoid data "fishing expeditions"** by anchoring the project in a meaningful clinical question.

2. Ensure Labeled Data Availability

Once a clinical hypothesis has been established, the next step is to confirm that labeled data exists to support model development. Supervised machine learning relies on historical data where the outcome of interest (label) is already known, allowing the model to learn patterns that distinguish between different patient trajectories. **Predictive AI cannot be effectively trained or validated without reliably labeled data.**

For a hypothesis to be suitable for predictive AI, the outcome it aims to predict must be identifiable within existing datasets. This can be determined through retrospective analysis, where past cases are reviewed to check whether the defined outcome has been recorded consistently. Additional steps, such as clinician annotations or proxy measures, may be needed to generate meaningful training data if the required labels do not exist or are inconsistently documented.

🦋 Why it Matters

The feasibility of a predictive AI model depends on whether the target outcome can be clearly and consistently labeled. The project may not be viable if the defined outcome in the hypothesis cannot be extracted from existing data sources. **Incomplete, inconsistent, or unreliable labels can degrade model performance and limit clinical applicability.**

🦋 Key Action

Before proceeding, **validate that the outcome (label) defined in the hypothesis is available and usable for model development**. Conduct an initial review of existing datasets to determine if past cases contain clear labels for the predicted outcome. Consider alternative hypothesis formulations or strategies to obtain labeled data if labels are absent or unreliable. Ensuring high-quality labeled data at this stage is critical, as poor labels lead to poor models and unreliable clinical predictions.

3. Assess Data Format and Structure

With labeled data availability confirmed, the next step is to assess how this data will be prepared for the AI model. At this stage, technical teams may need to get involved to determine the data format, structure, and preprocessing requirements. The goal is to ensure the identified labeled data can be efficiently transformed into a format suitable for model training.

🦋 Why it Matters

Many AI models perform best with structured data, such as lab values, ICD codes, and medication records, which are well-organized and directly usable. However, a **significant proportion of healthcare information exists in unstructured formats**, including free-text physician notes, diagnostic images, and continuous sensor streams from wearables. These **require specialized preprocessing techniques**, such as natural language processing (NLP) for text, computer vision for imaging, or signal processing for sensor data. Critical insights may be lost without proper structuring, making AI predictions unreliable.

🦋 Key Action

Determine whether the available labeled data is primarily structured, unstructured, or both, and assess the necessary preprocessing steps. If unstructured data is involved, plan for conversion tools such as LLM-powered natural language processing (NLP) for text-based records, computer vision for imaging, or signal processing for continuous sensor data. Early collaboration between clinical and technical teams is essential to ensure the data is properly formatted and ready for AI model development.

4. Prioritize Interpretability and Explainability

Predictive AI in healthcare must provide accurate risk assessments and explain its reasoning in a way that aligns with clinical decision-making.

🦋 Why it Matters

Clinicians need to understand why an AI model has flagged a patient or recommended a particular intervention. Black box models that lack explainability can face resistance from clinicians and regulators. **Explainable AI (XAI) helps foster confidence, regulatory acceptance, and clinical adoption.**

AI explainability approaches typically fall into two broad categories:

- **Interpretable Models**: Simple models like decision trees or logistic regression that provide direct, understandable reasoning.
- **Complex Models with Explainability Tools:** More advanced models, such as neural networks or ensemble methods, require additional techniques (e.g., SHAP, LIME) to clarify their decision-making.

A well-defined clinical hypothesis helps correlate predictions with known medical knowledge, ensuring AI insights remain aligned with healthcare decision-making. At the same time, **AI has the power to identify new patterns that clinicians may not have considered**, making it a growing area of research.

🦋 Key Action

Determine the necessary level of transparency early. If interpretability is critical, select inherently explainable models or plan to integrate explainability tools.

Note

Explainable AI is a broad and evolving field that extends much beyond the scope of this discussion. The complexities of making AI models more interpretable in healthcare warrant deeper exploration, potentially as a dedicated white paper.

We are actively investigating new research on explainability strategies and best practices to ensure that AI insights remain actionable, transparent, and safe for real-world clinical use. If you're interested in discussing these topics or collaborating on future research, please reach out to us.

5. Align with Financial Sustainability

While clinical outcomes are paramount, AI solutions must align with financial realities to ensure long-term adoption and impact. Just as clinical trials require funding, predictive AI must fit within the financial ecosystem. However, not all decisions are purely driven by cost. Financial considerations often reflect broader priorities, such as improving patient care, optimizing resource utilization, and ensuring equitable access.

🦋 Why it Matters

A clinically effective AI solution can fail without a clear adoption strategy or reimbursement model. AI tools that reduce hospital readmissions or improve early disease detection may have clear cost-saving incentives, but others, such as AI for personalized medicine or rare disease detection, may require alternative funding models. Understanding who benefits and who pays is essential for sustainability.

AI adoption should align with key priorities, such as:

- Reducing preventable complications to lower healthcare costs.
- Improving operational efficiency, such as reducing administrative burden.
- Enhancing patient experience with personalized care and proactive interventions.
- Supporting value-based care models, where reimbursement is tied to patient outcomes rather than volume of services.

🦋 Key Action

Analyze market and payer dynamics early in the process. Consider how frequently the targeted clinical problem occurs. Does it justify reimbursement through insurance, hospital cost savings, or direct-to-consumer models? Aligning AI solutions with existing healthcare priorities ensures financial viability without compromising clinical impact.

6. Mitigate Bias Proactively or Accept it

Bias in predictive AI models often stems from the data used during training. **Retrospective healthcare data can reflect existing inequities, making models less generalizable across diverse populations.** For example, a diabetes prediction model trained primarily on younger adults may underperform for older individuals or underrepresented groups.

🦋 Why it Matters

Unaddressed bias can lead to disparities in care. However, if adequately declared and understood, bias is not inherently bad**.** Certain models may be optimized for specific populations, but this must be explicitly stated. **This is why documenting source attributes is essential,** as it helps specify who is included in the dataset.

🦋 Key Actions

- **Review Source Attributes**: Assess dataset composition and ensure demographic diversity. Clearly document who the model applies to and where it may have limitations.
- **Use Model Cards for Transparency**: Leverage tools like CHAI's "Nutrition Label" Model Card to outline source attributes, performance metrics, and bias considerations.
- **Decide and Declare Applicability**: If a model works best for a specific demographic, communicate this clearly rather than assuming broad generalization.

By proactively addressing bias and ensuring transparency around data sources, healthcare organizations can develop AI models that are not only effective but also equitable, fostering trust and improving clinical outcomes.

7. Data Acquisition and Governance

With the model requirements established in the previous steps, the next critical phase is confirming how the necessary data will be acquired and governed. This step **ensures that the identified data sources** from Step 2 (Labeled Data Availability) and Step 3 (Data Structure and Preprocessing) **are accessible, compliant, and ready for real-world implementation.** At this stage, pilot planning begins, determining how data will flow securely into the model.

🦋 Why it Matters

AI in healthcare operates within strict regulatory frameworks, including HIPAA (U.S.), GDPR (EU), and evolving local policies. Accessing and using patient data requires robust governance, privacy safeguards, and clear data-sharing agreements. Ethical data use fosters trust with patients and providers, ensuring long-term adoption.

🦋 Key Actions

- **Confirm Data Access and Sources**: Define how the necessary data will be obtained - through hospital EHRs, registries, secure data-sharing agreements, or real-time patient-generated sources.
- **Establish Data Governance Policies**: Outline where and how data will be stored, encrypted, and processed to ensure compliance with regulatory requirements.
- **Plan for Secure and Scalable Pipelines**: If leveraging real-time data, ensure that data ingestion pipelines can handle continuous updates efficiently while maintaining security.
- **Design Pilot Studies**: Identify initial test sites or clinical partners where the AI model can be validated in real-world settings before broader deployment.

Regulatory Guidance

While a complete discussion of regulatory compliance is beyond the scope of this framework, it is a rapidly evolving area that must be considered at every stage of AI development. Regulatory requirements vary across regions and continue to evolve as healthcare AI adoption increases. Ensuring **alignment with regulatory expectations from the outset** can prevent delays in deployment and improve trust among healthcare stakeholders.

The FDA's evolving stance on Software as a Medical Device (SaMD) and similar international frameworks are key considerations when developing AI-driven clinical decision support (CDS).

- **Verify Regulatory Requirements**: Determine whether the AI tool needs regulatory approval and prepare documentation accordingly.
- **Maintain Transparent Model Documentation**: Keep detailed records of model training, validation, updates, and performance metrics for potential regulatory review.

By proactively addressing data acquisition, governance, and regulatory alignment, organizations can ensure that AI models transition from development to real-world clinical use responsibly and efficiently.

Having examined each critical stage of implementing predictive AI, from forming a robust clinical hypothesis to establishing data governance, we now see how a hypothesis-driven, structured approach can guide AI projects in healthcare. These steps help teams avoid "data fishing" pitfalls, ensure equitable patient representation, and build clinically relevant and financially sustainable models. In the next section, we will apply this framework to a practical, real-world scenario of predicting and preventing early-onset diabetes using data from continuous glucose monitors (CGMs).

Applying the 7-Step Framework

Case Study: Diabetes Prediction and Prevention Using Continuous Glucose Monitoring (CGM)

Continuous Glucose Monitors (CGMs) have revolutionized diabetes management by providing real-time insights into blood sugar levels. Traditionally prescribed for individuals with diabetes, recent advancements have led to the availability of over-the-counter (OTC) CGMs, such as Dexcom's Stelo and Abbott's Libre Rio, making these devices accessible to a broader population, including those without diabetes who are interested in monitoring their health.

Consider the potential of utilizing CGM data to predict the early onset of diabetes. By analyzing continuous glucose readings alongside electronic health records (EHRs) and lifestyle factors, we may be able to develop predictive models to identify individuals at risk before clinical symptoms emerge.

Let’s apply this framework to assess the feasibility of using OTC CGMs, which may be leveraged for early diabetes risk predictive AI solutions. We will illustrate each step's practical implementation.

Step 1: Begin with a Clinical Hypothesis

The first step in applying the AI Suitability Framework is to establish a **clear clinical hypothesis** that defines the problem, outcome, and key features relevant to the predictive model.

Can an AI-powered app predict early diabetes risk using data from over-the-counter CGMs, lifestyle factors, and EHR integration?

- **Outcome (Label)**: Progression to diabetes (*HbA1c ≥ 6.5%*) within two years.
- **Key Features**: CGM data (*time-in-range*), lifestyle data (*diet logs*), and clinical metrics (*BMI, family history*).
- **Hypothesis**: Combining CGM trends with lifestyle factors can detect prediabetes earlier and more accurately than standard screening alone.

A well-defined clinical hypothesis ensures the AI model has a clear purpose, a measurable outcome, and relevant input features grounded in a reasonable clinical assumption. This foundation helps ensure that the model is not just data-driven but also clinically meaningful and aligned with real-world medical knowledge, increasing its chances of adoption and impact.

Step 2: Ensure Labeled Data Availability

With a clear clinical hypothesis established, the next step is to confirm that the necessary labeled data exists to train and validate the AI model. Since the goal is to predict diabetes onset, **the labeled data must include individuals with CGM readings and follow-up HbA1c values** to determine whether they progressed to diabetes (HbA1c ≥ 6.5%).

🦋 Identifying Labeled Data Sources

To ensure the feasibility of this predictive AI solution, the dataset must include:

- **CGM Data**: Continuous glucose trends over time, preferably from OTC CGMs.
- **HbA1c Measurements**: Defined outcome label indicating if the individual progressed to diabetes.
- **Lifestyle & Clinical Data**: Supplemental factors such as diet logs, BMI, and family history.

🦋 Addressing Data Availability Challenges

Since longitudinal CGM datasets with follow-up outcomes may be limited in the near term, data acquisition strategies may include:

- **Partnering with Health Systems** to access retrospective EHR data that includes CGM readings and HbA1c values.
- **Recruiting Volunteers** to share OTC CGM data through a secure app, ensuring real-world applicability.

By validating the availability of labeled data upfront, we ensure that the AI model has **a reliable foundation for learning patterns and making accurate predictions.** Without sufficient labeled data, the feasibility of the predictive solution would be compromised.

Step 3: Assess Data Format and Structure

With labeled data identified, the next step is to **determine whether the available data is primarily structured, unstructured, or both** and assess the necessary preprocessing steps.

- **Structured Data**: Includes lab values (HbA1c, BMI) and medication history, which are already well-organized and directly usable.
- **Time-Series Data** (Structured but requires transformation): CGM data consists of continuous glucose readings over time. While structured, it must be transformed into meaningful features (e.g., average glucose levels, glucose variability, time spent above 140 mg/dL) for model training.
- **Unstructured Data**: Clinical notes require Natural Language Processing (NLP) to extract relevant information such as lifestyle factors or physician observations.

Data must be properly formatted and standardized before training to ensure model readiness. Appropriate conversion tools, such as NLP for text-based records and feature extraction techniques for time-series data, must be implemented if unstructured data is involved.

Early collaboration between clinical and technical teams is essential to ensure that data is clean, interpretable, and aligned with the AI model's needs, maintaining both accuracy and usability.

Step 4: Prioritize Interpretability and Explainability

Clinicians must understand and trust AI predictions. In this case, explainability may be more straightforward, as CGM trends and lifestyle factors align with known clinical risk factors for diabetes. However, explainability will become increasingly important as the model identifies new patterns.

Since different machine learning models offer varying levels of interpretability, ML experts should be involved in deciding the appropriate approach.

- **Start with interpretable models** (e.g., decision trees) where possible.
- **For more complex models** (e.g., gradient boosting, neural networks), use techniques like SHAP or LIME to provide insights into predictions.

While explainability may not be a significant challenge in the early stages, **as AI uncovers unexpected trends, we must ensure that insights remain clinically relevant and actionable.** This will require ongoing collaboration between clinical and ML teams.

Step 5: Align with Financial Sustainability

Diabetes is one of the most prevalent chronic diseases, making early detection a priority for both healthcare systems and insurers. For a predictive AI solution using CGM data to succeed, it must align with a sustainable financial model that ensures long-term adoption and impact. There are multiple potential strategies for bringing this type of AI to market.

🦋 Possible Market Approaches

- **Consumer-Facing App:** A free or low-cost app that allows users to monitor their glucose trends and receive risk insights, helping build a large dataset for model improvement.
- **Clinician-Facing Dashboard**: A premium version of the platform with advanced analytics for healthcare providers, supporting more personalized diabetes prevention strategies.
- **Payer and Employer Partnerships:** Collaborations with insurance companies and corporate wellness programs that aim to reduce long-term diabetes-related costs through early intervention and prevention.

Since not all AI-driven healthcare solutions follow the same financial pathway, defining a strategy early helps ensure viability. Whether through direct-to-consumer, payer-driven reimbursement models, or employer-based incentives, AI adoption should align with stakeholder priorities to maximize both clinical and financial value.

Step 6: Mitigate Bias

As we evaluate the suitability of this predictive AI solution, it is essential to consider potential biases that could impact model performance and fairness. Bias often originates from data imbalances, where specific populations may be underrepresented, **leading to skewed predictions and disparities in care.** In this case, several factors could introduce bias.

🦋 Potential Bias Risks

- **Underrepresentation of Older Adults and Minority Groups**: If the dataset primarily includes younger, tech-savvy users who adopt OTC CGMs, the model may not generalize well to older adults or underrepresented populations.
- **Limited Access to OTC CGMs:** Individuals without access to CGMs due to socioeconomic factors or insurance limitations may be excluded from the dataset, reinforcing disparities in diabetes prevention efforts.

🦋 Key Actions for Bias Mitigation

- **Expand Data Sources:** Partner with community clinics and health systems serving diverse populations to ensure broader demographic representation in the dataset.
- **Monitor Model Performance Across Subgroups:** Evaluate how well the model performs for different age groups, ethnic backgrounds, and socioeconomic statuses. If discrepancies are found, adjustments should be made to improve fairness.
- **Leverage Transparency Tools:** Use source attribute tracking and model cards (such as CHAI's Applied Model Card) to document model limitations and ensure responsible deployment clearly.

Since bias in AI cannot permanently be eliminated, **the key is to identify, document, and mitigate it proactively.** By ensuring the model is trained on diverse and representative data, we can increase fairness and build trust in its predictions.

Step 7: Data Acquisition and Governance

Securing and managing data effectively is crucial for developing a predictive AI solution using Continuous Glucose Monitoring (CGM) data. Recent initiatives have focused on enhancing the interoperability and sharing of CGM data, which can be leveraged in this context.

🦋 Efforts in CGM Data Sharing

- **Argonaut Project:** This private-sector initiative aims to advance industry adoption of modern, open interoperability standards. One of its focus areas is to develop standards for integrating CGM data into Electronic Health Records (EHRs), facilitating seamless data exchange between devices and healthcare systems. https://build.fhir.org/ig/HL7/cgm/
- **21st Century Cures Act:** Enacted in 2016, this legislation promotes the development of interoperable software, facilitating easier information sharing between different systems. It encourages the development of applications that allow for standardized data sharing, thereby enhancing patient care coordination.

🦋 Key Considerations

- **Consent & Compliance:** Ensure that patients opt-in under HIPAA/GDPR-compliant protocols. Clearly outline data usage, storage, and update cycles in the informed consent process.
- **Real-Time Data Pipeline:** Develop a system to manage streaming CGM data for timely updates. Validate platform security to maintain patient trust and data integrity.

By aligning with these initiatives and adhering to regulatory frameworks, organizations can responsibly acquire and govern the data necessary for developing effective predictive AI solutions in healthcare.

Bringing AI Suitability to Real-World Implementation

The case study presented in this document serves as a reference example to illustrate how the AI Suitability Framework can be applied to a real-world healthcare challenge. While we explored the feasibility of using over-the-counter CGM data to predict early diabetes risk, this was just one potential application of predictive AI in healthcare.

In practice, different use cases may require adaptations to the framework, such as:

- Addressing different clinical hypotheses and outcomes beyond diabetes prevention.
- Adapting to varied regulatory and data-sharing requirements across different regions and health systems.
- Modifying the financial strategy depending on reimbursement models, payer incentives, or direct-to-consumer approaches.
- Enhancing bias mitigation efforts based on population-specific challenges.

We recognize that real-world AI implementation is dynamic and requires continuous collaboration. As predictive AI continues to evolve, market feedback and stakeholder input are essential to refining how we evaluate and deploy AI-driven clinical decision support solutions.

About Darena Solutions

For over 15 years, Darena Solutions has developed practical solutions to improve healthcare delivery, focusing on real-world challenges like improving data sharing between systems, streamlining clinical workflows, and ensuring compliance with regulatory standards.

MeldRx Overview

MeldRx is Darena Solutions' flagship offering, an FHIR-first backend-as-a-service platform designed to simplify the building and deployment of custom healthcare solutions for organizations of all sizes.

🦋 MeldRx Workspaces

The power of the MeldRx platform comes from its **workspaces**, which are FHIR-ready backend databases that can be provisioned in seconds and scaled on demand. These workspaces provide:

- **Full Data Control**: Organizations can upload and manage their data independently, enabling complete customization of solutions.
- **Apps Integration**: MeldRx offers a comprehensive developer portal, allowing organizations to easily configure their own apps or use apps published by third-party organizations with their workspaces.

Beyond its core functionality, MeldRx workspaces include other features that simplify data acquisition and expand their usability:

Linked Workspaces for Real-Time EHR Integration

MeldRx workspaces can be seamlessly "linked" to any EHR's FHIR servers, enabling real-time access to patient data through apps. Linked Workspaces' unique distributed architecture enables apps to support features such as managing custom data and overcoming EHR limitations (e.g., inability to write data back to the EHR).

Consumer-Mediated Exchange

MeldRx workspaces also facilitate easy integration of consumer-mediated data exchange, empowering organizations to simplify capturing patient data directly into the workspaces.

Regulatory Compliance

MeldRx is ONC-certified, providing healthcare organizations and EHR vendors the confidence to meet evolving regulatory requirements. Its adoption by multiple EHRs highlights its reliability and flexibility, making it a trusted regulatory compliance and innovation partner.

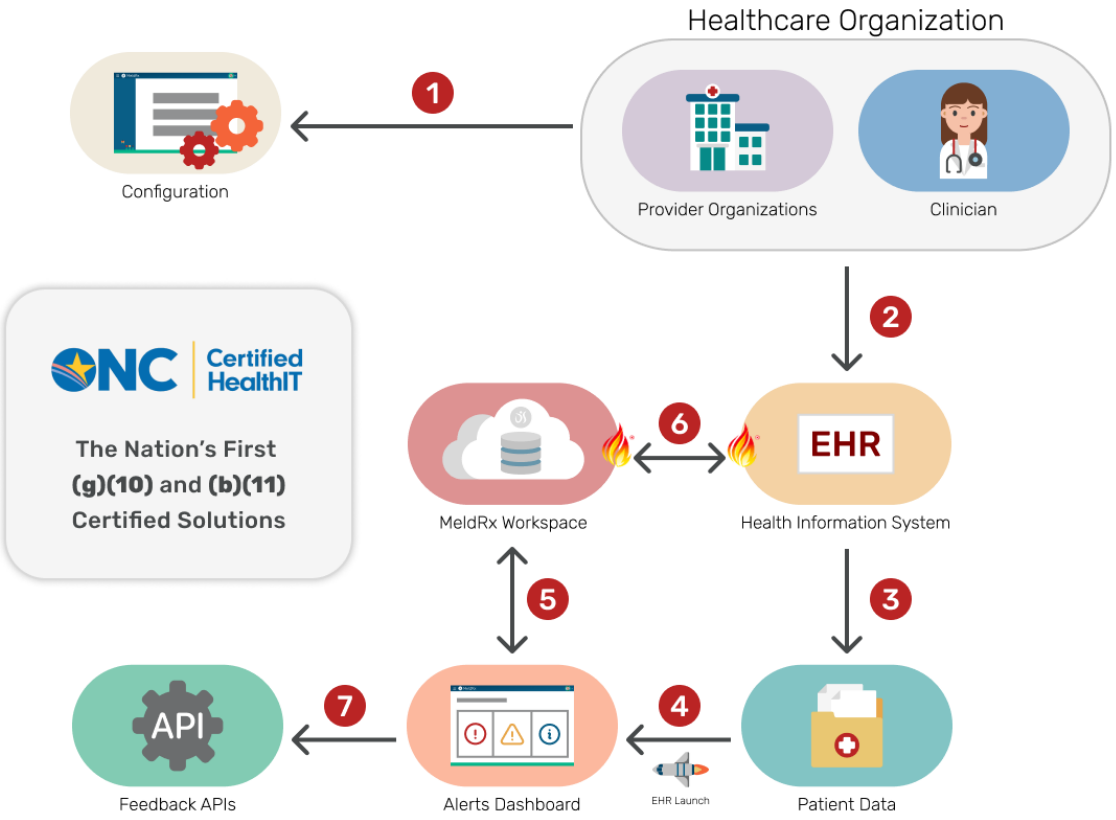
MeldRx CDS: Combining Predictive AI with Evidence-Based CDS

MeldRx Clinical Decision Support (CDS) is a **plug-and-play** component of MeldRx designed to streamline healthcare organizations' adoption of predictive AI in their current workflows. Through ongoing collaboration with EHRs, healthcare organizations, and AI solution developers, and guided by the key areas highlighted in this white paper, we continuously refine our approach. As we learn and adapt to real-world insights, we remain committed to ensuring practical and thoughtful adoption of AI in clinical workflows, balancing innovation with practicality.

MeldRx CDS leverages the core features of MeldRx workspaces and can be deployed as a standalone solution or integrated with any EHR. Additional key features include:

- **Unified Dashboard:** MeldRx CDS offers a fully configurable unified dashboard that consolidates alerts from evidence-based and AI-driven solutions. These solutions can be powered by third-party or in-house applications, allowing organizations to tailor the dashboard to their specific needs and workflows.
- **CDS Hooks**: MeldRx CDS uses CDS Hooks for alert delivery, actions, and collecting feedback. It can leverage CDS hooks even if the integrating EHR doesn't support them.
- **Real-Time EHR Integration**: MeldRx CDS can function as a standalone solution or seamlessly integrate with an EHR using SMART on FHIR.
- **Evidence-Based Alerts**: Built-in CQL designer allows the configuration of evidence-based rules and deploying them along with the predictive AI solutions
- **Multi-Model Enablement**: A robust developer portal for organizations to configure internal AI apps or use third-party solutions.
- **Feedback-Driven Alert Management**: A feedback system built to minimize alert fatigue.
- **Certified (b)(11) Compliance**: MeldRx was the nation's first certified (b)(11) solution.

Plug-and-Play Evidence-Based and Predictive AI CDS



1. Organization configures the **evidence-based** or **predictive AI** CDS protocols in MeldRx.
2. A clinician logs in to their Health Information System (e.g. EHR).
3. The clinician opens a patient chart. The chart shows them a button to launch the alerts dashboard.
4. The clinician launches the dashboard, which displays alerts, insights, or suggestions based on configured protocols and the patient's data from the EHR and/or the MeldRx workspace.
5. The clinician reviews the alerts and suggestions to make care decisions and take actions. Data generated from actions is synced back to the MeldRx workspace.
6. Data generated from actions *may* also be synced back to the EHR.
7. Clinicians share feedback that helps improve protocols over time and reduce alert fatigue.

Call to Action: Evaluating Your Predictive AI Strategy

By following a structured AI Suitability Framework, healthcare organizations can make informed decisions about when and how to implement predictive AI, ensuring it is clinically valid, financially viable, and ethically responsible.

1. **Train Multidisciplinary Teams**: Foster collaboration between clinicians, data scientists, ethicists, and policymakers to ensure AI solutions align with clinical needs and ethical considerations.
2. **Pilot AI Projects Using This Framework**: Apply a structured, hypothesis-driven approach to validate AI models in real-world healthcare settings.
3. **Advocate for Supportive Policies**: Work with regulatory bodies and stakeholders to shape policies that enable ethical and effective AI deployment in healthcare.

We look forward to working with healthcare organizations, technology providers, and industry partners to help them evaluate AI use cases, assess suitability, and guide deployment strategies. Whether it's a hospital evaluating AI for early disease detection, a payer exploring predictive models for cost reduction, or a technology company developing AI-powered health tools, we are committed to supporting responsible AI adoption that drives clinical and economic value.

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