EPIC COMMENTS
RE: PROPOSED PREDICTIVE DSI IN ONC HTI-1

1

Public Disclosure

ONC should limit disclosure requirements to users of predictive DSI

2

Other Developers

ONC should limit health IT developers' responsibilities to their own predictive DSI

3

Improve Definition

ONC should clarify and adjust the definition of predictive DSI

Includes IP Concerns

WHAT DOES IT TAKE TO MAKE AN EXCELLENT PREDICTIVE MODEL?

1 2

Public Disclosure

Other Developers

Effort for Sepsis v2:

Conduct literature review, clinician interviews, studying workflow and best practices, and curating training data sets to define outcome to be predicted

*12 months
4 FTEs*

Determine which model types & input variables are most predictive using feature engineering experiments (many simulations under different conditions)

Investigate potential bias by examining output when stratified by included & excluded variables, comparing to standard models, clinician review

*1 month
2 FTEs*

Finalize model type & input variables; calculate coefficients (overwritten by site-specific fitting later); complete documentation and tools

*2 months
6 FTEs*

WHAT DOES IT TAKE TO MAKE AN EXCELLENT PREDICTIVE MODEL?

Related source attributes:

Effort for Sepsis v2:

Conduct literature review, clinician interviews, studying workflow and best practices, and curating training data sets to define outcome to be predicted

§ 170.315(b)(11)(vi)(C)(1)(i) "output"
§ 170.315(b)(11)(vi)(C)(1)(ii) "intended use"
§ 170.315(b)(11)(vi)(C)(2)(i) "input features"

~80% of time and effort
12 months
4 FTEs

Determine which model types & input variables are most predictive using feature engineering experiments (many simulations under different conditions)

§ 170.315(b)(11)(vi)(A)(5) "demographic elements"
§ 170.315(b)(11)(vi)(A)(6) "SDOH elements"
§ 170.315(b)(11)(vi)(A)(7) "health status elements"

Investigate potential bias by examining output when stratified by included & excluded variables, comparing to standard models, clinician review

1 month
2 FTEs

Finalize model type & input variables; calculate coefficients (overwritten by site-specific fitting later); complete documentation and tools

Once you know model type and variables, and have verified that they produce fair outputs, the rest (coding, computation) is straightforward

2 months
6 FTEs

WHAT CONSTITUTES INTELLECTUAL PROPERTY?

1 **2**

Public Disclosure

Other Developers

WHAT HTI-1 ACKNOWLEDGES AS IP

"details of the specific code, pipeline, statistical processes, or algorithms used to generate model predictions... might be considered the developer's intellectual property"

--Federal Register, Vol. 88, No. 74, p. 23788

WHAT HTI-1 EXCLUDES FROM IP

"source attribute information related to data that was used to train the model, the proper (intended) use of the model, and the performance of the model as assessed through validation and fairness metrics"

--Federal Register, Vol. 88, No. 74, p. 23788

WHAT CAN BE PROTECTED AS A TRADE SECRET

"all forms and types of... information... [that] derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable through proper means by, another person who can obtain economic value from the disclosure or use of the information"

--18 U.S.C. § 1839(3); *see also Uniform Trade Secrets Act*

SOURCE ATTRIBUTES WITH ESPECIALLY STRONG IP CONCERNS

1 2

Public Disclosure

Other Developers

Source Attribute	Current Availability
§ 170.315(b)(11)(vi)(A)(5) "demographic elements"	End user-level
§ 170.315(b)(11)(vi)(A)(6) "SDOH elements"	End user-level
§ 170.315(b)(11)(vi)(A)(7) "health status elements"	End user-level
§ 170.315(b)(11)(vi)(C)(1)(i) "output"	End user-level
§ 170.315(b)(11)(vi)(C)(1)(ii) "intended use"	End user-level
§ 170.315(b)(11)(vi)(C)(1)(iii) "cautioned use"	End user-level
§ 170.315(b)(11)(vi)(C)(2)(i) "input features"	End user-level
§ 170.315(b)(11)(vi)(C)(2)(ii) "ensure fairness"	End user-level

MAKING DATA AVAILABLE TO THE PUBLIC

1

Public Disclosure

ONC should limit disclosure requirements to users of predictive DSI

DISCLOSURE TO USERS

Epic currently reports much of the proposed source attribute information to users through model briefs and in-software drilldown. Any trade secrets are protected by confidentiality agreements.

SHOULD DISCLOSURE BE PUBLIC?

Epic would be required to report detailed information (enough to recreate intellectual property) to non-users and competitors.

IP CONCERNS RE: OTHER DEVELOPERS

2

Other Developers

ONC should limit health IT developers' responsibilities to their own predictive DSI

For models developed by Epic customers' third-party developers...

SOURCE ATTRIBUTES AND IRM PRACTICES

Third Party Developer

Penn Medicine

Epic

Clinicians General Public

Other developers will similarly consider these source attributes to constitute intellectual property. Holding the IP of others unnecessarily increases many risks:

- Accidental infringement

- Accusations of "willful infringement"

- Anchoring bias in innovation

HTI-1: AN ASYMMETRIC SOLUTION

2

Other Developers

ONC should limit health IT developers' responsibilities to their own predictive DSI

Epic will not have full information re: predictive DSI that interfaces with customer systems.

- Epic cannot be aware of all predictive DSI customers have purchased and integrated

- Certification does not extend to non-EHR developers and most will not want to voluntarily submit IP, so in practice they will not send it

- Epic would then be required to label this predictive DSI as non-transparent, implying quality problems, when in fact they just don't want to disclose IP

The net result will be precisely the adverse selection ONC seeks to prevent.

- CEHRT will be required to disclose source attributes, third-party developers will not

- So CEHRT sellers will know about CEHRT, third-party developers will know about their own predictive DSI + CEHRT

- "Nutrition labels, medication fact labels, and clinical trial results" work because the entire industry is subject to the same disclosure requirements

RISK MITIGATION OF OTHERS

2

Other Developers

ONC should limit health IT developers' responsibilities to their own predictive DSI

Engaging in intervention risk management practices "includes determining whether or not the other party has engaged in risk management practices, such as through review of risk analysis, risk mitigation and governance information from the other party."

How can Epic perform meaningful evaluation on predictive DSI we didn't create?

- How would Epic verify the accuracy of the provided information?

- Requirements are to publish practices, not the actual outcomes of the analysis, but how can we know whether appropriate mitigation was performed if we don't know what the analysis concluded in the first place?

- Would users trust Epic's conclusions, or assume we sought competitive advantage?

A SIMPLE SOLUTION

2

Other Developers

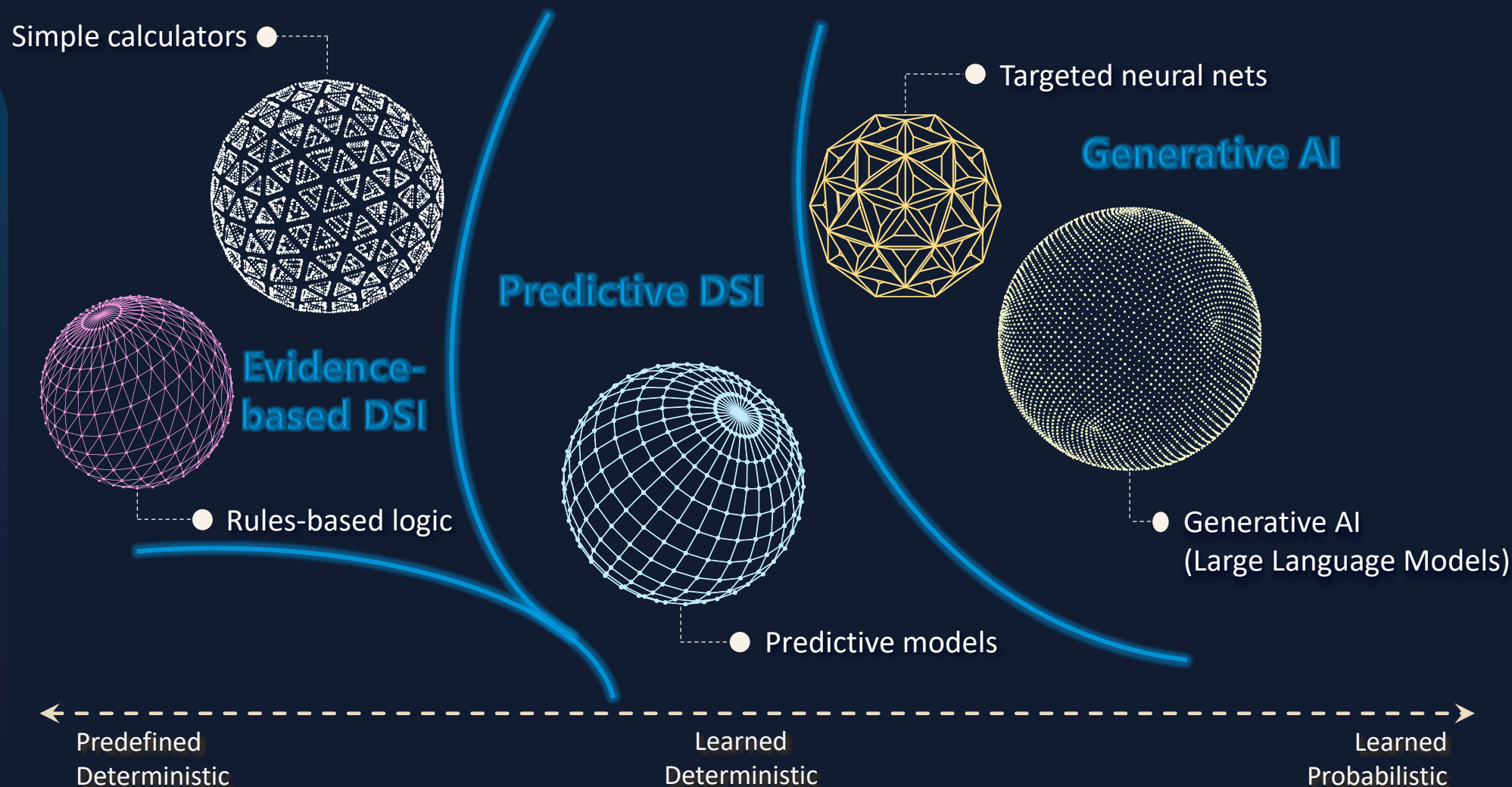*ONC should limit health IT developers' responsibilities to their own predictive DSI*

- Don't require CEHRT developer to collect source attribute information from others

- Don't require CEHRT developer to determine whether others did appropriate risk analysis and mitigation

- Instead, require CEHRT to create the functionality for the organization to display the information, and leave it up to the organization whether they want to display their own information or that of others

- ONC can request the authority it seeks through the A-19 process

THE SPECTRUM OF ALGORITHMIC TECHNIQUES

3

Improve Definition

ONC should clarify and adjust the definition of predictive DSI

Simple calculators

Targeted neural nets

Generative AI

Predictive DSI

Evidence-based DSI

Rules-based logic

Generative AI (Large Language Models)

Predictive models

Predefined Deterministic

Learned Deterministic

Learned Probabilistic

PREDICTIVE DSI VS. GENERATIVE AI

3

Improve Definition

ONC should clarify and adjust the definition of predictive DSI

		Predictive Model	Generative AI
Tool Creation	How it's made	Trained on targeted historical data	Ingests vast datasets, looks for probabilistic relationships
	What data is used to make it	Patient records, clinical outcomes, environmental factors, etc.	Text, images, videos, or a mix of different data types
Tool Use	How it's used	Provides predictions based on current input data	Generates new content or data
	What it's used for	Answers the same one question every time (e.g., sepsis?)	May be used to answer different questions each time
	What data does it use when it runs	A specific patient's medical data selected during model design	A prompt, optionally enhanced by a specific patient's medical data
	Output characteristics	Consistent output for a given input	Same inputs could yield different outputs

SOURCE ATTRIBUTES FOR GENERATIVE AI

3

Improve Definition

ONC should clarify and adjust the definition of predictive DSI

Example: source attributes for GPT-powered features yield unhelpful information

- Intended Use: to draft responses to patient messages

- Training Data: use of language on the internet

- Health Status Assessment Data Elements: impossible to enumerate

Other source attributes not included in HTI-1 could yield meaningful insight

- How is the output displayed to the user limited or controlled?
  Carefully engineered prompts limit nature and content of the output

- How can the user verify the accuracy of the output?
  Sources are cited, with hover links to that portion of the chart, for any facts stated

- Can the user override the AI's output? If so, how?
  The clinician can choose to accept or edit draft, or reject and start from scratch
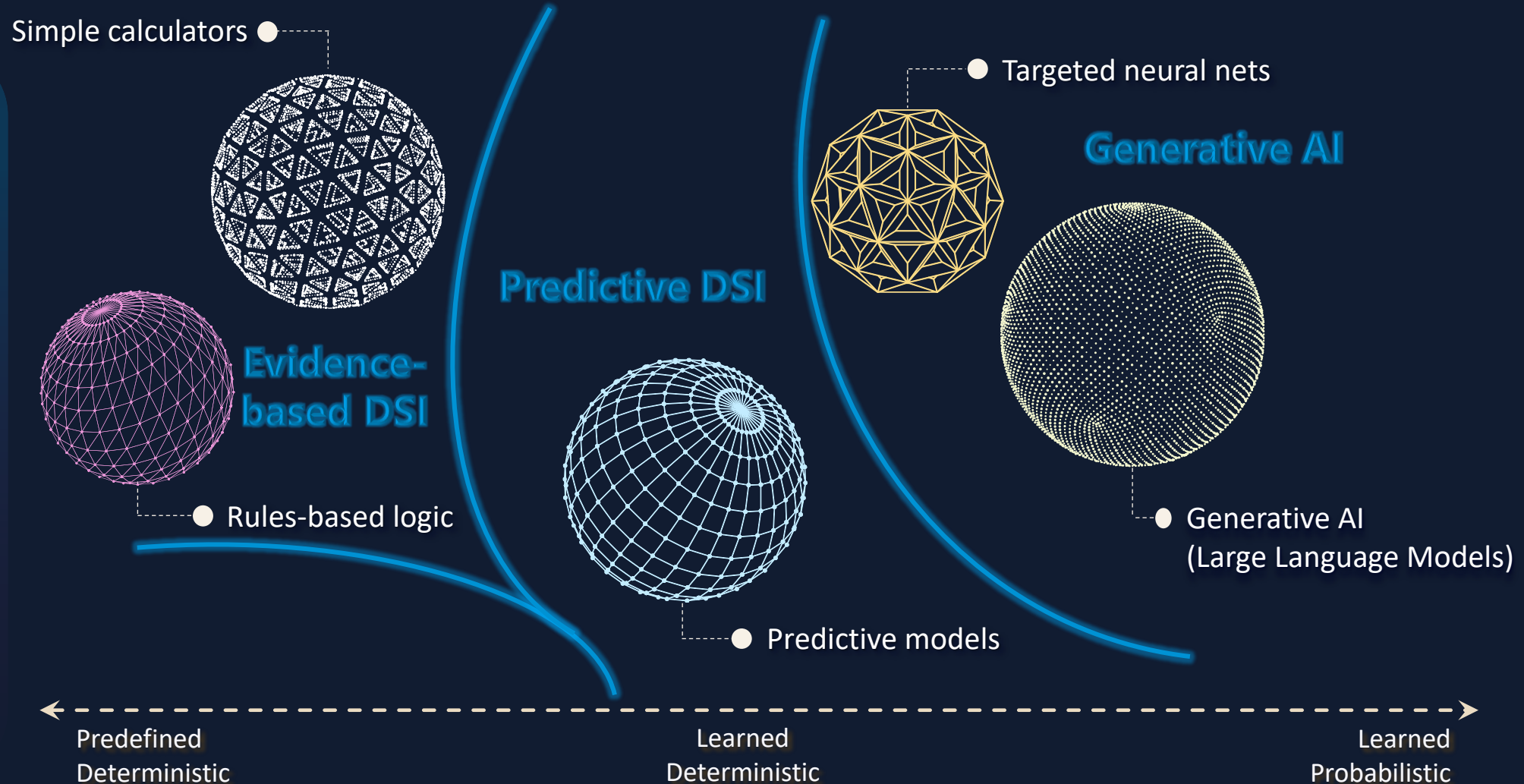
Conclusions:

- Key attributes of generative AI are not covered by HTI-1 source attributes, while HTI-1 attributes don't apply

- ONC should engage in a collaborative process to include source attributes for generative AI in HTI-2; meanwhile, HTI-1's predictive DSI definition should be narrowed

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(Large Language Models)

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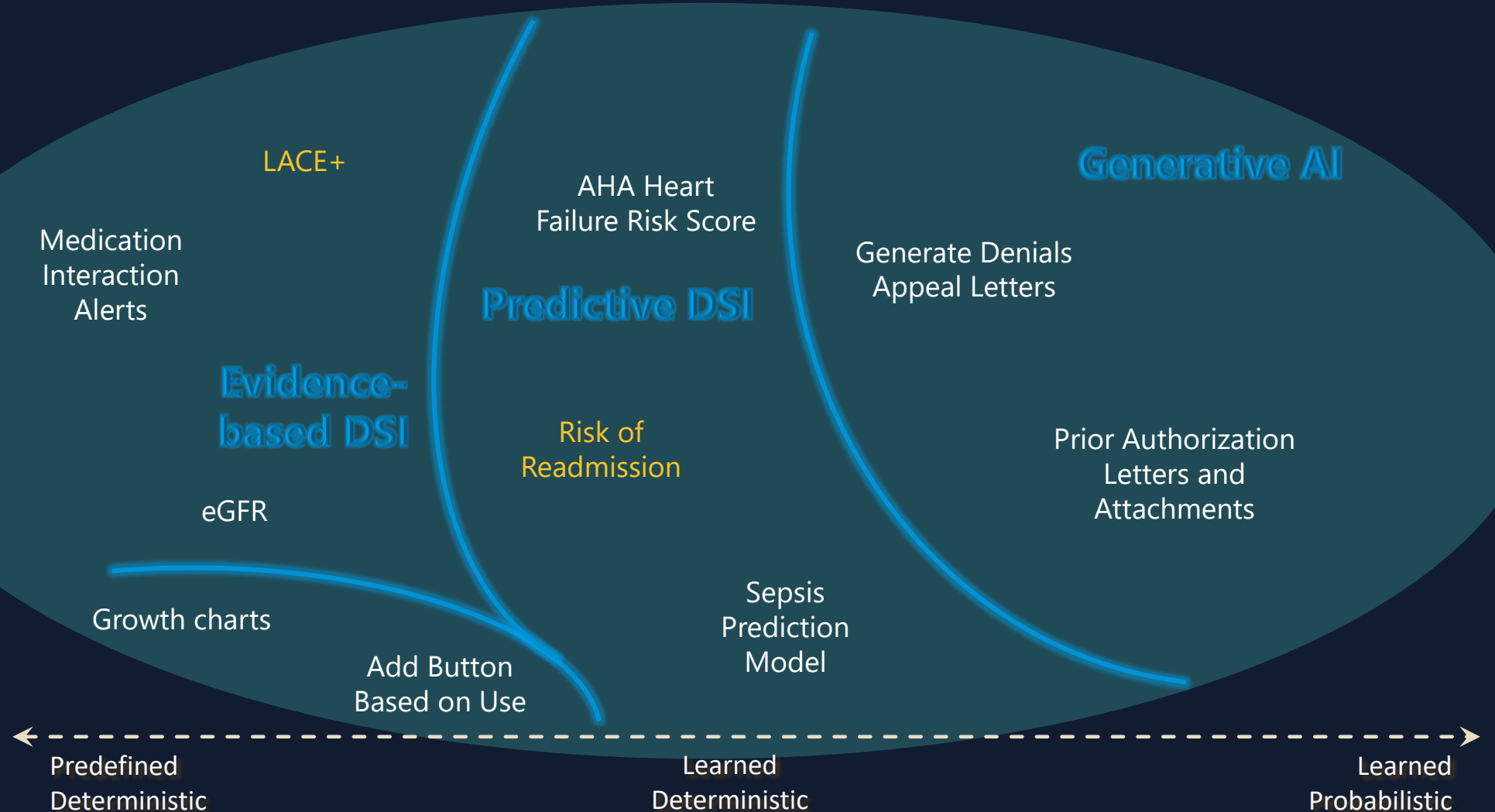Deterministic

Learned
Probabilistic

SCOPE OF DEFINITION OF PREDICTIVE DSI

"Technology intended to support decision-making based on algorithms or models that derive relationships from training or example data and then are used to produce an output or outputs related to, but not limited to, prediction, classification, recommendation, evaluation, or analysis."

3

Improve Definition

ONC should clarify and adjust the definition of predictive DSI

LACE+

AHA Heart Failure Risk Score

Generative AI

Generate Denials Appeal Letters

Medication Interaction Alerts

Predictive DSI

Evidence-based DSI

Risk of Readmission

eGFR

Prior Authorization Letters and Attachments

Growth charts

Add Button Based on Use

Sepsis Prediction Model

Predefined Deterministic

Learned Deterministic

Learned Probabilistic

PROPOSED DEFINITION OF PREDICTIVE DSI

"Technology intended to support clinical decision-making based on models that derive relationships from training using machine learning techniques, which are then used to produce an output or outputs to predict a future event."

3

Improve Definition

ONC should clarify and adjust the definition of predictive DSI

LACE+

Generative AI

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