Achieving scale | Improving access & affordability | Improving quality

Use Case: Use of AI to Predict Donor Variability & Manufacturability for *Ex-vivo* CAR-T

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Disclosures

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Leaning in with AI for personalized medicine

Since the CGT exuberant times of 2021, we now see 2025 funding tracking to the following

Headwinds in CGT

50% of start-up biotechs are **failing to raise institutional seed funding**, and then

50% of the seed funded start-ups are **failing to raise a Series A**

Running fast to get clinical data is showing many flaws in start-up's practices

Prof. Dr. Wolfram Carius, EVP, Cell & Gene Therapy, Bayer

ARM, 2025 Meeting on the Mesa, Private Presentation

*When approaching Bayer with a CGT therapy for investment, it is now fundamentally essential to **show the use of artificial intelligence and data to drive prediction and analysis**. Bayer will diligence this capability…… think about using AI with a few humans to do what 50 scientists would do 5 years ago.*[1]

[1] Paraphrased comments interpreted by the presenter

The AI landscape

Non-exhaustive list; logos are Trademarks of the respective organizations

Follow the money not the naysayers

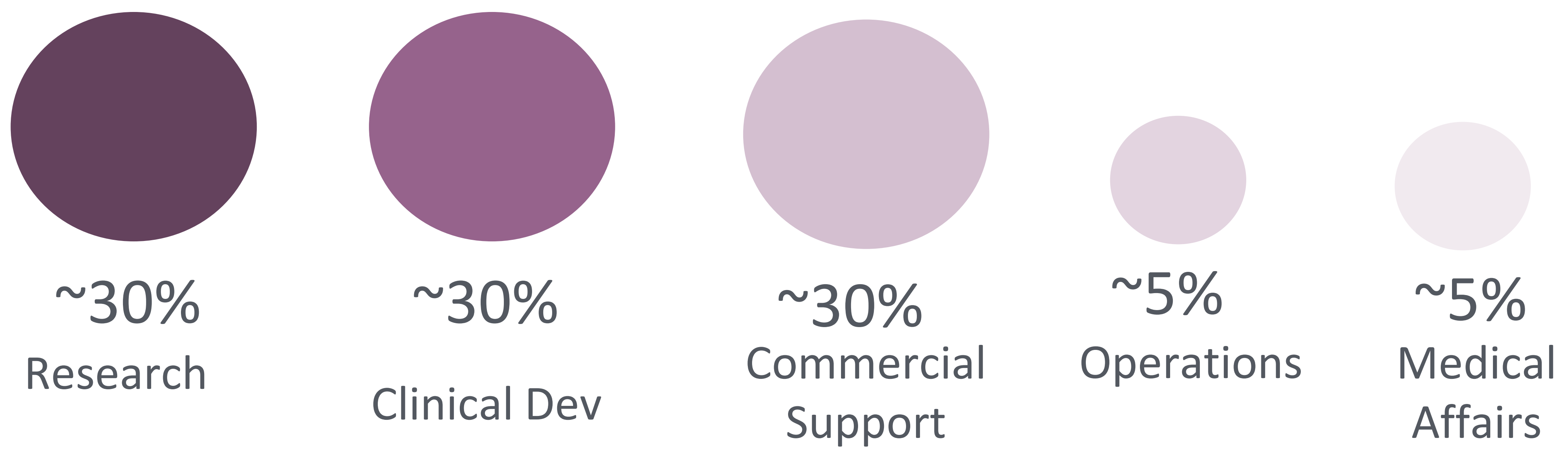
US$ 1.2+ Trillion

2025 Committed Spend in AI Infrastructure[1]

- Stargate $500B
- Hyperscalers $400B
- Sovereigns $250B
- LLMs $110B (*excl. OpenAI which is Stargate*)

US$ 60-100 B

Annual Value for AI in Pharma[2]



[1] Sources are SEC filings, press releases, public statements

[2] McKinsey & Co 2024 White Paper, Generative AI in the pharmaceutical industry

Focusing on autologous CAR-T

1 ~11K Treatments in 2025 → ~3M Treatments by 2032 [1]

Total CAR-T Eligible Population	Approx Patients
North America	1,136,,000
EU + UK	1,385,000
Japan	370,000
Australia	77,000
TOTAL ESTIMATE	**2,968,000**

CAR-T Eligible by Indication Class	Approx Patients
Hem Onc	170,000
Solid Tumors	2,728,000
Autoimmune	70,000
TOTAL ESTIMATE	**2,968,000**

Access, Affordability, and Scale are Serious Blockers

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[1] Internal modeling developed using approved CAR-T indications and open clinical trials with sensitivity to inclusion/exclusion

Autologous CAR-T
Assessing Cost, Access, and Reimbursement

Patient Reimbursement & Hospital Burden
A Sankey graph helps visualize patient reimbursement buckets via DRGs

Identifying Barriers : Costs, Prescribing Rates, Reimbursement, Access, and Tx Toxicity
The visualization highlights major expense categories and barriers, revealing inefficiencies in resource allocation.

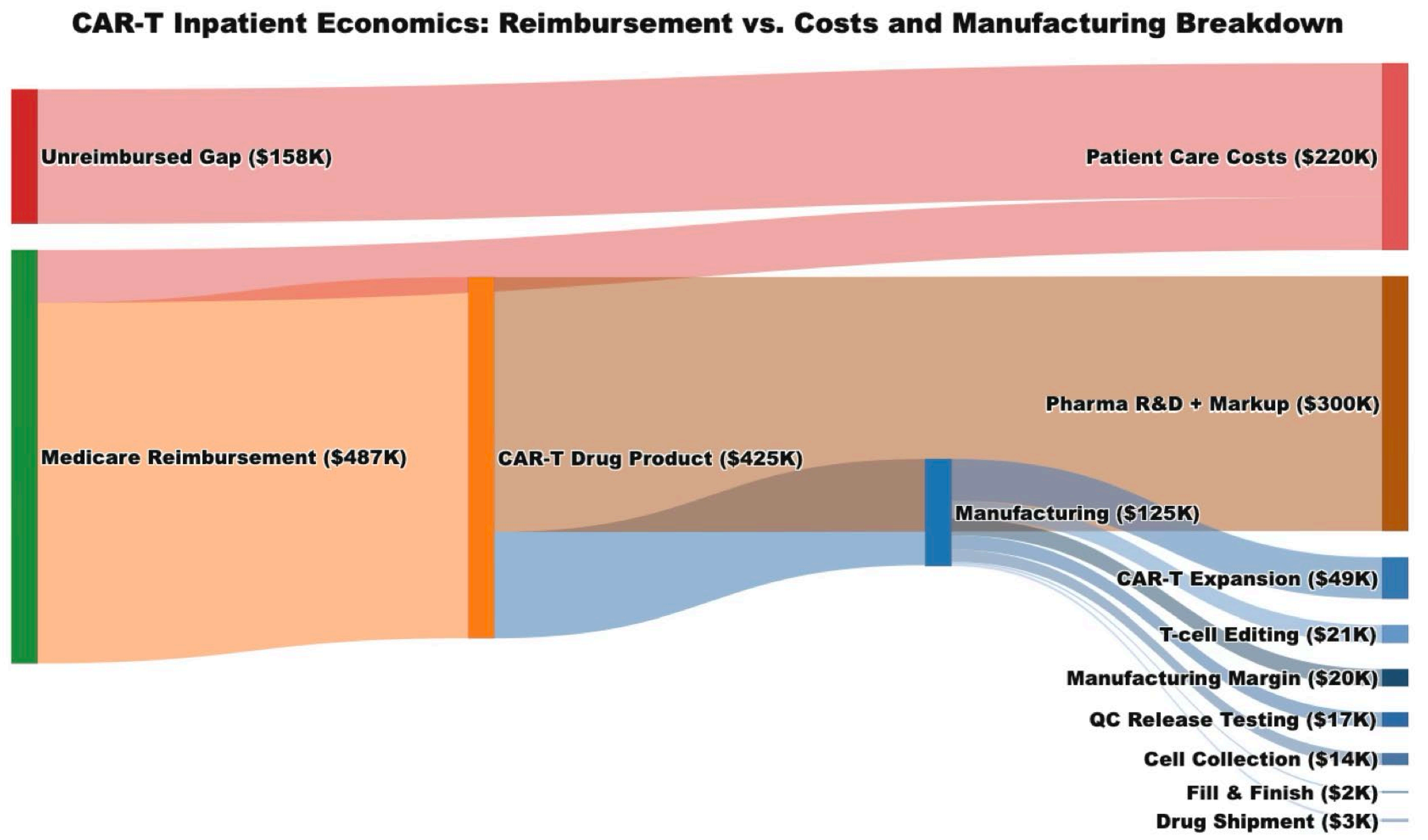
Targeting Solutions using AI
Mapping blockers by personas enables stakeholders to focus tools, systems, and processes that improve patient access (prescribing rates, cost, reimbursement, geography)and overall reduce healthcare costs.

Improve provider network so local geo therapy possible (toxicity, cost, training)

Reduce batch failure rates
Reduce cost and time to manufacture
Improve cold chain management
Improve manufacturing capacity

Improve predictive models in the EMR to aid in prescribing
Improve Care Pathways in EMR to handle Adverse Events
Improve batch failure rates
Reduce toxicity
Reduce cost/ Improve reimbursement / Reduce Pre-Authorization Burden

Patient Requiring Inpatient Management[1]



<160 clinical sites in USA

<30% of eligible patients receive Rx

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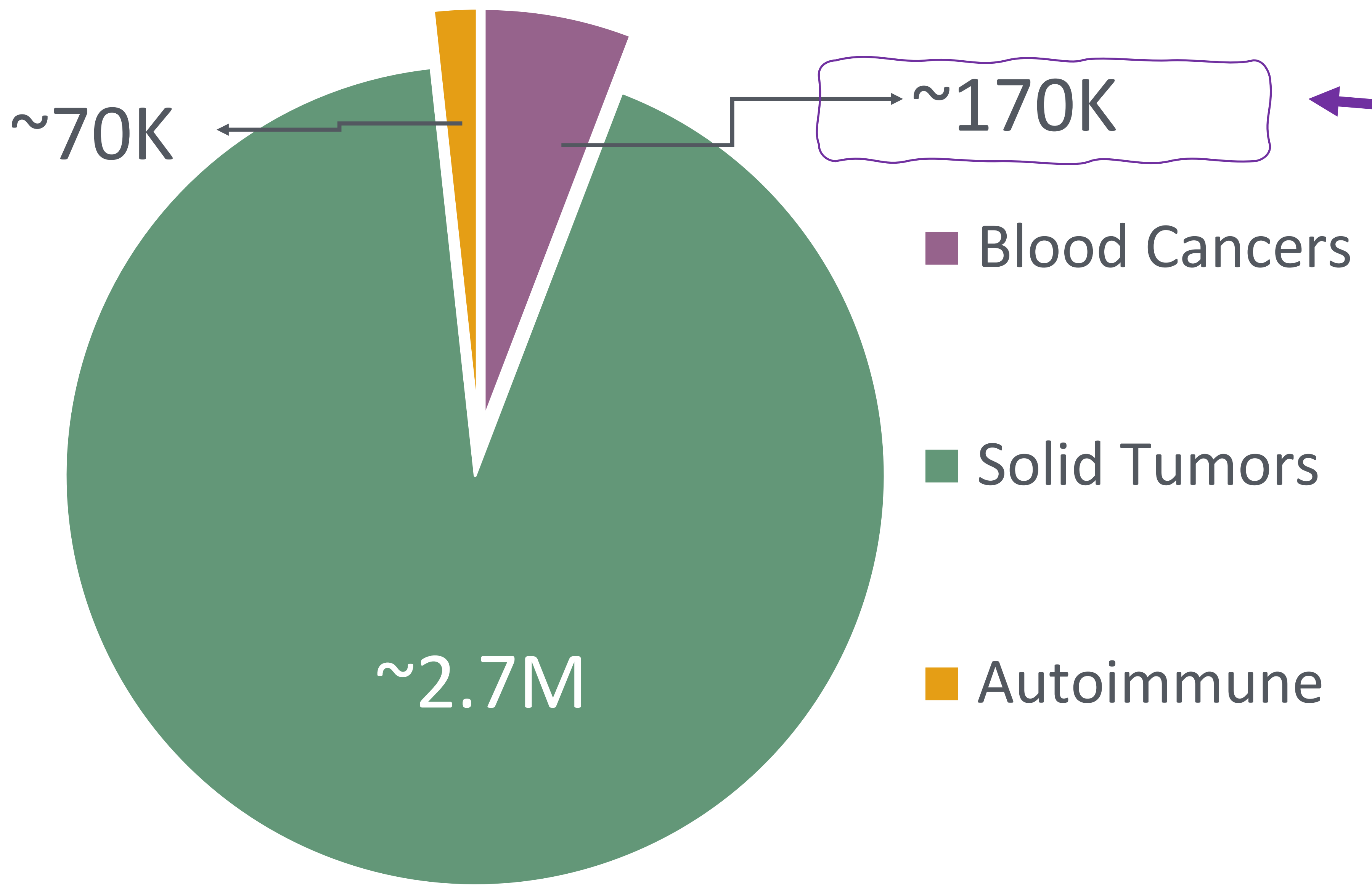
[1] Internal modeling ; published DRG; Hospitalization rates from multiple publications

Focusing on autologous CAR-T

1. ~10K Treatments in 2025 → ~3M Treatments by 2032
2. Up to 25% of cancer patients **fail** to produce an "in-spec" CAR-T drug product [1]

[1] Baguet et al, Early predictive factors of failure in autologous CAR T-cell manufacturing, Blood Advances, Jan 2024

NA, EU, UK, AU, JP. Patients Eligible for CAR-T by 2032



~11 K Doses/Patients

2025 Extrapolated Batches on Commercial Product

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Focusing on autologous CAR-T

1. ~10K Treatments in 2025 → ~3M Treatments by 2032
2. Up to 20% of cancer patients fail to produce an "in-spec" CAR-T drug product
3. Failed batches consume manufacturing capacity, contribute to higher overall costs, and erode patient and clinician confidence

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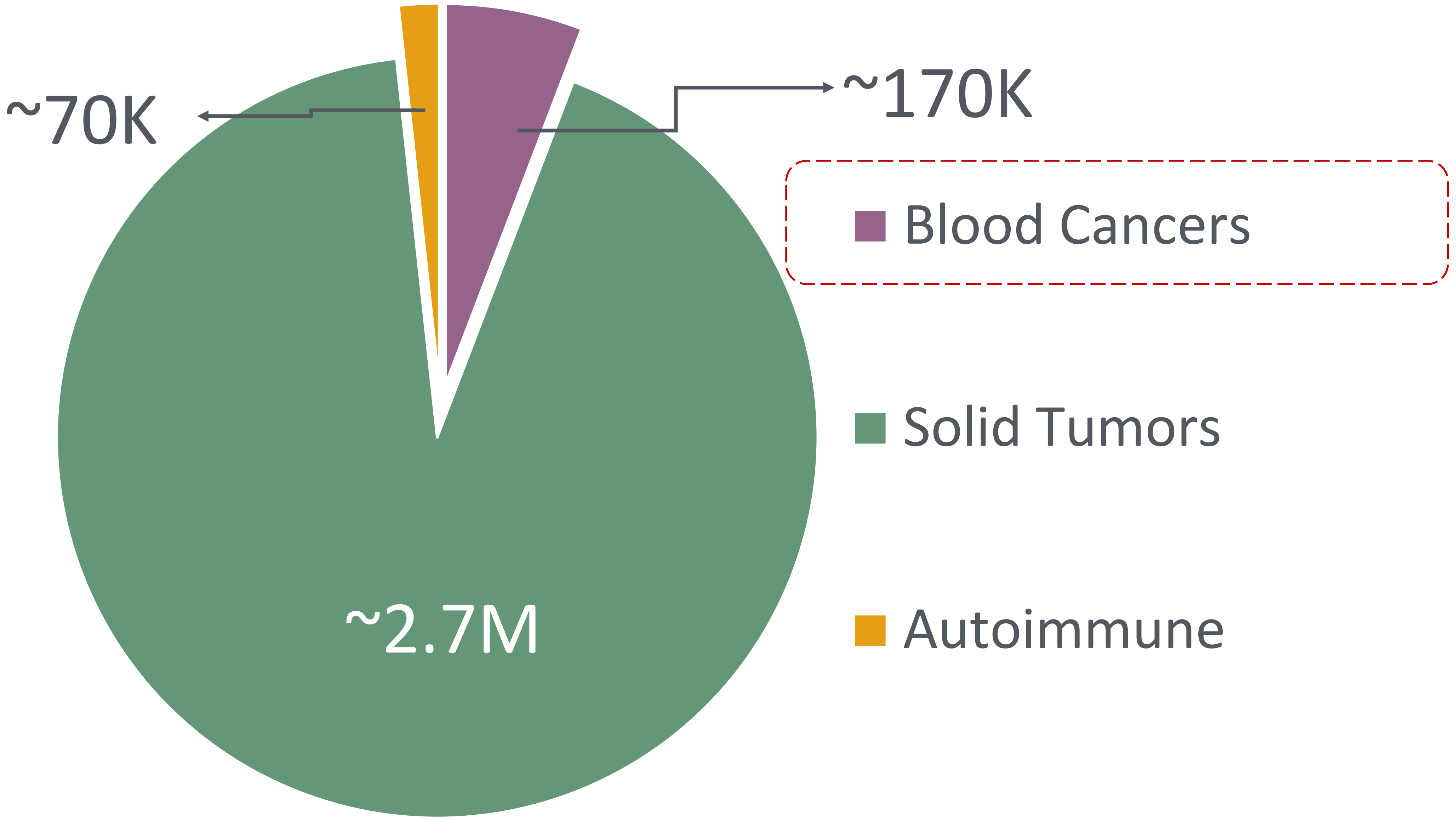
NA, EU, UK, AU, JP. Patients Eligible for CAR-T by 2032



<u>AI Model Use Case #1</u>

Donor Exclusion Score for Manufacturability

US Patent Pending

OmniaBio AI Strategy Pro

Prediction of donor manufacturability

Autologous CAR-T : Assessing pre-apheresis/pre-lymphodepletion t-cells

GOAL:	To predict whether a patient's t-cell population (pre-apheresis/pre-lymphodepletion) can expand into an **in-specification** drug dose post CAR transduction. Goal is to achieve an AUC of 0.8.

BENEFIT:	Will aid the patient, clinician, and manufacturer in assessing the likelihood of a successful CAR-T manufactured dose to meet the IND/BLA specification criteria. (note, this does not predict efficacy)

METHOD:	Uses an **artificial intelligence modular platform** (machine learning algorithms and neural networks) based on molecular readouts and historical clinical responses to predict t-cell expansion capability.

Creating the model (Sandboxing)

1 DATA

Public Datasets (Hem Onc Pre infusion, Clinical)
Public Datasets (Human t-cell transcriptomes)
Confidential Datasets (Hem Onc Pre infusion, Clinical, Manufacturing Outcomes)

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2 PREPROCESSING

Data Cleaning
Feature Extraction
Annotation/Labeling

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Inferencing (Regression analysis, decision trees, random forest, etc)
Multimodal
Fine Tuning

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4 PREPARE for VALIDATION

Preliminary **prediction value is 0.88 [exceeds our goal]**
Testing model with “wild type” data

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Next Steps

Validation/Verification/Adjusting | Field Use | Commercial Use

3rd PARTY DATA → Add'l Fine Tuning

IND

Regulatory Review

Clinical Decision Support

Regulatory Review → **Software as a Medical Device**

EMR Incorporation

CHAI[1] Certification

New FDA Draft Guidance Documents

Considerations for the Use of Artificial Intelligence to Support Regulatory Decision-Making for Drug and Biological Products

Guidance for Industry and Other Interested Parties

DRAFT GUIDANCE

Contains Nonbinding Recommendations

Draft – Not for Implementation

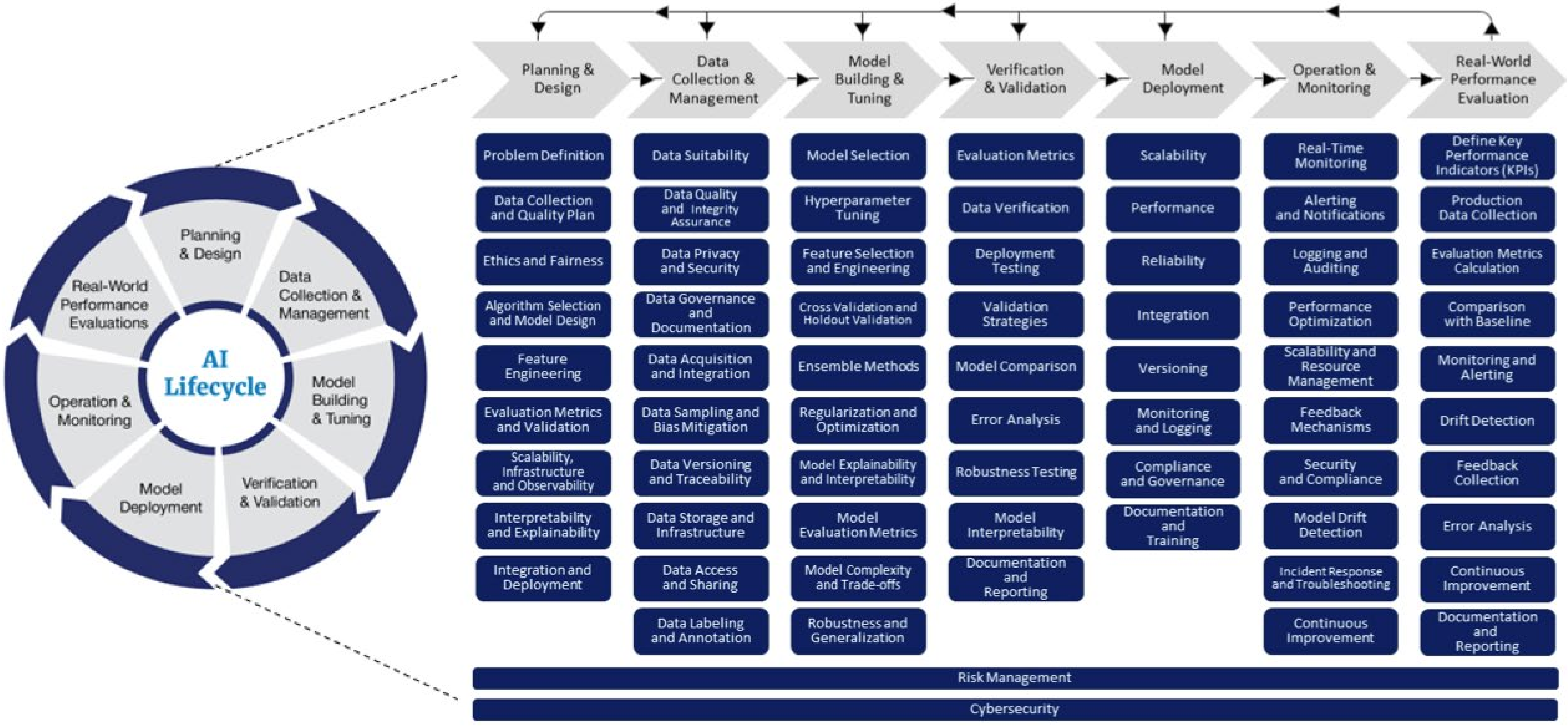
Artificial Intelligence-Enabled Device Software Functions: Lifecycle Management and Marketing Submission Recommendations

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

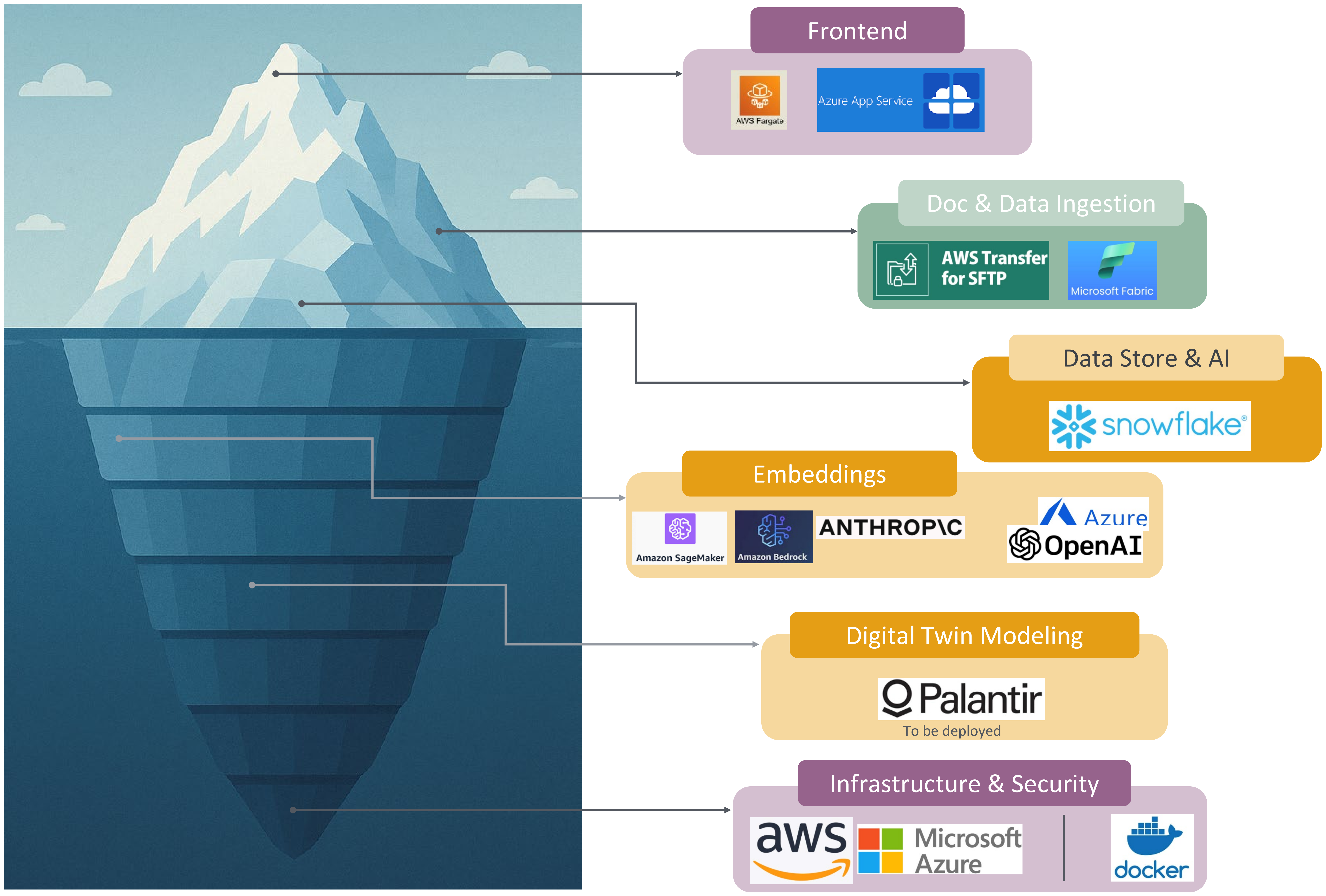
[1] CHAI is the Coalition for Health AI offering Assurance Certification for health AI solutions. www.chai.org

The AI Lifecycle expanded to illustrate per-phase considerations



https://www.fda.gov/medical-devices/digital-health-center-excellence/blog-lifecycle-management-approach-toward-delivering-safe-effective-ai-enabled-health-care

Overview of the IT infrastructure



Secured Cloud Infra.

Multicloud

US HIPAA Compliant

IAM

Thank You

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