



Background

Oncology research increasingly incorporates technologies that do not fit squarely into traditional drug or device regulatory pathways, including in vitro diagnostics (IVDs), companion diagnostics, AI-enabled software, Software as a Medical Device (SaMD), clinical decision support tools, and algorithm-driven platforms. These technologies can create uncertainty around FDA jurisdiction, Investigational Device Exemption (IDE) applicability, investigational requirements, and submission strategy. Having a large academic Investigational New Drug (IND)/IDE portfolio, delayed or inconsistent regulatory assessment can lead to protocol activation delays, avoidable revisions, and unexpected FDA feedback.

Goals

Memorial Sloan Kettering Cancer Center (MSK) manages more than 320 MSK-sponsored research INDs with increasingly complex technologies. In a rapidly evolving regulatory landscape, emerging technologies often require “building the plane while flying it,” as FDA guidance and precedent develop alongside innovation.

To address this, MSK’s Investigational New Drug Office (INDO) has established the following goals:

Identify	Standardize	Align	Support
Identify emerging technology early in trial development	Standardize FDA jurisdiction and IDE applicability assessments	Align study teams, institutional stakeholders, and FDA expectations	Support submission readiness through earlier regulatory planning

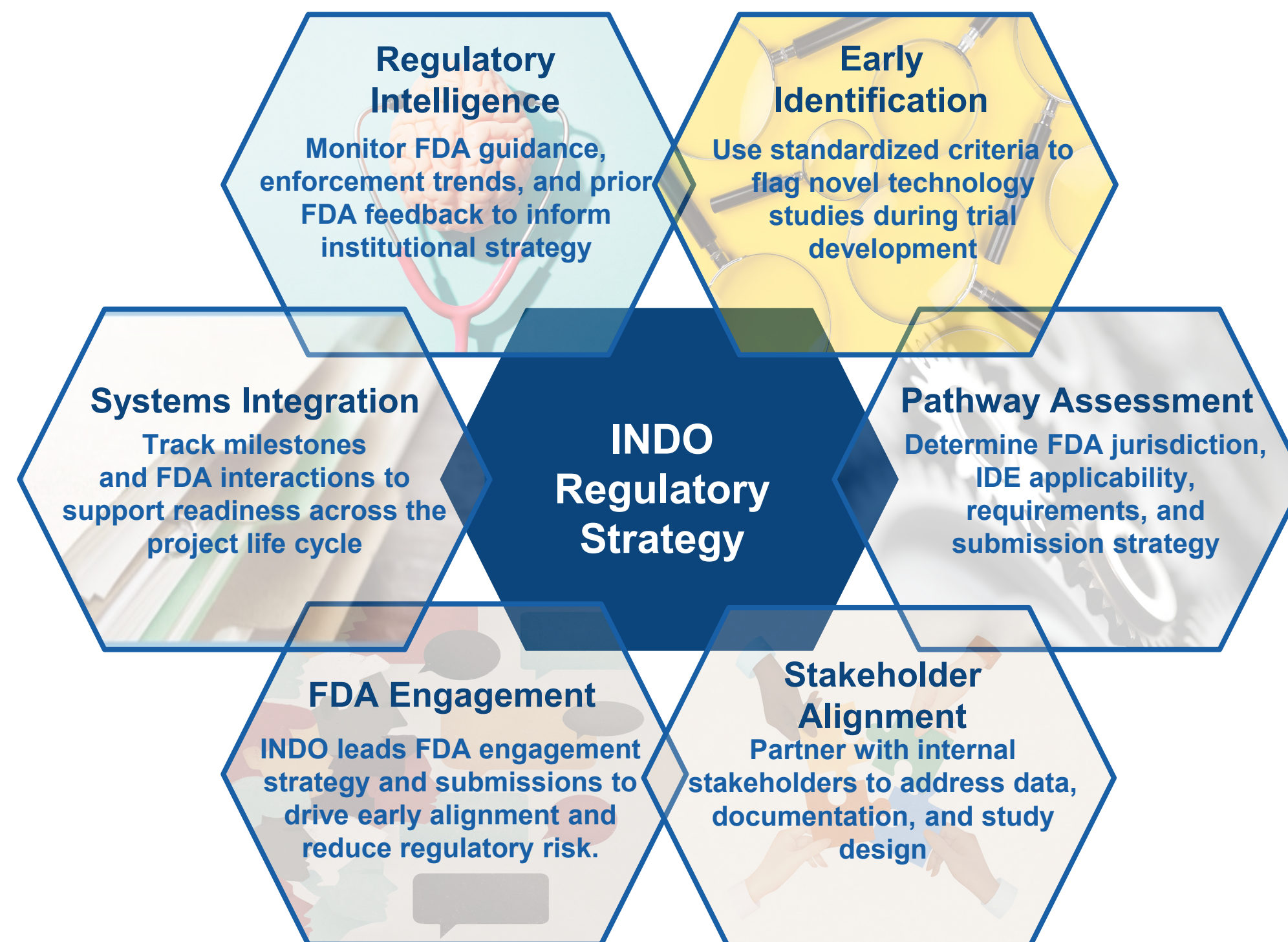
Definitions

Emerging Technology*: diagnostic, computational, or data-driven technologies with evolving or limited FDA guidance at the time of assessment. *Examples: IVDs, AI-enabled software, SaMD/CDS tools*

Interventional/Conventional Technology: hardware-based therapeutic or procedural technologies that generally follow more established FDA regulatory pathways and precedents. *Examples: implants, pumps, prosthetics*

*The FDA does not formally define “emerging technology” as a single regulatory category. This working definition was developed for institutional review and risk stratification based on technology types with evolving FDA expectations.

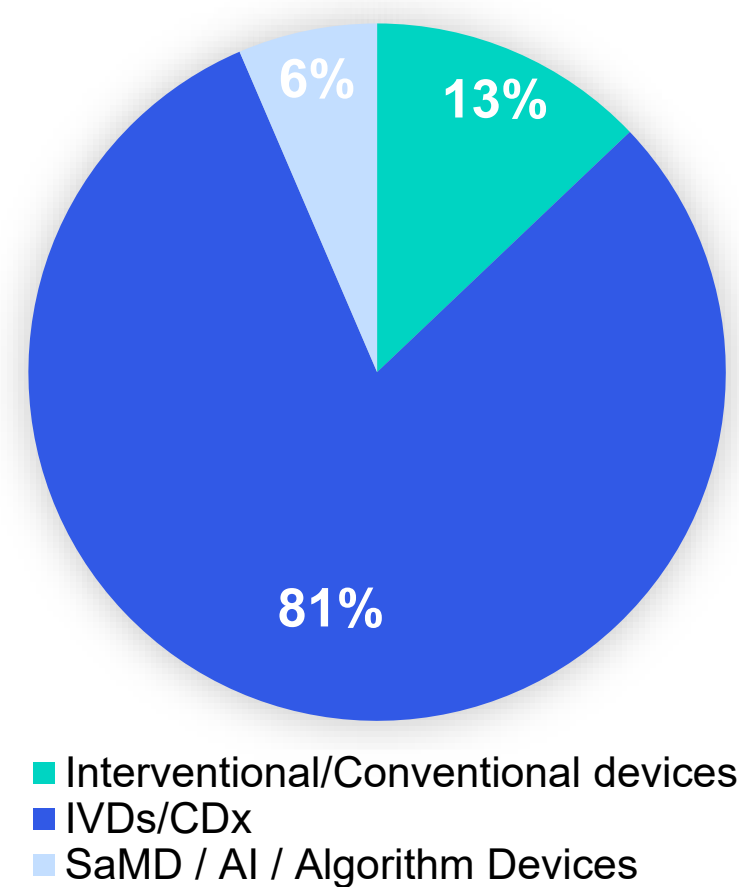
Solutions and Operating Model



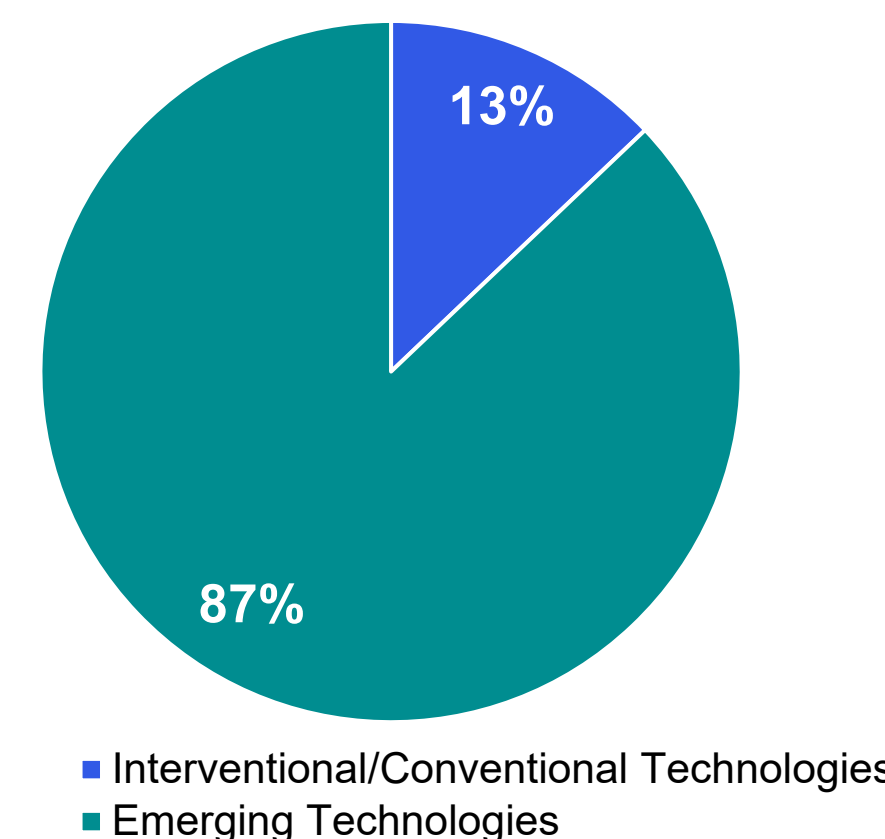
Data Analysis

A targeted subset of 31 trials reviewed from 2020–2026 was analyzed to identify how emerging technologies appear in MSK-sponsored IND/IDE trials and where regulatory ambiguity arises. Trials were selected based on internal review and FDA feedback, in which specific technologies were flagged for regulatory consideration. This subset does not represent the full volume of trials reviewed by INDO; instead, it was used to identify recurring technology categories, IDE applicability questions, and opportunities for earlier regulatory intervention.

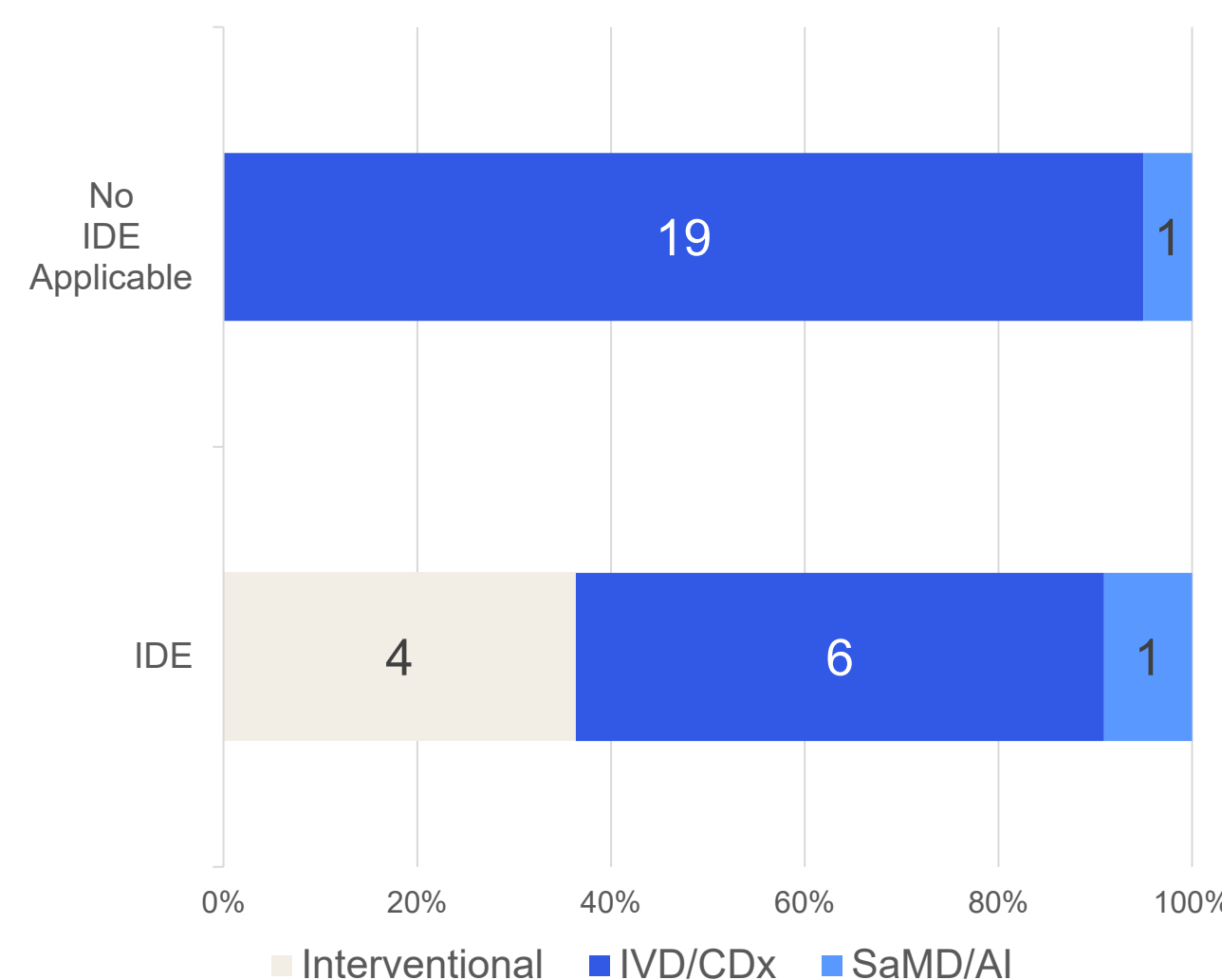
Distribution of Technology Types in Reviewed Trials (2020-2026)



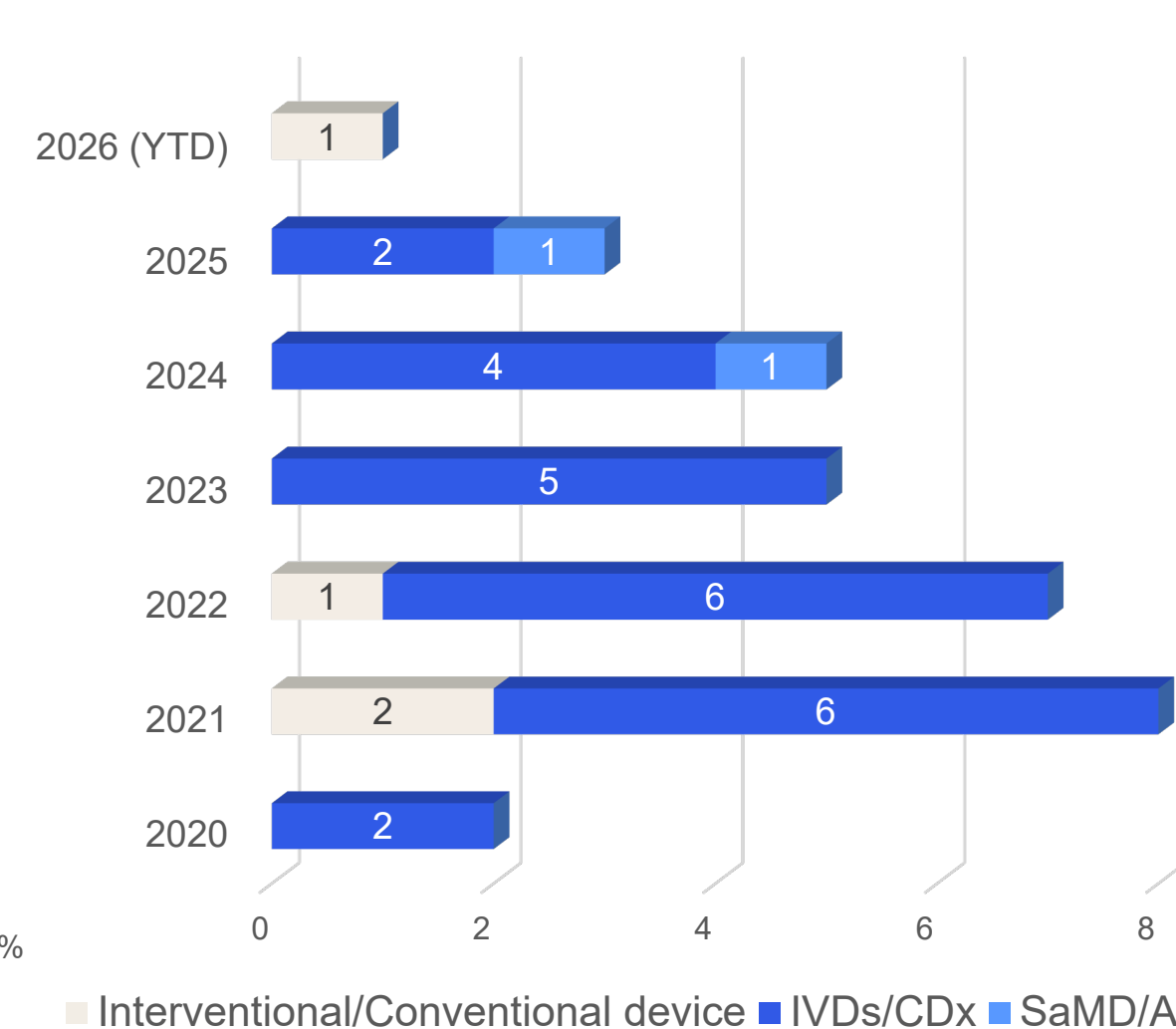
Technologies Identified Within Reviewed Trials (2020-2026)



Regulatory Pathway Determinations: IDE Required vs. Not Applicable



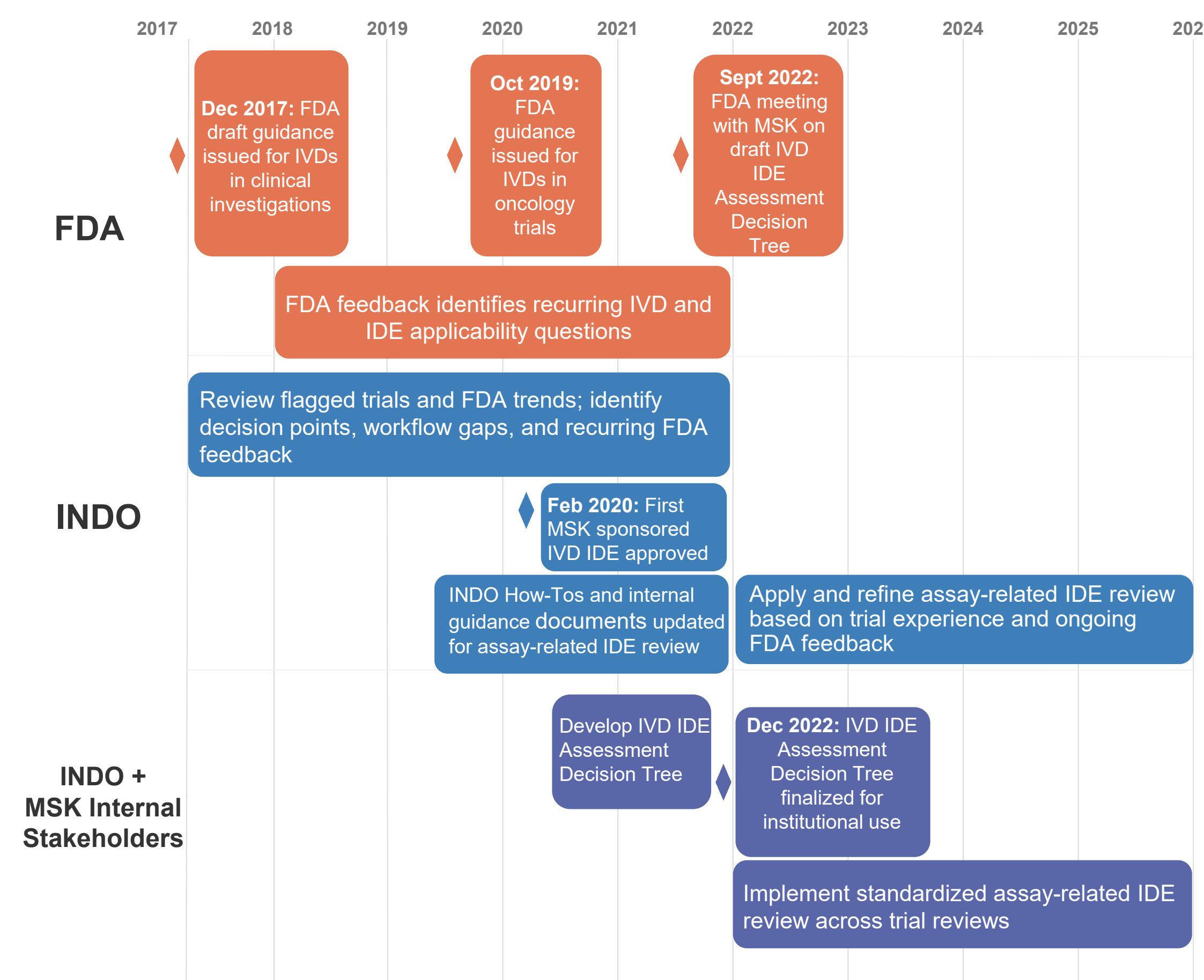
Snapshot of Technology Composition of Reviewed Trials Over Time



Key Outcomes

- Shifted emerging technology review earlier in the trial lifecycle, allowing regulatory considerations to be addressed before submission planning
- Improved consistency in evaluating FDA jurisdiction, IDE applicability, and investigational pathway assessments across technology-enabled studies
- Established a repeatable framework for translating FDA feedback, regulatory intelligence, and internal review trends into institutional tools and workflows
- Aligned regulatory strategy with operational infrastructure by enabling electronic common technical document (eCTD)-supported lifecycle submissions, including more than 185 submissions related to IVD/CDx IND programs

Operating Model in Practice: IVD IDE Decision Tree



Implementation Impact: earlier risk identification, more consistent determination pathways, and stronger internal alignment. Note: Orange items reflect FDA guidance and feedback; purple items reflect joint INDO and MSK stakeholder development and use

Lessons Learned

- Treat FDA feedback as actionable intelligence**: FDA signals and internal review trends should inform future determination pathways
- Standardize tools scale consistency and reduce downstream delays**: Institutional tools translate evolving FDA expectations into repeatable institutional practice
- Effectiveness of regulatory strategy depends on operational infrastructure**: Tracking, documentation, and submission operations support consistent lifecycle oversight

Next Steps

