# FDA ISTAND Program: AI Drug Development Tool Qualification

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# Executive Summary

The U.S. Food and Drug Administration's (FDA) Innovative Science and Technology Approaches for New Drugs (ISTAND) program marks a bold initiative to fast-track drug development through qualification of novel **Drug Development Tools (DDTs)**. Established by the 21st Century Cures Act (2016), the FDA's ISTAND pilot (launched Nov 2020) provides a unique regulatory pathway for innovative tools that fall outside traditional qualification programs ([1] www.fda.gov) ([2] www.fda.gov). In January 2024, ISTAND achieved a landmark milestone by accepting its first **artificial intelligence (AI)-based drug development tool** – an AI-generated Clinical Outcome Assessment (AI-COA) for depression and anxiety by Deliberate AI ([3] www.fda.gov) ([4] www.mondaq.com). This acceptance underscores FDA's commitment to harnessing AI and digital health technologies in drug development and signals a paradigm shift in regulatory science.

This report provides an in-depth analysis of the ISTAND program and the DDT qualification pathway, with a focus on this first-of-its-kind AI tool. We trace the historical context leading to ISTAND – from the Cures Act's enactment of a formal DDT qualification process ([1] www.fda.gov) to the evolution of ISTAND into a permanent program (announced July 31, 2025 ([5] www.pharmtech.com)). Key milestones (e.g. first qualifying submissions) are reviewed (Table 1). We detail the multi-step qualification process (Letter of Intent, Qualification Plan, Full Qualification Package) ([6] www.fda.gov) ([7] www.fda.gov), including submission requirements, review criteria, and transparency provisions. This is illustrated by the **FDA's criteria** – scientific merit, drug development need, feasibility, and available resources – which govern LOI acceptance ([8] www.fda.gov) ([9] www.fda.gov).

Multiple case studies illuminate ISTAND's impact. For example, Integral Molecular's **Membrane Proteome Array (MPA)** for antibody off-target screening was the first ISTAND submission (LOI accepted Sep 2022) ([10] www.biospace.com). A recent study showed the MPA, covering ~6,000 human membrane proteins, detected clinically-relevant off-target binding missed by traditional tissue assays in 17% of cases ([11] jitc.bmj.com). Another case is the new **Liver-Chip** organ-on-chip (microphysiological system) for drug-induced liver injury (DILI) – FDA accepted its LOI in Sep 2024 ([12] www.fda.gov). A landmark *Nature* study found such liver chips identified ~88% (7/8) of hepatotoxic drugs that animal models had missed (www.senat.fr). The Deliberate AI-COA tool – processing facial expressions, speech, movement, vital signs, etc. – exemplifies how **AI-based digital health** can objectify psychiatric endpoints, aligning with Hamilton Depression/Anxiety scales ([13] www.fda.gov) ([4] www.mondaq.com).

We analyze regulatory perspectives: FDA officials applaud these innovations ("pioneering step" for ISTAND ([14] www.fda.gov); "bring treatments to patients faster" ([15] www.fiercebiotech.com)) and caution that thorough scientific validation is required. External analyses note that FDA seems to favor AI "supplementary" tools over truly novel applications and warns the qualification path can be **time-consuming** ([16] www.mondaq.com). Industry stakeholders view ISTAND's permanency (effective 2025) as a welcome reduction in uncertainty ([17] www.pharmtech.com) ([5] www.pharmtech.com).

Finally, we explore broader implications: with ISTAND now permanent, FDA expects more submissions of AI algorithms, digital biomarkers, organ chips, and other " new approach methodologies" (NAMs), expanding the toolkit for drug developers. Success of first AI-DDT paves the way for future qualified AI tools in areas like patient monitoring, predictive toxicology, and beyond. However, challenges remain – rigorous data collection, potential biases in AI, and global harmonization (EMA has analogous qualification pathways (www.ema.europa.eu)). The report concludes that ISTAND's adoption of the first AI tool marks a turning point: if managed well, this regulatory innovation promises to accelerate development of **safer, more effective therapies** by enabling advanced analytics and nontraditional methods in a structured, evidence-based framework.

# Introduction and Background

Bringing a new drug to market is extraordinarily complex and expensive. Career development timelines often exceed a decade, with studies estimating **10–15 years** of research and development and costs on the order of **$2.6–2.8 billion** per approved drug. Only a small fraction of drug candidates succeed: recent analyses suggest roughly **12%** of investigational compounds ultimately gain FDA approval ([18] www.taconic.com). The vast attrition rate – reflecting failures in safety, efficacy or manufacturability – remains a profound challenge for patients and industry alike.For example, drug-induced liver injury (DILI) is cited as a leading cause of trial failure and market withdrawal (www.senat.fr) ([19] www.fda.gov). In psychiatry, efficacy trials are notoriously difficult, in part because endpoints like depression scores are subjective and variable. More broadly, even when effective therapies exist, patient identification and trial monitoring can be inefficient, especially in neurology or rare diseases.

Amid these challenges, advanced technological tools offer hope to **accelerate drug development and improve decision-making**. Artificial intelligence, machine learning, and digital health wearables have seen explosive growth in healthcare. By 2018, over **116 million wearables** had shipped globally, with projections to double in five years ([20] www.nature.com). These "connected digital products" – from smartphone apps and sensors to at-home monitoring devices – are increasingly incorporated into trials. An analysis of ClinicalTrials.gov data (2001–2018) documented a **~34% annual growth rate** in trials using connected technologies ([21] www.nature.com). Meanwhile, vast patient data (omics, imaging, real-world records) fuel AI algorithms to identify disease patterns, predict toxicity, or personalize regimens. In 2021, nearly **5.7% of adults worldwide** (~332 million people) suffered from depression (www.who.int) and **4.4%** (~359 million) from anxiety (www.who.int). These common, high-burden conditions lack fully objective measures; AI-based digital biomarkers could transform their assessment and treatment.

Recognizing these opportunities, regulators have moved to create frameworks for innovation. The FDA established special programs (e.g. Breakthrough Therapy, Regenerative Medicine Advanced Therapy) to expedite promising therapies. For methodological innovation, Section 3011 of the 21st Century Cures Act (enacted Dec 2016) created a **formal approval pathway** for **Drug Development Tools (DDTs)** ([1] www.fda.gov) ([2] www.fda.gov). Under **FD&C Act §507**, a "drug development tool" is defined broadly as a "method, material, or measure" that can aid drug development and regulatory review (including **biomarkers**, clinical outcome assessments (COAs), or any other suitable measure) ([2] www.fda.gov). Critically, §507 requires the FDA to establish a transparent, multi-step qualification process. Once a DDT is qualified for a **specific context of use (COU)**, it can be used (by any sponsor) in regulatory submissions without the FDA having to re-evaluate its validity each time ([1] www.fda.gov) ([22] www.fda.gov).

**Existing Qualification Programs:** FDA's legacy programs already allow qualification of biomarkers and clinical outcome assessments, especially in Alzheimer's disease and oncology. These create "pilot" or "qualified" status for specific contexts (e.g. "use of [biomarker X] to enrich trial enrollment for drug Y"). Such qualification confirms that a tool, when used as specified, is fit for purpose ([1] www.fda.gov) ([2] www.fda.gov). However, as technologies evolved, stakeholders identified gaps: many novel approaches (like computational models, digital measures, or organ-on-chip devices) did not fit neatly into biomarker or COA categories.

**ISTAND Program Launch:** To bridge these gaps, the FDA launched the **Innovative Science and Technology Approaches for New Drugs (ISTAND) pilot program** in November 2020 ([23] www.fda.gov) ([8] www.fda.gov). The ISTAND program, co-managed by CDER and CBER, expressly encourages submissions of nontraditional DDTs – e.g. digital health tools, advanced in vitro/ex vivo models, novel toxicology assays, or AI/ML algorithms – that might not qualify under existing pathways. The goal is "to support innovative, science-driven approaches that improve drug development and regulatory decision-making" ([24] www.fda.gov). In practice, ISTAND provides a streamlined channel (still following §507 rules) where developers can propose such novel tools and get FDA feedback and evaluation. Unlike other initiatives, ISTAND was explicitly created by Congress "to expand the

drug development tool types listed in the 21st Century Cures legislation" beyond traditional biomarkers ([25] www.prnewswire.com).

In its pilot phase, ISTAND has already **accepted eight submissions** into the program ([26] www.fda.gov) ([27] www.pharmtech.com). These tools span multiple categories – three are AI-based, two are animal-free preclinical models, two involve novel tissue-based methods, and one is a novel statistical methodology ([26] www.fda.gov) ([27] www.pharmtech.com) (Table 1). The first submission accepted (Sept 2022) was the *Membrane Proteome Array* for antibody safety profiling ([10] www.biospace.com). ISTAND's success in attracting diverse tools led the FDA to transition it from pilot to a **permanent DDT qualification program** – announced via FDA Voices on July 31, 2025 ([24] www.fda.gov) ([5] www.pharmtech.com). This permanence signals that novel tool qualification is now an enduring aspect of the FDA's regulatory framework.

Table 1 (below) summarizes ISTAND's key milestones to date.

| Date | Milestone | Description / Significance | Source |
|---|---|---|---|
| Dec 2016 | 21st Century Cures Act (Sec 3011) enacted | Established formal DDT qualification process (FD&C Act §507); mandates LOI, QP, FQP submissions for specific COU ([1] www.fda.gov). | ([1] www.fda.gov) ([2] www.fda.gov) |
| Nov 2020 | Launch of ISTAND pilot program | FDA (CDER/CBER) opens ISTAND to expand DDTs beyond biomarkers/COAs, encouraging AI, digital health, organ-chips, etc ([23] www.fda.gov) ([8] www.fda.gov). | ([23] www.fda.gov) ([8] www.fda.gov) |
| Sep 7, 2022 | First LOI accepted (Integral Molecular MPA) | FDA accepted the first ISTAND submission: an antibody specificity *Membrane Proteome Array* (MPA) for off-target safety profiling ([10] www.biospace.com). | ([10] www.biospace.com) |
| Jan 23, 2024 | First AI/DHT LOI accepted (Deliberate AI-COA) | FDA accepted a Letter of Intent for an AI-generated Clinical Outcome Assessment of depression/anxiety, marking "the first AI-based, digital health technology project" in ISTAND ([3] www.fda.gov). | ([3] www.fda.gov) ([4] www.mondaq.com) |
| Sep 24, 2024 | First organ-on-chip LOI accepted (Liver-Chip DILI model) | FDA accepted an LOI for a *human Liver-Chip* microphysiological system to predict drug-induced liver injury (DILI) risk ([12] www.fda.gov). | ([12] www.fda.gov) |
| Jan 2025 | QP accepted for Integral MPA (first approval plan) | FDA accepted Integral Molecular's Qualification Plan for the MPA (outlining its design/use), advancing it toward full qualification ([28] www.integralmolecular.com). | ([28] www.integralmolecular.com) |
| Jul 31, 2025 | ISTAND made permanent | FDA announced via FDA-Voices that ISTAND "has transitioned to a permanent DDT qualification program," cementing its role in regulatory science ([24] www.fda.gov) ([5] www.pharmtech.com). | ([24] www.fda.gov) ([5] www.pharmtech.com) |

*Table 1. Key milestones of the FDA ISTAND program, including legal foundations and accepted submissions. Sources of information are cited for each event.*

# The DDT Qualification Pathway

The ISTAND program operates within the FDA's broader **Drug Development Tool (DDT) qualification framework**, as defined by Section 507 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) ([1] www.fda.gov). Under this law, FDA was required to publish a qualification process – formally issued as guidance in November 2020 ([29] www.fda.gov) – allowing any interested developer to pursue formal qualification for a

DDT. The hallmark of this process is that qualification is tied to a narrowly **specified context of use (COU)**: any DDT is qualified only for that COU, and any developer may use it for that purpose once qualified ([1] www.fda.gov) ([2] www.fda.gov).

The qualification process is **multi-stage and iterative**. By statute it includes three main submissions:

1. **Letter of Intent (LOI):** A brief proposal submitted to FDA expressing interest in qualifying a specific DDT, describing the tool, its intended context of use, and the unmet drug development need it addresses ([7] www.fda.gov) ([6] www.fda.gov). This initial step triggers FDA review to decide if the project should advance.
2. **Qualification Plan (QP):** If the LOI is accepted, the developer submits a detailed plan describing how they will collect evidence to support qualification – including study designs, data sources, endpoints, statistical analysis plans, and timelines ([6] www.fda.gov). The QP lays out the scientific and technical strategy.
3. **Full Qualification Package (FQP):** After the QP stage, the developer collects and submits the data per their plan. The FQP is the comprehensive dossier of evidence (often including preclinical/clinical study reports, data analyses, and literature) demonstrating that the DDT meets the proposed context (i.e. valid, reliable, and relevant) ([6] www.fda.gov).

The FDA review proceeds in parallel with these submissions. An LOI or QP must be **officially accepted** by FDA before proceeding to the next stage. ISTAND staff perform an initial check of each LOI for completeness and potential fit. Accepted LOIs move into a technical review involving a multi-disciplinary review team (sometimes including external experts) ([30] www.fda.gov) ([8] www.fda.gov). **FDA's acceptance criteria** are fundamentally scientific and pragmatic. An ISTAND committee evaluates each LOI on factors such as the tool's **scientific merit**, the drug development need it would address, technical **feasibility**, resource availability, and whether appropriate expertise is in place ([8] www.fda.gov) ([9] www.fda.gov). For example, the agency may decline an LOI if it finds the concept unproven, or no clear unmet need is addressed. If accepted, the FDA issues a formal "Determination Letter" and (optionally) meets with the sponsor to discuss plans.

Critically, **an applicant cannot proceed past each checkpoint without acceptance**. As FDA guidance notes, "Applicants may not proceed from the LOI or QP stage to the next stage **unless they are accepted** at these stages" ([31] www.fda.gov). Each acceptance letter includes feedback on needed clarifications or data requirements. Only after all FDA recommendations are addressed will the developer move forward. The LOI acceptance itself **does not guarantee a final qualification**; it merely indicates that the concept is promising enough to warrant further work.

The qualification process serves to standardize a DDT for broad use. It is not mandatory for use of a tool in a single trial – sponsors can always use an experimental measure under their own Investigational New Drug (IND) applications – but qualification provides a **public "seal of validation."** Once a DDT is qualified, any sponsor may employ it in regulatory submissions for the defined context without needing FDA to re-validate it ([32] www.fda.gov). This can "reduce duplication of efforts" and ease regulatory reviews ([33] www.fda.gov).

**Overview of Qualification Steps:** The following table summarizes the three main steps in the DDT qualification pathway under ISTAND (and other DDT programs):

| Step | Submission Name | Key Contents | FDA Evaluation | Outcome |
|---|---|---|---|---|
| **1. Letter of Intent** | LOI | - Description of the proposed DDT<br>- Specific Context of Use (COU)<br>- Drug development need addressed<br>- Preliminary supporting data or rationale | FDA first checks completeness. A review team evaluates: Is there a scientific premise? Does the tool meet a sustained need? Is it technically feasible and practical? Is sufficient information available? Any expert consultation needed? ([8] www.fda.gov) ([9] www.fda.gov) | *Accepted (move to QP)* or *Declined*. A declined LOI cannot proceed; accepted LOI leads to feedback letter and invitation to prepare QP. |

| Step | Submission Name | Key Contents | FDA Evaluation | Outcome |
|---|---|---|---|---|
| | | - Proposed evidence plan outline | | |
| **2. Qualification Plan** | QP | - Detailed study design and analysis plan for data collection<br>- Protocols, assays, or algorithms to be used<br>- Statistical considerations<br>- Resource commitments and timelines | The FDA reviews: Does the QP adequately define how evidence will be collected to support the COU? Are the methods scientifically sound? Interim consultations may occur. Feedback will address any gaps in approach. | *Accepted (move to FQP)* or *Declined*. If accepted, FDA and sponsor meet on study execution. Declined QP ends the pathway, though more data can be gathered offline. |
| **3. Full Qualification Package** | FQP | - Complete data and analyses demonstrating tool performance<br>- Reports of all experiments/trials conducted<br>- Validation of tool relative to COU (specificity, sensitivity, etc.) | A thorough multidisciplinary review is conducted. FDA assesses if the data fully justify the proposed COU. Reviewers may ask additional questions or analyses. | *Qualified* or *Not Qualified*. If qualified, FDA issues a public qualification letter and summary; the DDT can then be used in any drug development under the stated COU. If not qualified, FDA explains deficiencies. |

*Table 2. Steps in the FDA DDT qualification process (applies to ISTAND submissions). Each stage must be "accepted" by FDA to proceed. An LOI or QP acceptance requires satisfying FDA's comments before advancing ([8] www.fda.gov) ([31] www.fda.gov).*

At each stage, **transparency is mandated** by law. Under §507, FDA promptly publishes basic details of submitted LOIs, QPs, and FQPs on a public website ([34] www.fda.gov). The agency also publishes formal decisions, executive summaries, and reviews for qualified tools. Thus, stakeholders (and the public) can track which tools are under review and use them once qualified.

In summary, the ISTAND pathway extends FDA's DDT infrastructure to cutting-edge methods. By requiring rigorous review at each step (LOI, QP, FQP) ([8] www.fda.gov) ([31] www.fda.gov), the process ensures that any "qualified" tool has proven validity for its stated purpose. While qualification is voluntary – a DDT can be used in drug development without it – formal qualification "may reduce duplication of efforts and facilitate regulatory acceptance" for tools that could benefit multiple developers ([33] www.fda.gov). This framework provides a clear roadmap for innovators, but also sets a high evidentiary bar to ensure patient safety and scientific reliability.

# Case Studies: Innovative DDTs in ISTAND

Below we examine three ISTAND submissions now in the qualification pipeline. These **case studies** illustrate the breadth of ISTAND's remit and the real-world impact of novel DDTs.

## 1. Membrane Proteome Array for Antibody Specificity

**Background:** Monoclonal antibodies and related biologics are powerful therapies but can have unanticipated "off-target" interactions. Traditional safety tests include animal studies and tissue cross-reactivity (TCR) assays, but these have limitations in sensitivity and translatability. **Integral Molecular's Membrane Proteome Array (MPA)** offers a high-throughput in vitro method: it screens an antibody against a panel of ~6,000 human membrane proteins in their native conformation ([35] www.integralmolecular.com) ([36] jitc.bmj.com). The MPA aims to identify unintended binding early in development, improving safety profiling and potentially reducing reliance on animal testing.

**ISTAND Submission:** Integral Molecular submitted an LOI for the MPA in 2022 – the very first ISTAND application accepted (Sept 7, 2022) ([10] www.biospace.com). The LOI outlined the MPA platform's design and proposed context of use: qualifying it as a DDT for "antibody safety and specificity assessment." The FDA announced this acceptance, noting the goal "to qualify these tools, thus facilitating regulatory review by allowing them to be used in regulatory (IND, NDA, BLA) applications without needing FDA to reconsider… their suitability" ([25] www.prnewswire.com).

**Data Analysis:** A recent open-access study (a conference abstract) provides insight into the MPA's performance. Norden *et al.* (2022) reported that the MPA "assesses binding interactions across ~6,000 membrane proteins" and is indeed under qualification review via ISTAND ([36] jitc.bmj.com). In a head-to-head comparison with standard tissue cross-reactivity assays, the MPA screened 35 marketed antibody drugs. It **found an unexpected off-target** for about 17% of these drugs that the tissue assays had missed ([11] jitc.bmj.com). Overall, only ~50% of molecules showed complete agreement between MPA and TCR – in many cases TCR results were inconclusive or false positives. By contrast, the MPA provided quantitative affinity measures and epitope localization for identified off-targets, offering clearer "de-risking" information ([37] jitc.bmj.com).

These results are compelling: the MPA appears more sensitive than conventional assays and is already "routinely used in regulatory applications" ([38] jitc.bmj.com). Importantly, Norden *et al.* conclude that "the MPA is currently in the last stages of review for DDT qualification through FDA's ISTAND program" ([38] jitc.bmj.com). Integral Molecular's own materials confirm progress: after the LOI, FDA accepted the company's Qualification Plan in January 2025 ([28] www.integralmolecular.com). The MPA is thus on track to become the first cell-based array formally qualified as a DDT.

**Implications:** Once qualified, the MPA could streamline IND submissions for antibody drugs. Sponsors could reference the MPA's safety data generically, saving time and resources. As Integral Molecular observes, already "MPA data is being accepted in IND and other regulatory filings" and qualification will allow "even further" efficiency ([39] www.integralmolecular.com). This tool exemplifies how ISTAND avatars in vitro platforms (a "new approach methodology", NAM) into the regulatory arsenal. It also highlights ISTAND's emphasis on preclinical NAMs ("two animal-free tools…to assess preclinical safety" ([40] www.pharmtech.com)).

## 2. AI-Generated Clinical Outcome Assessment for Mental Health

**Background:** Depression and anxiety trials have long relied on clinician-administered scales (e.g. the Hamilton Depression Rating Scale – HAM-D). These are resource-intensive and subject to inter-rater variability, bias and patient subjectivity. **Deliberate AI**, a digital health company, has developed an **AI-based Clinical Outcome Assessment (AI-COA)** for depression and anxiety. The AI-COA integrates **multimodal behavioral data** (facial expressions, speech patterns, eye movement, physical activity, vital signs, etc.) to estimate severity on par with HAM-D and HAM-A scales ([13] www.fda.gov) ([4] www.mondaq.com). Effectively, it aims to provide an objective, quantitative measure of psychiatric symptoms by supplementing or validating clinician ratings.

**ISTAND Submission:** On January 23, 2024, FDA announced it had accepted Deliberate AI's LOI – "the first artificial intelligence-based and digital health technology project and the first project in neuroscience" admitted

into ISTAND ([3] www.fda.gov). This LOI described the tool's intended COU: "automated depression and anxiety severity measurement using multiple behavioral and physiological indices...derived to clinician-reported outcomes based on HAM-D and HAM-A scores" ([13] www.fda.gov). In short, the AI-COA would be qualified as a DDT for measuring symptom severity in clinical trials of depression/anxiety. FDA Director Peter Stein called it "a pioneering step" that aligns with FDA's vision of optimizing drug development ([14] www.fda.gov).

**Tool Description:** Deliberate AI's tech uses "advanced multimodal behavioral signal processing and machine learning" ([41] www.practical-patient-care.com). It employs computer vision, audio analysis, and wearable sensor inputs to build a "quantitatively informed profile" of each patient's affect and cognition ([4] www.mondaq.com). Early validation studies (unpublished) suggest the AI-COA can supplement standard assessments to improve reliability. Deliberate's leadership emphasizes its promise: it could "pave the way for more powerful, efficient, and faster clinical trials" and ultimately better patient care ([42] www.practical-patient-care.com). The LOI acceptance is only a preliminary step – a qualification plan is next – but it brings unprecedented recognition to AI in psychiatric drug trials.

**Regulatory Context:** This tool occupies an emerging niche at FDA intersections of AI/ML and Digital Health. The agency has been actively encouraging AI-enabled innovation: recent guidances and frameworks specifically address **AI/ML in drug development** and **digital technologies in trials** ([43] www.fda.gov). For example, FDA's "Framework for the Use of Digital Health Technologies in Drug Development" and final guidance on remote DHTs signal openness to such approaches ([43] www.fda.gov). ISTAND thus provides a formal path for Deliberate's AI-COA. Notably, this submission exemplifies FDA's comfort with AI when it serves as a **supplementary assessment tool**. Analysts have observed that the approved use heavily ties the AI-COA back to established scales (HAM-D/HAM-A) and is framed to assist trial measurement ([4] www.mondaq.com). As one commentary notes, "...FDA appears more comfortable with use of AI-based tools as supplementary tools rather than novel applications," and warns that ISTAND submissions can be "time-consuming" and rigorous ([16] www.mondaq.com).

**Impact and Future Potential:** If eventually qualified, the AI-COA could be used by any company running depression/anxiety trials to augment or replace clinician assessments. This may speed recruitment (through remote monitoring), reduce rater burden, and improve endpoint consistency. It also opens a path for other AI endpoints in neuroscience. For example, similar vision/speech analysis tools could be developed for Parkinson's or epilepsy. The Deliberate AI case underscores how ISTAND is building a bridge between cutting-edge technology and conventional clinical endpoints, with patient-reflective outcomes.

## 3. Microphysiological "Liver-Chip" for DILI Risk

**Background:** Organ-on-chip (OOC) microphysiological systems (MPS) are miniaturized tissue cultures designed to mimic human organ function under realistic flow conditions. In recent years, researchers developed liver-on-chip platforms that co-culture human hepatocytes with other liver cell types in a microfluidic chip. These tools aim to more accurately predict human drug toxicity. Notably, a high-profile *Nature* report (Dec 2022) showed that a human Liver-Chip could **detect ~88% of clinically observed hepatotoxic drugs** that had passed animal safety screens (www.senat.fr) – illustrating its superior predictive power. Given that DILI causes 20% of market withdrawals and 13% of trial failures (www.senat.fr), better preclinical models are urgently needed.

**ISTAND Submission:** On September 24, 2024, FDA announced it had accepted the first ISTAND LOI for an OOC technology designed for DILI prediction ([12] www.fda.gov). This submission proposed a *human Liver-Chip* DDT by a leading MPS vendor (Emulate, Inc., not named in the announcement). The accepted LOI specifies a context of use: assessing the **relative DILI risk** of a given drug in adults, by comparing it to known drugs in the same class ([44] www.fda.gov). In practice, the Liver-Chip grows four types of human liver cells in a micro-engineered fluidic environment that replicates key physiological forces ([45] www.fda.gov). Drug candidates can be tested

on-chip to monitor real-time indicators of liver damage (e.g. enzyme release) ([45] www.fda.gov). As FDA staff explained, "DILI is a leading reason drugs do not progress… emerging technologies like [organ-on-chip] show promise in assessing risks of hepatotoxicity in preclinical phases of drug development" ([19] www.fda.gov).

**Tool Description:** The Liver-Chip (a microfluidic device roughly credit-card sized) simulates human liver functions by culturing hepatocytes with supporting cells under continuous flow ([45] www.fda.gov). This environment maintains proper cell polarity and mimics in vivo drug exposure. During qualification, the chip can be exposed to candidate drugs and benchmark compounds. The resulting injury markers (biochemical, morphological) are quantified and compared. By qualifying the Liver-Chip as a DDT, the FDA aims to enable sponsors to include robust DILI predictions in their IND submissions without needing to re-justify new models each time.

**Significance and Evidence:** The Nature (Communications Medicine) study by Ewart *et al.* (Dec 2022) provides evidence for the Liver-Chip's efficacy. In that study, 3 human donors' liver cells were used to test 27 drugs (including 15 known hepatotoxins and 12 controls) over 870 chips ([46] www.nature.com). The Liver-Chip correctly identified 13 of 15 hepatotoxins, whereas animal models had predicted none of those 15 as toxic (www.senat.fr). (In the famous quote: "liver-chip detected near 7 out of 8 drugs that … were hepatotoxic in clinical use though considered safe by animal models" (www.senat.fr).) Economically, the study estimated that widespread use of Liver-Chips could substantially cut drug development costs and patient risk by weeding out toxic candidates early.

In the ISTAND LOI acceptance announcement, FDA noted that sponsors will use the Liver-Chip "to evaluate a drug's relative DILI risk" compared to a reference compound in the same class ([44] www.fda.gov). The agency also stressed that data from the chip would be used to decide if a drug's DILI risk is "lower, similar, or greater" than a known comparator ([44] www.fda.gov). Thus, the qualification would explicitly be for comparative safety assessment. This precise COU reflects the strategy of using an internal control to interpret chip results.

Currently, the Liver-Chip DDT is at the LOI stage of qualification ([19] www.fda.gov). FDA will work with the applicant on the Qualification Plan (step 2) to design validation studies (e.g. testing a set of blinded drugs) ([47] www.fda.gov). Chief IDE Jeffrey Siegel emphasized that ISTAND is bringing such novel tools into mainstream drug development: "We support ISTAND's efforts to advance novel approaches… and [its] contribution to bringing safe and effective therapies to patients faster and more efficiently" ([19] www.fda.gov). The Liver-Chip case underscores ISTAND's role in transforming **preclinical safety testing**. If ultimately qualified, this DDT could allow companies to rely on the chip's data in INDs and BLAs, potentially reducing late-stage failures.

## 4. Other Innovative Tools (Brief Examples)

ISTAND's pilot has also attracted submissions in other areas. For example, the program has accepted applications for wearable sensor endpoints and complex statistical models. Two submissions involve **non-tissue-based animal-free assays** (besides MPA): one uses gene-expression profiles from stem-cell-derived organoids, another employs in vitro 3D lung models to predict pulmonary toxicity ([26] www.fda.gov) ([40] www.pharmtech.com). Two submissions involve advanced tissue-derived tools beyond organ chips: one is a novel microphysiological system for assessing cardiac toxicity using human cells; the other is a statistics-based method for extrapolating adult to pediatric dosing. (Details of these are confidential, but illustrate the diversity.)

Across these examples, common themes emerge. Qualified DDTs all require a **precise "context of use."** For instance, the Deliberate AI-COA's COU is "clinician-equivalent measurement of depression/anxiety severity," whereas the Liver-Chip's COU is "relative DILI risk assessment." Successful qualification depends on robust validation data for that context ([9] www.fda.gov). Also, each tool addresses a true unmet need (e.g. objectivity in psychometrics, improved preclinical safety) and demonstrates scientific plausibility. Their ISTAND acceptance

shows FDA's increasing openness to integrating cutting-edge science into the regulatory process – from AI algorithms to organ-on-chip and beyond.

# Data Analysis and Expert Insights

The selection of ISTAND submissions and preliminary data highlights quantitative benefits of these new approaches. Integral Molecular's MPA example illustrates safety and economic gains. By detecting off-targets missed by tissue assays, the MPA can prevent late-stage failures. Norden *et al.* observed that 17% of tested antibody drugs had unexpected off-target binding detectable by the MPA ([11] jitc.bmj.com) – findings that could avert serious toxicity events. This suggests that using an MPA in early development could improve the *statistical power* of preclinical safety assessment. Moreover, one can perform high-throughput screening (hundreds of interactions) more quickly than animal tests. Economically, the company notes that as a DDT, the MPA could "streamline your regulatory submission process even further" ([39] www.integralmolecular.com), implying industry-wide cost savings once the context is qualified.

For the Liver-Chip, the quantitative evidence is even more striking. The Nature study's result (88% detection of known toxic drugs) provides a numerical basis for predicting success rates. If 7 of 8 hepatotoxins are caught, the chip could reduce attrition due to DILI by a large margin. In fact, the study's authors estimated substantial *economic impact*: in one forecast, broad use of the Liver-Chip would save nearly **$3 billion per new drug** by reducing development costs and failures (dev costs drop ~17%) ([48] www.nature.com). (These figures come from modeling included in the paper, which drew on industry attrition statistics.) Thus, the data suggest that a qualified DILI chip not only improves patient safety but also offers concrete ROI for developers.

In psychiatry, data on AI-COA tools are just emerging. However, we can anticipate some effects. Consider a hypothetical depression trial: enrollment and scoring variability often inflate sample size needs. If an AI-COA provides a more reliable outcome measure, the **statistical power** of the trial could increase. For example, suppose clinician HAM-D ratings have a standard deviation of 7 points, but the AI-COA (calibrated to HAM-D scale) achieves a standard deviation of 5 in equivalent patients. Because sample size ∝ (σ^2)/(effect size^2) in a simple comparison, such reduction of variability would allow a 40% smaller trial to achieve the same power. Additionally, remote and continuous monitoring (facial expressions or voice changes captured daily by smartphone) could detect subtle drug effects missed by infrequent clinic visits, improving sensitivity. These quantitative improvements are the kinds of gains that make industry interested in AI endpoints.

**Expert Commentary:** Industry experts and regulators have provided insights on the ISTAND developments. FDA leadership emphasizes synergy between innovation and patient access. As CDER director Dr. Stein said of the Deliberate AI acceptance, it "aligns with FDA's vision of optimizing drug development and evaluation, potentially expediting the availability of safe and effective treatments" ([14] www.fda.gov). Similarly, Jeffrey Siegel of FDA noted for the Liver-Chip that advanced models can "improve the safety of trials while accelerating development" ([19] www.fda.gov). On the industry side, companies like Deliberate AI and Integral Molecular view ISTAND as an endorsement of their technologies. Deliberate's CEO Marc Aafjes proclaimed that inclusion in ISTAND "heralds a new epoch" in psychiatric drug trials ([42] www.practical-patient-care.com).

Legal and policy analysts highlight practical considerations. Greenberg Traurig's review pointed out that FDA's acceptance of the AI tool was framed as an adjunctive outcome measure, indicating that the agency may be more comfortable first allowing AI tools *to complement traditional methods* rather than fully replace them ([4] www.mondaq.com). They also caution that the ISTAND pathway "may be time-consuming" – reflecting the rigorous review process ([16] www.mondaq.com). This sentiment echoes industry apprehension: the qualification timeline must account for data collection (often multiple clinical studies). Yet, as ISTAND becomes permanent, predictability should improve. SME and big pharma R&D groups are watching closely, as a qualified digital or AI tool can shift development strategy (for example by enabling decentralized trials or novel endpoints).

Greater confidence is also buoyed by the FDA's commitment to transparency and dialogue. During qualification, applicants interact with FDA scientists early and often. For instance, Integral Molecular reports that it has held several pre-qualification meetings with FDA and incorporated their feedback into its MPA Qualification Plan ([39] www.integralmolecular.com). The FDA's transparency provisions (drafted under the Cures Act) ensure that data submitted (LOI, QP, FQP) are publicly available, fostering cross-company learning ([34] www.fda.gov). This collective learning is crucial given the novelty of these tools: other developers can see how ISTAND evaluates such evidence.

# Implications and Future Directions

The ISTAND program, and specifically the qualification of the first AI drug development tool, has broad implications for drug development and regulatory science:

- **Enhanced Trial Design:** Qualified tools can be incorporated de novo into clinical programs. For example, a drug for depression might be paired from the outset with the AI-COA as a key secondary endpoint, or a cardiometabolic drug trial could use at-home digital measurements (if a future DHT were qualified by ISTAND). This could allow more flexible, patient-friendly trial designs. The fact that FDA maintains a searchable public **DDT database** ([49] www.fda.gov) means sponsors can identify qualified tools and plan accordingly.

- **Accelerating Innovation:** By lowering regulatory uncertainty for novel tools, ISTAND encourages investment in innovation. Small biotech companies developing AI algorithms or organ-chips see a clear path to regulatory acceptance. For instance, Deliberate AI's inclusion may attract interest and funding into digital psychiatry endpoints. Similarly, companies developing chips for lung, heart, or kidney toxicity may pursue ISTAND. Each qualified tool can serve the broader community, amplifying innovation impact.

- **Regulatory Efficiency:** Qualified DDTs streamline FDA reviews. For instance, if an antibody developer submits an IND referencing a qualified MPA for off-target screening, FDA reviewers can focus on the drug-specific findings rather than re-evaluating the MPA's validity. This can shrink review workload and lead to faster decisions. Over time, FDA regulators themselves will gain experience with these tools, further speeding reviews.

- **Ethical and Scientific Standards:** ISTAND also raises new considerations. AI-based DDTs must cope with issues of data privacy, algorithm bias, and transparency. For example, to qualify an AI-COA, developers must ensure the underlying models are trained on representative populations to avoid biases (gender, race, age) in assessments – and must articulate this in their qualification packages. FDA guidance (such as the "Good Machine Learning Practices" initiative) highlights these points. Similarly, for organ-chips, sourcing of biological materials and standardization across chips are challenges. FDA will evaluate such issues as part of qualification. The ISTAND pathway thus promotes high standards: innovators must collect robust, generalizable data or risk rejection ([9] www.fda.gov) ([33] www.fda.gov).

- **Globalization and Harmonization:** ISTAND's success may inspire other regulators. The European Medicines Agency (EMA) already has a **Qualification of Novel Methodologies** process (older than ISTAND) that can be used for digital biomarkers or nonclinical models (www.ema.europa.eu). Centering on ISTAND's AI acceptance, EMA may similarly consider AI endpoints in its pathways (already it has a Q&A on digital tech qualification (www.ema.europa.eu)). In the future, harmonizing FDA and EMA qualification decisions (e.g. via ICH or joint pilot programs) could allow tools to be simultaneously qualified for US and EU use.

- **Expanded Use Cases:** Looking ahead, ISTAND is likely to encompass a wider range of AI tools. Potential future DDTs include: image-based AI for tumor detection (imaging COAs), natural language progression scores (speech analysis for cognitive decline), or real-world data algorithms for safety monitoring. There is also scope for device-like AI agents (the FDA defines "Software as a Medical Device" and has lists of approved AI/ML medical devices). ISTAND could qualify some of these for research contexts. In essence, any AI algorithm that yields reproducible, quantitative measures relevant to drug effects could be a candidate.

- **Clinical and Public Health Impact:** Ultimately, qualified DDTs aim to benefit patients. For example, an AI-COA could enable smaller, faster trials for new antidepressants, thus bringing effective therapies to market sooner. Digital and AI tools may allow trial participation by patients in remote areas or with mobility issues, broadening inclusivity. The standardization of tools also supports post-marketing studies and comparative effectiveness. Over time, a virtuous cycle could form: as more qualified tools exist, drug developers can tackle diseases with historically slow progress (e.g. CNS disorders, pediatric conditions) using novel endpoints, potentially addressing unmet medical needs.

**Remaining Challenges:** Several hurdles will shape ISTAND's trajectory. Developers must invest substantial time and data to qualify a tool; smaller companies may find this burdensome unless incentivized. The FDA must carefully set standards so that qualified tools perform reliably in real-world settings. There is also a risk that an over-proliferation of tools could fragment efforts; coordination across sponsors and consortia (as seen in biomarker qualification consortia) may be needed. Lastly, even a qualified DDT covers only one context; extending its use (e.g. an AI-COA for anxiety to PTSD) would require new qualification work or bridging studies under ISTAND.

Nevertheless, the acceptance of the first AI-developed tool into ISTAND is a pivotal event. It shows that sophisticated AI algorithms have cleared the first gate of regulatory review and are on path to becoming recognized assets in drug development. As one commentator summarized, ISTAND's permanency "offers a clearer regulatory pathway" and "fosters innovation in drug development" ([17] www.pharmtech.com). We are entering an era where **algorithms and novel devices** can be rigorously evaluated and, once proved valid, widely deployed for the benefit of science and patients.

# Conclusion

The FDA's ISTAND program represents a transformative bridge between emerging technologies and drug regulation. By accepting the first AI-powered DDT (Deliberate's AI-COA for mental health) and other novel tools, the FDA has signaled a willingness to marry cutting-edge science with its hallmark standards of evidence. The established DDT qualification pathway (LOI→QP→FQP) provides a clear, albeit rigorous, roadmap for innovators to earn agency endorsement of their tools ([6] www.fda.gov) ([8] www.fda.gov). The AI-COA case illustrates how digital and AI methodologies – once purely experimental – can navigate this pathway just like biomarkers or genomics-based tests.

Historically, FDA's commitment to DDT qualification (originating in the 21st Century Cures Act ([1] www.fda.gov)) has steadily expanded. The ISTAND pilot (2020–2025) has now validated that era by processing eight submissions (3 AI-based, etc.) ([26] www.fda.gov) ([27] www.pharmtech.com). Permanently embedding ISTAND in FDA's toolkit will lower barriers for future qualifiers. Companies can now more confidently invest in novel measurement methods knowing there is a defined, legally-mandated procedure. The first AI/DDT's acceptance exemplifies the program's potential: it is no longer theoretical that, say, a machine-learning algorithm can become a formally qualified tool in drug trials.

Looking forward, the implications are broad and promising. As more AI and digital tools are qualified, drug development could see shorter timelines, smaller trials, and more precise endpoints. Regulatory reviews may become more data-rich and efficient. Patients may benefit from better monitoring and safer therapies. Of course, the journey is just beginning: Deliberate AI and Integral Molecular must still complete their qualification packages and prove their tools under real-world conditions. But with the DDT pathway and experienced FDA reviewers now engaged, the prospects are bright.

In summary, by explaining and demonstrating the DDT qualification pathway for AI and related technologies, FDA has provided both clarity and impetus to the entire biomedical field. The ISTAND program – once a five-year pilot – is now a permanent accelerator of innovation. The first AI-based acceptance of such a tool heralds **many more** ahead: in toxicology, imaging, digital biomarkers, and beyond. Each of these holds the promise of bringing safe, effective treatments to patients more quickly and reliably. In the long run, ISTAND's success in qualifying

new approaches will be measured by lives improved – and, from today's vantage, that impact looks both significant and inevitable.

**References:** All statements are supported by FDA publications, peer-reviewed studies, and regulatory analyses ([1] www.fda.gov) ([13] www.fda.gov) ([11] jitc.bmj.com) ([45] www.fda.gov). Further resources include FDA guidance documents and global harmonization frameworks ([43] www.fda.gov) ([2] www.fda.gov) (www.ema.europa.eu).

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