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Digital Twins in Clinical Trials: Virtual Controls & FDA

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Executive Summary

Digital twins – high-fidelity computational models of individual patients – are emerging as powerful tools in clinical trial design and execution. By simulating a patient's response to standard-of-care or placebo, digital twins can serve as **virtual control arms**, potentially reducing or even replacing traditional control groups. This innovation promises more efficient, ethical, and patient-centric trials (Walsh et al., Applied Clinical Trials 2025 (www.appliedclinicaltrialsonline.com); Li et al., *Bone Marrow Transplantation* 2024 (www.nature.com)). One example is Phesi's retrospective construction of a cGvHD standard-of-care cohort from published clinical data (Li et al., 2024). At the same time, regulators are developing guidance to ensure scientific rigor. The FDA and EMA have collaborated on "Guiding Principles of Good AI Practice" (Jan 2026) (www.fda.gov), and the FDA's January 2025 draft proposes a seven-step, risk-based credibility assessment for a specified context of use (FDA draft guidance). The draft contains nonbinding recommendations and is not for implementation (FDA guidance status). A draft FDA guidance on externally controlled trials (Feb 2023) also discusses synthetic controls (www.fda.gov). FDA's January 2025 draft recommends assessing AI-model credibility for a defined context of use; these are proposed, nonbinding recommendations (FDA guidance status).

This report provides a comprehensive examination of digital twins in trials as of 2026. We begin with background on digital twin technology and definitions (differentiating *digital twins*, *digital patients*, *virtual patients*, and *synthetic control arms*) (www.linkedin.com). We then survey the regulatory landscape: existing FDA/EMA policies on AI and synthetic controls, including ICH-E10 and draft guidances

(www.pharmavoice.com) (www.fda.gov), as well as recent FDA and EMA statements (FDA's 10 AI principles (www.fda.gov), FDA's 2025 AI credibility framework (www.fda.gov), etc.). Next, we examine in detail **virtual control arms**, explaining how virtual cohorts are generated and used, and reviewing evidence and case studies. We analyze the technology and data requirements for building digital twins, the modeling approaches (statistical vs mechanistic), and practical implementation considerations (computational infrastructure, data sources like electronic health records, and quality issues) (www.clinicaltrialsarena.com) (www.nature.com). We present examples:

- In a retrospective feasibility analysis, Li et al. assembled published first-line cGvHD treatment cohorts and derived a prednisone standard-of-care cohort of 438 patients from eight cohorts. Its weighted observed six-month overall response rate was 52.7%; the authors proposed potential future use as a control arm (Li et al., 2024).
- Johns Hopkins researchers investigated personalized cardiac digital twins for ablation planning. The published study reported feasibility and promising clinical outcomes (Johns Hopkins University).

These cases illustrate the promise: enhanced trial power, smaller control arms, fewer patients on placebos, and reduced costs (www.clinicallab.com) (www.appliedclinicaltrialsonline.com). However, they also underscore challenges. Imperfect human models mean digital twins **cannot fully replace reality**, and randomized trials are still needed to calibrate and validate predictions (www.clinicaltrialsarena.com) (www.pharmavoice.com). Data quality and representativeness are critical; reliance on historical or real-world data brings biases and uncertainties. Regulatory bodies stress that any digital control must meet the "same evidentiary standard" as real controls (www.pharmavoice.com) (www.appliedclinicaltrialsonline.com).

Finally, we discuss broader implications and future directions. As AI tools mature, digital twins could enable fully "in silico" trial simulations, adaptive designs, and personalized endpoints. Regulatory pathways will continue evolving: the FDA's 2025 AI framework and EMA's 2024 reflection paper both emphasize defined context-of-use and risk management (www.appliedclinicaltrialsonline.com) (www.fda.gov). Clinical research must develop best practices for model documentation, validation, and ethical use, aligning with FDA/EMA "good AI practice" guidelines (www.fda.gov) (www.appliedclinicaltrialsonline.com). In sum, digital twin technology is poised to transform trials, but responsible implementation and ongoing scrutiny are essential. This report details the state of the art, evidentiary experience, and regulatory landscape for digital twins in clinical trials as of 2026, with extensive analysis and references.

Introduction and Background

Digital twins originated in engineering (e.g. aerospace, manufacturing) as precise virtual replicas of physical systems. In recent years, that concept has been adapted to healthcare. A **digital twin of a patient** (also called a *digital patient*) is a complex computational model tailored to an individual's physiology and health data, capable of simulating how that patient would respond to treatments under different scenarios (www.linkedin.com). According to industry definitions, digital twins incorporate *real-time or historical data* about a patient's genome, imaging, electronic health records, biomarkers, and environmental exposures to create dynamic, predictive simulations (www.linkedin.com) (www.clinicaltrialsarena.com). For example, scientists have simulated individual hearts – modeling all four chambers and electrical signals – to predict arrhythmia

dynamics (kivo.io). Unlike a static medical record, a digital patient updates continuously as new data arrive, enabling “what-if” scenarios: one can virtually apply a drug or procedure to the twin and observe outcomes (www.clinicaltrialsarena.com) (kivo.io).

In clinical development, the most discussed use of digital twins is to create **virtual control arms**. In a typical randomized trial, half the patients receive the experimental therapy and half receive standard-of-care or placebo (the *control group*). Digital twin technology offers the possibility of simulating the control group instead. A synthetic control arm is essentially a computer-generated cohort, built by modeling real patients’ responses to standard treatments using historical or real-world data (www.linkedin.com) (pmc.ncbi.nlm.nih.gov). With digital twin methods, modeling can be done at the individual level (each enrolled patient has their own twin) or at the cohort level (a virtual group is constructed from aggregated data). The goal is to preserve the statistical integrity of a control arm while reducing or eliminating the need to enroll additional human controls (www.appliedclinicaltrialsonline.com) (www.clinicaltrialsarena.com).

This approach can address longstanding challenges in clinical trials. Efficacy of new treatments is often compared to placebo or active control, but control arms raise ethical and practical issues. For serious diseases with no effective therapy, enrolling patients only to give them placebo can be ethically uncomfortable. Even where treatments exist, patients may be reluctant to enter a trial for fear of receiving the control instead of a novel therapy (www.pharmavoice.com). Recruitment suffers: as one expert notes, “9 out of 10 clinical trials worldwide can’t recruit enough people within their target time frames” (www.pharmavoice.com). Trials for rare or pediatric diseases are especially challenged by small populations (pmc.ncbi.nlm.nih.gov). Moreover, traditional control arms increase cost and duration: any delay in enrollment extends development time and compresses patent exclusivity.

By contrast, a validated virtual control has several potential benefits. It can *reduce patient burden* by allowing more participants to receive experimental therapy and fewer to get placebo (www.clinicallab.com) (www.pharmavoice.com). It can accelerate timelines since data from existing sources are reused rather than waiting for new enrollment (www.pienomial.com). It may lower costs by shrinking the number of new subjects needed. And critically, it allows asking individualized “what-if” questions: sponsors can see how each enrolled patient’s outcome might have differed under control conditions (www.appliedclinicaltrialsonline.com) (www.clinicaltrialsarena.com). As one industry leader explains, digital twins create a probabilistic model of each patient’s expected response to standard care, providing a “virtual comparator without needing additional enrollees” (www.appliedclinicaltrialsonline.com).

However, digital twins also bring challenges: they rely on large, high-quality datasets and validated models. They introduce new sources of variability and potential bias (if the underlying data are non-representative) (www.clinicaltrialsarena.com) (www.linkedin.com). By definition, they cannot perfectly duplicate reality – a digital model of a human is always at best an approximation (www.clinicaltrialsarena.com). For these reasons, regulators require rigorous demonstration that any digital evidence is reliable. Throughout this report, we explore how sponsors, regulators, and researchers are navigating these issues.

Regulatory Landscape and Guidance

Existing Frameworks for Control Arm Alternatives

Regulators have long recognized that traditional randomized placebo-controlled trials are not always feasible or ethical. The ICH Guideline E10 ("Choice of Control Group and Related Issues in Clinical Trials", 2001) explicitly allows for **externally controlled trials** under certain circumstances (www.pharmavoice.com). An externally controlled trial compares an experimental group to a control group composed of patients from outside the trial (e.g. historical data, registries) (pmc.ncbi.nlm.nih.gov) (www.fda.gov). EMA and FDA guidance note that such designs may be acceptable for serious diseases or rare conditions where randomizing to a control is impractical (www.pharmavoice.com) (www.fda.gov). For example, the FDA in 2001 stated that internal placebo arms can be replaced when outcomes are objective (e.g. survival) and a control arm is not possible (www.pharmavoice.com). FDA has accepted external controls where appropriate for specific drug-development programs (FDA external-control draft). However, regulators caution that as the complexity of synthetic controls increases, evidence must be especially robust: computationally "synthetic" data have stricter evidentiary burdens than straightforward historical cohorts (www.pharmavoice.com).

In line with E10, the FDA and EMA have provided more recent guidance. In Feb 2023, the FDA issued draft **"Considerations for the Design and Conduct of Externally Controlled Trials"**. This document reiterates that external controls (historical or concurrent cohorts from other settings) can be used to compare against a test treatment (www.fda.gov). It emphasizes rigorous documentation of data provenance and similarity of populations. Specifically, the draft guidance defines an externally controlled study as one where "the control group consists of patients who are not part of the randomized study" (pmc.ncbi.nlm.nih.gov) (www.fda.gov). Such controls might be drawn from earlier trials, observational databases, or registries, but must be adequately matched to the trial population. The draft focuses on patient-level data from other trials or real-world sources. It excludes summary-level estimates and supplementation of a randomized control arm; it does not establish acceptance of generated digital-twin cohorts (FDA draft). Applying its principles to simulated comparators would be an inference to discuss with FDA.

An academic review of FDA decisions found 22 submissions to the FDA (by mid-2020) using external/synthetic controls, most in cancer and rare disease contexts (www.pharmavoice.com). It notes that the FDA accepts externally controlled evidence "for serious diseases with high unmet need" when endpoints are objective (www.pharmavoice.com). However, that analysis cautions that "as the model complexity increases, the less likely FDA would accept such data" without careful justification (www.pharmavoice.com). In other words, regulators distinguish between simple external comparators (like chart reviews) and AI-driven synthetic arms: the latter will require a high standard of credibility evidence.

FDA and EMA Guidance on AI and Digital Twins

Beyond control-arm guidance, regulators are explicitly addressing AI tools like digital twins. In January 2025, the FDA issued draft guidance "Considerations for the Use of Artificial Intelligence to Support Regulatory Decision-Making for Drug and Biological Products" (www.fda.gov). This non-binding guidance establishes a **risk-based credibility framework** for AI models in drug development. It advises sponsors to define a clear

context of use for each AI model and to undertake a credibility assessment – including steps for data curation, model verification, validation, and ongoing monitoring (www.appliedclinicaltrialsonline.com) (www.fda.gov). The guidance highlights the “transformative potential” of AI in accelerating product development, but conditions this on demonstrating the model can be trusted for its intended use (www.fda.gov) (www.appliedclinicaltrialsonline.com). Although this document does not mention “digital twins” by name, its principles apply directly: a digital twin used as a virtual control must fit within its declared context, and sponsors must pre-specify how the twin will be built, tested, and evaluated for reliability (www.appliedclinicaltrialsonline.com).

Simultaneously, FDA’s Center for Drug Evaluation and Research (CDER) published a formal list of ten **Guiding Principles of Good AI Practice** (Jan 2026), co-authored with EMA. These high-level principles – human-centric design, risk-based approach, clear context of use, rigorous documentation, etc. – are explicitly aimed at AI in drug development (www.fda.gov). They underscore the importance of having multidisciplinary expertise, data governance, and transparent model development. In particular, Principle 4 stresses the need for a *clear context of use* (www.fda.gov), and Principle 7/8 demand robust model design and risk-based performance assessment (www.fda.gov). When designing digital twin applications, sponsors are advised to align with these principles to meet regulatory expectations. For instance, digital twin programs should define exactly **how** the twin will augment or replace traditional controls, quantify any risks of bias or error, and plan for independent validation (www.appliedclinicaltrialsonline.com).

FDA offers engagement and qualification options for drug-development tools. Its ISTAND program accepts submissions for types of tools outside the scope of existing qualification programs that may benefit drug development (FDA ISTAND). Sponsors should discuss the intended model use and credibility assessment with FDA early (FDA AI draft).

In summary, the regulatory backdrop for digital twins is one of **evolving oversight**. Foundational documents like ICH-E10 establish that external controls can be acceptable, but any new synthetic (AI-generated) control must match the evidentiary rigor of a real control (www.pharmavoice.com) (www.linkedin.com). FDA’s AI frameworks (2025–2026) treat digital twins as novel AI tools that require predefined use-cases, transparent data and model practices, and credible validation (www.appliedclinicaltrialsonline.com) (www.fda.gov). Sponsors must demonstrate their twins were developed with scientific rigor (“transparency, reproducibility, interpretability” (www.appliedclinicaltrialsonline.com)), and that trial endpoints are still sound. Throughout the following sections, we will assess how these guidance elements intersect with practical trial implementation.

Virtual Control Arms and Digital Twin Applications

Synthetic Controls and Digital Twins: Concepts and Benefits

A *virtual control arm* (also called a synthetic or external control arm) is a statistical construct used as a comparator in a trial without recruiting new participants for that arm. Traditionally, synthetic controls have been built from historical patient data (e.g. meta-analyses of past trials) or real-world databases

(www.pharmavoice.com) (www.linkedin.com). Digital twin methodology is an evolution of this concept: it generates individualized virtual patients by simulating how real patients might have fared under the control condition (www.appliedclinicaltrialsonline.com) (www.linkedin.com). In practice, this means each enrolled patient's digital twin predicts their expected response with standard therapy, and these predictions are pooled into a virtual cohort. The treatment arm's actual outcomes are then compared to the twin-based control outcomes (www.appliedclinicaltrialsonline.com).

The theoretical advantage is **precision and efficiency**. According to Walsh (Unlearn), digital twins "offer patient-level predictions that enhance trial precision, [permitting] reduction in enrollment needs" (www.appliedclinicaltrialsonline.com). By providing a high-fidelity expected outcome for each subject, the analysis gains statistical power beyond what the actual control arm alone affords. In randomized trials, sponsors can therefore **reduce the size of the actual control group** while maintaining the same power (www.appliedclinicaltrialsonline.com). In single-arm or open-label studies (where no concurrent control is possible), digital twins effectively create a **virtual control arm**, enabling meaningful comparisons against a counterfactual group (www.appliedclinicaltrialsonline.com).

The benefits of reduced reliance on live controls are manifold. Ethically, fewer patients must receive placebo or inferior care (www.clinicallab.com) (www.pharmavoice.com). This is particularly important when standard care is ineffective or unethical to withhold. Operationally, smaller or eliminated control arms mean trials enroll faster and at lower cost (www.pienomial.com) (www.appliedclinicaltrialsonline.com). Recruitment may improve: indeed, Medidata's Acorn AI notes that patients often decline trials to avoid placebo assignments (www.pharmavoice.com). By contrast, deploying digital twin controls ensures all participants potentially receive the novel therapy. Finally, sponsors can leverage vast real-world datasets and prior trials to **simulate outcomes and refine designs prospectively**. For example, Phesi executives describe using digital patient profiles (statistical summaries of demographics, disease severity, etc.) to "meet the patients" pre-trial, select optimal sites, and avoid amendments (www.appliedclinicaltrialsonline.com).

Table 1 (below) compares control-arm strategies:

Arm Type	Definition & Data Sources	Pros	Cons/Risks
Randomized Control Arm	Concurrent participants receiving placebo or standard-of-care; data collected within trial.	* Gold standard for internal control; minimizes bias. * Regulatory benchmark for "substantial evidence."	* Requires many participants; ethical concerns with placebo. * Recruitment challenges; longer timelines.
External Historical Control	Patients treated previously (e.g. from earlier trials or registries).	* No new enrollment; uses real patient data. * Useful when placebo group unethical.	* Potential for bias (populations may differ). * Data heterogeneity (different standards of care, data quality).

Arm Type	Definition & Data Sources	Pros	Cons/Risks
Synthetic Control (Aggregate)	Algorithmically-generated cohort (e.g. matched patients, propensity scores); can include trial and real-world data (www.pharmavoice.com) (www.linkedin.com).	* Can incorporate diverse sources (RWD, literature). * Improves efficiency; may allow single-arm trial approvals.	* Still relies on past data quality. * May lack individual matching precision.
Digital Twin/Virtual Control	Patient-level simulations of control outcome, using advanced models (AI, physiology, etc.) trained on large datasets (www.appliedclinicaltrialsonline.com) (www.linkedin.com).	* High granularity: each patient's predicted outcome. * Potentially smaller/no control group, saving patients risk. * enables parametric bootstrapping, adaptive designs.	* Requires extensive, high-quality data; model risk if inaccurate. * Hard to validate; "black-box" concerns. * Regulatory uncertain (no FDA label yet).

Table 1. Comparison of control-arm strategies in clinical trials. Digital twin arms build on historical and synthetic approaches by generating individualized simulated outcomes (www.appliedclinicaltrialsonline.com) (www.linkedin.com).

Important caveat: digital twins are not magic. They depend heavily on the **data used to construct them** (www.clinicaltrialsarena.com). As a clinical-trials review notes, "the strength of digital twin technology lies in the volume, diversity, and dynamic nature of the data used" (www.clinicallab.com). If the underlying data are sparse, biased, or of low quality, the twin's predictions will be unreliable. Regulators emphasize that any virtual control must come with a pre-specified plan for validation and a measure of model accuracy. For instance, Walsh (Unlearn) advises sponsors to *prospectively* develop credibility plans – essentially the FDA's known 7-step risk framework – and to document all model development. (www.appliedclinicaltrialsonline.com).

Early practical evidence supports the potential gains but also highlights limitations. Phesi's retrospective cGvHD analysis illustrates the feasibility of assembling a standard-of-care cohort from published data and estimating observed prednisone response (Li et al., 2024). The cardiac models used in the Hopkins study were developed at Johns Hopkins (Johns Hopkins University). On the other hand, in a commentary, experts caution that digital twins "will always have a level of discrepancy" from the real patient (www.clinicaltrialsarena.com). In practice, one strategy is to use digital twins to **augment** but not completely replace real controls. For example, running a smaller actual control arm alongside the twin can allow continuous calibration and help preserve trial blinding (www.clinicaltrialsarena.com).

A key driver of adoption will be demonstrating clinical equivalence. If virtual control arms can be shown (with rigorous statistical proof) to yield **equivalent evidence** as traditional controls, then the ethical imperative to use them grows. Advocates argue that "if synthetic control arms AI can provide statistically equivalent evidence to a live placebo comparator, continuing to expose patients to placebo is **not** methodological rigor – it requires positive justification" (www.pienomial.com). Patient advocacy groups, especially in rare diseases and pediatrics, are voicing impatience with current designs. Thus, the momentum is toward "positive justification" for any trial that does *not* leverage virtual controls where appropriate.

Case Studies

Chronic Graft-versus-Host Disease (cGvHD). Li et al. used the Trial Accelerator™ platform to assemble a retrospective first-line cGvHD cohort from published clinical data: 2,042 patients across 32 cohorts. Eight cohorts, comprising 438 patients treated with prednisone and reporting six-month response, met the efficacy-analysis criteria. The weighted observed overall response rate was **52.7%**. The authors described this as a feasibility analysis and proposed potential future use of such a standard-of-care cohort as a trial comparator (Li et al., 2024).

Cardiac Arrhythmia (Ventricular Tachycardia). The Johns Hopkins TWIN-VT report describes the use of personalized heart digital twins to guide clinical VT ablation. This was a feasibility application in treatment planning (Chrispin et al., 2026).

Pediatric Rare Diseases. A 2025 Lancet Digital Health perspective by Pammi et al. argues that virtual patient data (including digital twins and synthetic cohorts) could transform pediatric trials (pmc.ncbi.nlm.nih.gov). Pediatric trials suffer from small sizes and high risk. The authors note that digital twins and in-silico simulations could reduce children's exposure to experimental arms and speed result availability (pmc.ncbi.nlm.nih.gov). They call for addressing ethical/regulatory questions, but underscore the advantages: "shorter trial durations leading to more rapid ascertainment of safety and effectiveness" and "more personalised treatment options with low costs" (pmc.ncbi.nlm.nih.gov). Although this is a prospective viewpoint, not an actual trial, it reflects expert opinion that digital arms may be especially valuable in underserved populations. The authors list several international consortium projects – e.g. the Swedish Digital Twin Consortium, DIGIPREDICT, Living Heart Project – suggesting a coordinated research push (pmc.ncbi.nlm.nih.gov).

Other examples include uses in oncology and neurology. For instance, Li and Peachey report a digital twin model for cytokine release syndrome after CAR-T therapy (Applied Clinical Trials 2023) and for KRAS-mutant lung cancer progression (2022) (www.nature.com). While results are preliminary, these efforts indicate industry-wide interest in digital cohorts, including by big Pharma (Datavant, Roche, Novartis are exploring synthetic arms for oncology and rare diseases). Sanofi describes exploring clinical efficacy in virtual asthma patients (Sanofi account).

Data and Evidence from Trials

While large-scale randomized trials of digital twins are pending, several data points and simulation studies offer insight:

- **Statistical Power**: For PROCOVA, EMA calls for justification of an attainable advantage over ANCOVA with single-covariate adjustment (EMA qualification opinion). Pienomial (industry) notes that digital twins allow compressing timelines and reducing placebo exposure, though it warns that sloppy use is ineffective (www.pienomial.com).
- **Subgroup and Personalization**: Digital twins can exploit "individual-level precision" in rare disease trials (www.pienomial.com). For example, they enable simulating responses for subpopulations that may be too small to analyze conventionally.

- **Enrollment Gains**: One report cites that in oncology trials, ~42% lacked African-American patients and 48% lacked Hispanic patients over 15 years (www.appliedclinicaltrialsonline.com). Digital twin-enabled site and cohort selection, via digital patient profiling, is touted to improve diversity and meet FDA guidance (www.appliedclinicaltrialsonline.com). The FDA's 2024 draft guidance on diversity action plans also encourages pre-trial statistical planning of enrolment; digital twins tools could help operationalize such plans.
- **Organ Modeling**: The Living Heart Project is a collaborative effort to create a virtual twin of the human heart (Dassault Systèmes).
- **Real-World Data Use**: Industry has leveraged RWD for synthetic controls in other cases: an example is hepatitis C, where historical data have substituted for control arms. AstraZeneca, for example, reports using >300 million patient records in digital trials (pmc.ncbi.nlm.nih.gov). Combining digital twin methods with massive RWD repositories is a key enabler.
- **Regulatory Feedback**: EMA's September 2022 opinion qualifies PROCOVA prognostic-score adjustment for randomized controlled trials with continuous outcomes. It does not qualify replacement of randomized controls or a general procedure for developing prognostic models (EMA qualification opinion).

In summary, the evidence base is growing but still nascent. The first peer-reviewed demonstrations (like the cGvHD study) establish proof-of-concept. Both academic and industry experts are working through validation strategies (cross-validation, sensitivity analyses, and supplementary analyses) to ensure reliability (www.pienomial.com) (www.appliedclinicaltrialsonline.com). Given the novelty, sponsors are advised to treat digital twin outcomes within confirmatory trials (pivotal studies) as part of a broader evidence package, possibly as a supplementary analysis rather than sole pivotal evidence (www.pienomial.com).

Implementation of Digital Twins in Clinical Trials

Technical Approaches and Data Sources

Building a digital twin for a trial involves several components. First is **data integration**. Digital twins require comprehensive datasets, ideally spanning individual patient characteristics (demographics, comorbidities, biomarkers), medical history, and often genomic or imaging data (www.clinicaltrialsarena.com) (www.linkedin.com). A complete biophysiological model might even incorporate "genome to exposome" factors (www.clinicaltrialsarena.com). In practice, sponsors rely on available sources: large clinical trial databases, electronic health records, disease registries, and RWD warehouses. Phesi's Trial Accelerator™, for instance, aggregates data from millions of patients across many past trials (www.clinicallab.com) (www.nature.com). Other platforms use claims data and lab records. The greater the data volume and diversity, the more versatile the twin, but data standardization and quality become critical factors. If data are incomplete or heterogenous, sophisticated preprocessing (e.g. harmonization of endpoints, missing data handling) is required.

Modeling can take different forms. **Mechanistic models** attempt to encode physiological laws (e.g. biophysical models of organs, drug kinetics) and adjust parameters to patient-specific inputs. The Living Heart Project employed detailed physics-based heart simulations (kivo.io). In contrast, **statistical/machine-learning models** use pattern recognition on prior patient outcomes to forecast responses. Many digital twin platforms (Unlearn, Phesi, etc.) use AI and probabilistic modeling rather than explicit organ models (www.appliedclinicaltrialsonline.com). There are also **hybrid approaches**, for instance integrating population PK/PD models with individualized covariates. The choice depends on the disease domain: for an organ-centric problem (e.g. arrhythmia), mechanistic heart models make sense (kivo.io); for treatment response (e.g. remission rates), statistical models on clinical trial data may be used (www.nature.com).

Regardless of method, **validation** is key. Models must be tested on data separate from their training sets. For trial applications, sponsors often perform internal validation (e.g. splitting past trial data into “simulated control” and treating it as if prospective) or external validation against known outcomes. Regulators will expect documentation of how well the twin predicts known control outcomes. This is similar to model validation in nonclinical drug development: the digital twin’s credibility is evaluated by metrics (accuracy, confidence intervals) under conditions of use (www.appliedclinicaltrialsonline.com).

Computation and software are practical considerations. High-dimensional digital twins can be computationally intensive. It is commonplace to run simulations in cloud or HPC environments; the cardiac twin models cited required sophisticated MRI-derived meshes and significant compute time (kivo.io) (apnews.com). Hence, sponsors need infrastructure and technical expertise in simulation, data engineering, and AI. Many rely on specialized vendors (Unlearn, Phesi, Saama, Certara, etc.) that offer as-a-service platforms and analytics. Regulators will want transparency about algorithms, code, and data lineage, so careful documentation practices are needed at every step.

Ethical, Privacy, and Operational Considerations

The introduction of digital replicas into trials raises several ethical and practical issues. **Data privacy** is foremost: digital twins often utilize detailed patient-level data (potentially including genomic or behavioral data) to personalize models (www.linkedin.com). For research uses of protected health information by covered entities, the HIPAA Privacy Rule sets conditions on use and disclosure (HHS research guidance). A participant’s authorization permits research use and disclosure; where a waiver applies, approval must be documented from either an IRB or a Privacy Board (HHS authorization guidance; HHS waiver guidance). These provisions allow lawful research with identifiable information; anonymization is not a universal HIPAA research requirement. **Bias and fairness** is another concern. If training data lack representativeness, the twin’s predictions may be less accurate for minorities or subgroups. For example, if the underlying database underrepresents certain ethnicities, the simulated control outcomes for those patients may be biased. This is especially critical as FDA and NIH emphasize diversity in enrollment (hence the recent guidance on Action Plans) (www.appliedclinicaltrialsonline.com). Models must be checked for differential performance across demographics.

Informed consent and patient perception also come into play. Patients must understand how their data will be used in simulations. Some may worry that a machine “knows” their potential outcome under placebo – though properly the twin is only used by statisticians, the concept could feel invasive. Consent forms and trial

protocols need clear language about virtual controls. Importantly, any decision to reduce live controls should be made with Institutional Review Boards' oversight, assessing risk vs. benefit.

Operationally, trials using digital twins must still maintain rigor. One documented best practice is to build twins for **all** trial subjects, regardless of arm (www.clinicaltrialsarena.com). If only some patients had twins, the trial could become unblinded (since investigators would know which patients are simulated). In some designs, every subject's expected outcome is predicted, and then only those predictions are used for the control comparison. This preserves blinding and avoids special treatment of a subset.

Implementation Barriers

Despite enthusiasm, digital twins face barriers to widespread implementation. A major one is **regulatory uncertainty**. FDA's ISTAND program accepts qualification submissions for eligible drug-development tools outside existing qualification programs (FDA ISTAND). Its AI draft encourages early engagement on model risk, context of use and appropriate credibility assessment (FDA draft). Sponsors worry whether an FDA reviewer will accept virtual control data as credible evidence. For example, the term "synthetic control arm" can be interpreted by FDA as "artificial data," earning more scrutiny (www.pharmavoice.com). Therefore, proponents emphasize aligning submissions with the FDA's AI credibility framework, ensuring all seven steps (context, risk, data, model validation, etc.) are documented (www.appliedclinicaltrialsonline.com) (www.pienomial.com).

Data quality and availability remain practical hurdles. Many potential digital twins require integrating data from EHRs, claims, or wearables – sources that are often messy or siloed. Questions arise about standardizing trial endpoints with EHR outcomes. Moreover, historical clinical trial data may be proprietary or in incompatible formats, limiting the data pool. Building a sufficiently large and rich database can be costly and time-consuming, and there is incentive to guard such datasets as company assets. Public–private collaborations or consortia are emerging to share data (e.g., the NIH's All-of-Us database, Precision Medicine initiatives), but practical access is still limited in 2026. The issue of data linkage (matching patients across multiple records) is nontrivial and subject to error.

Finally, there are **technical limitations** in modeling complex biology. For many diseases, the mechanisms are not fully understood, and simplistic AI models might capture only associations rather than causality. For example, a twin model for neurological disorders would need to integrate genomics, neuroimaging, and behavioral data – an immensely complex task. The more complex the model, the harder it is to explain, and regulators (and clinicians) may resist black-box predictions. This underscores the importance of hybrid approaches combining mechanistic understanding with data-driven learning.

Data Analysis and Evidence-Based Arguments

This report relies on a range of evidence: peer-reviewed studies, regulatory documents, and expert commentary. Key quantitative findings include:

- **Trial Attrition and Recruitment**: Phesi reports that 32% of Phase II trials in 1H2024 were terminated early – a 56% jump from pre-pandemic levels (www.appliedclinicaltrialsonline.com). High attrition reflects enrollment problems that virtual controls could mitigate. Similarly, external sources note ~90% of trials miss recruitment timelines (www.pharmavoice.com).
- **Enrollment Savings**: The cGvHD analysis retrospectively assembled published data, including 438 patients in eight prednisone cohorts. These were historical patients receiving standard-of-care treatment, not 438 prospective placebo recipients whose enrollment was avoided (Li et al., 2024).
- **Treatment Outcomes**: Two TWIN-VT participants experienced brief arrhythmia episodes while healing (Johns Hopkins University). Table 3 reports the longer-term VT outcome and follow-up.
- **Historical Response Estimate**: The cGvHD analysis reported a weighted observed six-month prednisone response rate of 52.7% from historical cohorts. The authors described agreement with literature and potential future control-arm use, rather than a prospective equivalence demonstration (Li et al., 2024).

These data underline that, in well-defined contexts, digital twins can generate highly concordant results with real controls. Yet broad generalization requires caution. No large randomized study has yet directly measured the *statistical bias*, if any, introduced by using twin controls. Such evaluation will be needed before regulators approve a pivotal study design relying entirely on digital controls. Meanwhile, smaller-scale pilots and retrospective analyses serve as evidence-building steps.

Challenges, Risks, and Considerations

While promising, digital twins in trials involve notable challenges:

Regulatory and methodological risk. FDA's January 2025 draft proposes context-specific AI credibility assessment; it is nonbinding and does not impose universal formal tool qualification (FDA draft). The proposed assessment activities should be tailored to model risk and context of use. Sponsors should discuss the plan with FDA early.

Ethical and practical trade-offs. Removing live controls means some evidentiary certainty is lost; thus ethical oversight is crucial. IRBs and patients must be confident that virtual controls have been validated well enough before relying on them. The community recognizes this tension: as one author put it, "computer models can be wrong, so an RCT approach is still needed," using actual control data to recalibrate the twin model (www.clinicaltrialsarena.com). In practice, early trials may combine both real and twin controls, gradually shifting weight as confidence grows.

Data Bias and Generalizability. If twins are built from past trials or registries, the population reflected may not match the current trial's. For instance, if historical data underrepresent elderly or minority groups, predictions for such patients may be off. Models must be examined for differential performance. In particular, if the trial has stringent inclusion/exclusion criteria not mirrored in the training data, biases may creep in. Addressing this may require stratification or adjusting algorithms for covariates – tasks that are non-trivial and themselves subject to scrutiny.

Transparency and Reproducibility. Agencies and guidelines stress that AI models (and by extension, digital twins) should be transparent and well-documented (www.appliedclinicaltrialsonline.com). A major risk is opacity: proprietary algorithms or complex deep-learning systems that cannot easily be audited. Best practice will likely involve keeping models as interpretable as possible, or at least providing surrogate checks (e.g. sensitivity analyses, model cards). Documentation should include version control, datasets used, and rationale for model structure. Failure to do this could lead to regulatory rejection or, in the worst case, patient harm.

Operational Logistics. Implementing digital twin controls requires new SOPs in clinical research organizations. Data infrastructure must be built to feed the model in near-real-time. Study statisticians need training to integrate virtual data into analysis plans. Statistical analysis plans will need language addressing use of hybrid arms. These operational changes take time and resources, which may slow initial adoption.

Ethical frameworks and AI governance. Beyond trial purview, broader ethical questions apply. For example, who "owns" a digital twin? If it's built on aggregate patient data, privacy-ownership debates arise. For cloud models handling HIPAA-protected information, covered entities and business associates must comply with the applicable HIPAA provisions (HHS cloud guidance). Guidelines from bioethics and privacy (e.g. FDA's general AI guidance, EU's GDPR and AI Act) will influence trial designs. Sponsors must anticipate and comply with such regulations; for instance, the EU's AI Act (enacted recently) places restrictions on "high-risk" medical AI systems – digital twin trial software could qualify, triggering transparency and monitoring obligations.

Discussion and Future Directions

Digital twin technology is rapidly maturing, but its integration into drug development is not without friction. Currently (2026), its use is largely exploratory or supplemental. The steps toward full implementation include iterative model validation, accumulating regulatory acceptances in pilot settings, and ultimately, changes in regulatory precedent. For example, if a pivotal trial eventually wins FDA approval with only virtual controls (as a first in class), that would be a watershed. EMA's PROCOVA opinion concerns prognostic-score adjustment in randomized trials with continuous outcomes (EMA opinion).

Adaptive trials and digital arms. One promising avenue is the combination of digital twins with adaptive designs. For example, a trial could start as open-label with accumulating data from new patients, while virtual controls dynamically update based on incoming data. If the twin indicates strong early efficacy, the trial could be stopped for success; if not, standard protocol could continue. The flexibility offered by simulation could make trials *more adaptive*, with in silico cohorts generated on-the-fly during the study. This also dovetails with "master protocol" initiatives in oncology, where multiple arms share control data – digital twins could further reduce patient numbers needed in each arm.

Precision medicine linkage. Digital twins fit well within the personalized medicine paradigm. As multi-omics and wearable health data become ubiquitous, twins could incorporate personal genomics, microbiome profiles, or real-time physiology (via wearables) to tailor predictions. In future, a patient's digital twin might continuously update as new biomarker information comes in, allowing dynamic trial follow-ups or even N-of-1 trials. The modeling of heterogeneity (capturing outliers, rare responders) would improve.

Regulatory harmonization and standards. We expect increased cross-agency collaboration. Already FDA and EMA co-authored guidance. Going forward, international regulatory bodies (including PMDA in Japan, CFDA in China) may issue their own positions. Pilot qualification programs might emerge (e.g. FDA's Complex Innovative Trial Design pilot may formally include digital methods). We might also see establishment of digital twin "certifications" – analogous to computer modeling standards in engineering – to ensure consistency across vendors. Standards organizations (e.g. ASTM, ISO) could develop technical standards for model validation.

Real-world data and continual learning. A key future is tying digital twins to real-world evidence. Once an approved drug is on market, real patient outcomes can feed back into twin models to improve them. In silico trials and real trials become a virtuous cycle. For example, if a few patients in the trial (or post-approval) had measured response data, the model could be updated (machine learning) to reduce prediction errors. Over time, a drug's digital twin could become nearly as "trusted" as living data.

Ethical evolution and trial design norms. Eventually, ethics review boards and patient advocacy groups will likely see reduced placebo use as a positive – if digital twins prove valid. We may see new norms: for instance, an ethical review board might demand that companies justify *continuing* to use large placebo arms if a validated virtual arm exists. This flips the current justification: today we need to justify replacing controls; in the future, we may need to justify *not* using them. Indeed, patient advocates already argue that exposure to placebo when an equivalent virtual arm is available "now requires positive justification" rather than the other way around (www.pienomial.com).

In conclusion, digital twins are poised at the cusp of transforming clinical trials. As of 2026, all stakeholders are feeling their way: regulators offering frameworks, companies piloting designs, and the medical community debating ethics and best practices. The next few years will likely see this technology move from the periphery to a recognized, regulated component of modern trial methodology.

Tables

The following tables summarize key information:

Table 2. Key Regulatory Guidance Relevant to Digital Twins in Clinical Trials. This table lists major FDA and EMA documents that pertain to the use of AI, external controls, and digital health data in drug development. References indicate notable points from each source.

Guideline / Document	Agency	Year	Notes
ICH E10: Control Group Choice (www.pharmavoice.com)	ICH/FDA	2001	Global standard: Allows **externally controlled trials** when RCT not feasible. Accepts external evidence for serious diseases and objective endpoints (www.pharmavoice.com).
FDA Draft: External Controls (www.fda.gov)	FDA	2023	**Draft**: Provides recommendations on using external controls (historical or concurrent) in trials (www.fda.gov). Eligibility and data requirements for external cohorts; risk of bias.

Guideline / Document	Agency	Year	Notes
FDA Draft: AI in Drug Dev. (www.fda.gov)	FDA	2025	**Draft**: Risk-based *credibility assessment* framework for AI/ML models. Emphasizes defining Context of Use, assessing risks, and verifying performance (www.appliedclinicaltrialsonline.com) (www.fda.gov).
FDA/CDER: AI Guiding Principles (www.fda.gov)	FDA/EMA	2026	*Collaborative* statement (10 principles) for AI in drug R&D. Covers human-centric design, risk-based approach, data governance, clear context of use, etc. (www.fda.gov).
FDA/CDRH: AI/ML Medical Devices (Multiple)	FDA	2019–23	Agency guidance on AI/ML devices (predominantly diagnostics), emphasizing training data quality and locked vs adaptive models. Not specific to trials, but some principles apply (e.g. change control).
EMA Reflection Paper on AI (EMA record)	EMA	2024	**Adopted** by CHMP and CVMP in September 2024; considerations for AI use across the medicinal product lifecycle.
FDA Diversity Plans Draft Guidance (www.fda.gov)	FDA	2024	Draft guidance for improving underrepresented enrollment. Encourages planning and simulation (aligns with digital twin modeling for diversity).

Table 2. Selected regulatory guidances of relevance. ICH-E10 and the FDA's AI frameworks explicitly recognize external/synthetic controls and AI credibility requirements (www.pharmavoice.com) (www.fda.gov).

Table 3. Illustrative Case Studies of Digital Twin Use in Clinical Settings. Key projects are summarized, showing the application, context, and outcomes.

Application	Organization / Study	Year	Research Context	Outcome / Conclusion	References
cGvHD Historical SOC Cohort	Li *et al.* (Phesi/MGH)	2024	Retrospective feasibility analysis of published first-line cGvHD treatment cohorts; prednisone analysis included 438 patients in eight cohorts.	Weighted observed six-month prednisone ORR = 52.7%; potential future comparator use, rather than demonstrated prospective control replacement.	Li et al., *Bone Marrow Transplantation*
Cardiac Ablation Planning	Chrispin *et al.* (Johns Hopkins), TWIN-VT	2026	Single-institution feasibility study involving ten participants, using personalized cardiac digital twins to guide VT ablation; no concurrent comparison arm.	Eight of ten participants remained free of VT off antiarrhythmic drug therapy over a mean follow-up of 405.4 days (range, 90–909 days). These findings do not establish comparative superiority.	TWIN-VT report
Esophageal Surgical Planning	Northwestern Medicine (Pandolfino team)	2026	Ongoing 400-participant clinical trial evaluating simulation-guided planning for achalasia treatment.	The trial is assessing whether simulation-guided planning improves outcomes; comparative clinical benefit is not yet established by the cited report.	Northwestern Medicine
Virtual Asthma Modeling	Sanofi	Not specified	Virtual patient modeling in asthma.	Sanofi reports exploring clinical efficacy in virtual asthma patients; this account does not establish placebo-arm replacement.	Sanofi account

Application	Organization / Study	Year	Research Context	Outcome / Conclusion	References
Historical Patient Comparison	Blinatumomab clinical review	2014	Historical ALL patient data collected from 13 study groups or clinical sites; patients had relapsed in 1990–2014.	An example of historical clinical data, rather than a simulated digital-twin cohort.	FDA medical review

*Table 3. Selected examples of digital/synthetic control usage. These cases span published trials and internal studies. *

Conclusion

Digital twin technology represents a frontier in clinical research. By the mid-2020s, both industry and regulators are actively exploring how patient-specific virtual models and synthetic cohorts can be integrated into trials. The overarching drivers are clear: improved trial efficiency, ethical gains from fewer placebo exposures, and the ability to leverage digital data fully.

Current evidence includes retrospective feasibility work: the cGvHD analysis assembled published clinical data and proposed potential future standard-of-care comparator use (Li et al., 2024). Regulators recognize the potential and are crafting guidance to harness it responsibly. The FDA and EMA emphasize that any digital twin model must be rigorously validated within a clearly defined use-case (www.appliedclinicaltrialsonline.com) (www.fda.gov). Sponsors must meticulously follow frameworks for AI credibility, ensuring transparency in data and algorithms.

Looking forward, we expect digital twins to move gradually from experimental to standard practice in certain niches – particularly in rare diseases, pediatrics, and other areas where conventional controls are problematic. Nevertheless, full regulatory and clinical adoption will require overcoming the chicken-and-egg problem of validation data: more pilot successes will build confidence, which in turn will enable larger trials with twin controls. By 2030, it may be routine to see hybrid trials combining real and virtual controls.

In conclusion, digital twins have the potential to transform clinical trials architecture. Realizing this potential will demand interdisciplinary collaboration – engineers, biostatisticians, clinicians, and regulators working together. As this review has shown, foundations are in place (guidance principles, methodological advances, early case successes) but careful stewardship is needed. If done properly, digital twin–augmented trials could make drug development faster, cheaper, and more ethical, ultimately benefiting patients by bringing innovative therapies to market sooner.

References

[All cited sources are listed inline. Key references include FDA/EMA guidance documents (www.fda.gov), peer-reviewed studies on digital twins (www.nature.com), and commentary from industry experts (www.appliedclinicaltrialsonline.com) (www.clinicaltrialsarena.com), which collectively inform this analysis.]

Source links

Links cited in this article, in order of first appearance. Full addresses are provided for readers using extracted text.

1. https://www.appliedclinicaltrialsonline.com/view/using-digital-twins-improve-efficiency-accuracy-clinical-research
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