RÉSUMÉ DIGEST

ACT 886 (HB 1223) **2026 Regular Session** **McFarland**

New law creates the La. Clinical Trial Competitiveness and Patient Access Act.

New law provides for the purpose of new law.

New law provides for what new law shall not be construed to do.

New law defines "confidential business information", "contract research organization", "covered clinical project", "department", "designee", "external central institutional review board", "patient-identifying information", "protected health information", "research entity", and "sponsor".

New law allows the Louisiana Economic Development (department) to administer new law and to act through a designee.

New law allows the department to coordinate, verify, aggregate, and market voluntarily provided or verified La. clinical-trial capabilities to sponsors, contract research organizations, federal partners, site-selection teams, and other persons involved in clinical-trial development, site selection, patient access, or economic-development activities in a neutral, nonexclusive, and capability-based manner.

New law provides that certain implementation activities outlined in new law are voluntary and nonexclusive.

New law allows a research entity to voluntarily provide certain information to the department or its designee for statewide clinical-trial marketing.

New law allows the department to enter into confidentiality agreements and other lawful agreements to support implementation of new law.

New law provides that nothing in new law authorizes the department to take certain actions outlined in new law.

New law provides that nothing in new law shall transfer ownership of research programs, clinical operations, faculty governance, medical judgment, licensure standards, credentialing authority, contracting authority, budget authority, institutional review authority, or clinical decision-making authority from a research entity to the department or its designee.

New law provides that a designee with a certain affiliation shall not receive, collect, access, store, transmit, or control certain information from another research entity unless each affected person provides written consent or the information is otherwise lawfully available to the designee.

New law provides relative to coordination in accordance with new law.

New law allows the department to establish by rule or guidance categories, formats, and criteria for voluntarily provided or aggregate speed-to-trial and capability information useful to sponsors, contract research organizations, and site-selection teams. New law provides that rules or guidance may vary.

New law provides for what shall not be a rule or guidance.

New law provides that no research entity shall be required to route certain information through another research entity, the department, or a designee affiliated with a competing healthcare provider or research entity.

New law provides relative to confidential business information.

New law provides that nothing in new law shall prohibit voluntary collaboration, consolidated feasibility responses, hub-and-spoke arrangements, decentralized trial arrangements, teletrial arrangements, shared-investigator participation, specialist-access

planning, community-access partnerships, local follow-up support, or patient-access support, where lawful, clinically appropriate, operationally feasible, and consistent with patient consent, privacy law, institutional credentialing, sponsor requirements, protocol requirements, and clinical judgment.

New law provides that nothing in new law shall require a research entity to accept, open, activate, or enroll a covered clinical project for which the research entity reasonably determines that sufficient patient population, clinical expertise, investigator availability, facility readiness, staffing, data capacity, credentialing, coverage analysis, or operational capability is lacking.

New law requires that certain provisions of new law shall apply regardless of participation in department-coordinated activity.

New law provides that when an external central institutional review board is designated as the institutional review board of record or has approved the covered clinical project, a research entity shall not require separate local institutional review board approval or conduct duplicate local institutional review board ethical review.

New law provides that for certain trials a research entity shall rely on an external central institutional review board as the institutional review board of record where permitted by law and where a federally compliant reliance arrangement is available, unless in certain circumstances.

New law provides that lack of a preexisting master agreement alone shall not make an external central institutional review board unavailable if a lawful study-specific reliance arrangement can be executed.

New law provides that if an external central institutional review board has been designated as the institutional review board of record, a request pursuant to new law is effective only in certain circumstances. New law further requires that if an external central institutional review board has approved the covered clinical project, local institutional review board ethical review shall not occur.

New law provides that for a Phase II clinical trial or Phase III clinical trial, a research entity shall rely on an external central institutional review board as the institutional review board of record where permitted by law and where a federally compliant reliance arrangement is available, unless either of the following applies:

(1) The sponsor or its authorized representative requests in writing that the research entity's institutional review board serve as the institutional review board of record.

(2) The chancellor, chief executive officer, or highest-ranking executive officer of the research entity or institutional operating unit with formal legal or operational responsibility for the covered clinical project approves and signs a written project-specific exception based on certain criteria.

New law provides that new law shall not apply to certain clinical trials, clinical investigations, or studies.

New law provides that for a covered clinical project not described in new law and designated by rule, pilot, cooperative endeavor agreement, or written agreement of the affected parties, external central institutional review board reliance standards may be established by rule, pilot, cooperative endeavor agreement, or written agreement of the affected parties.

New law prohibits the delegation of approval required pursuant to new law.

New law requires a written exception pursuant to new law to state the basis for the exception with reasonable specificity, to be limited to the covered clinical project, and not to establish a standing institutional exception. New law further provides for the transmission of the written exception.

New law provides for what exemptions shall not be solely based on.

New law provides that a research entity that relies on its own institutional review board pursuant to new law shall maintain documentation supporting such reliance and report aggregate, non-identifiable information to the department on a schedule established by rule or guidance. New law further provides what the report shall not include.

New law provides for what new law shall not inhibit.

New law provides that local institutional review shall not be used to duplicate institutional review board ethical review or delay a covered clinical project based solely on certain circumstances.

New law provides that nothing in new law shall require a research entity to waive or disregard legal requirements, safety obligations, federal research requirements, federal award conditions, accreditation standards, cancer-center designation requirements, reliance agreement responsibilities, or documented institutional responsibilities.

New law allows the department to require only aggregate, non-identifiable information reasonably necessary to evaluate implementation of new law and to publish aggregate reports, implementation summaries, speed-to-trial information, capability information, and recommendations.

New law provides relative to public reporting.

New law provides that nothing in new law shall be construed to do any of the following:

(1) Create a state warranty of site performance, patient outcome, sponsor selection, site selection, enrollment success, clinical outcome, federal designation, regulatory approval, investment outcome, or commercial success.

(2) Create a private cause of action based solely on implementation of new law.

(3) Require disclosure of information prohibited from disclosure by federal or state law or by enforceable contractual obligation.

(4) Require or authorize the department or its designee to receive, store, transmit, access, control, collect, maintain, audit, or validate certain identifiable data or information except as authorized by federal and state law, contract, protocol, consent, and applicable federal requirements.

(5) Create immunity from certain laws.

(6) Require or authorize certain allocation and coordination among competitors.

New law allows the department to adopt rules and issue guidance and other materials to implement the provisions of new law.

New law provides for what rules or guidance may be established.

New law requires the department to consult with certain entities.

New law provides relative to the appropriation of funds.

New law allows the department to establish voluntary programs or other agreements to support new law.

New law provides that the requirements of new law shall apply prospectively to covered clinical projects for which the initial sponsor, contract research organization, site-selection, or feasibility submission is received on or after the effective date of new law. Requirements established by rule, guidance, capability tool, criterion, or other implementation material apply prospectively only after the effective date of that rule, guidance, tool, criterion, or material.

Effective upon signature of governor (June 9, 2026).

(Adds R.S. 51:3301-3306)