

ACT No. 886

2026 Regular Session

HOUSE BILL NO. 1223

BY REPRESENTATIVE MCFARLAND

1 AN ACT

2 To enact Chapter 70 of Title 51 of the Louisiana Revised Statutes of 1950, to be comprised
3 of R.S. 51:3301 through 3306, relative to creating the Louisiana Clinical Trial
4 Competitiveness and Patient Access Act; to provide for purpose; to provide for
5 definitions; to provide for responsibilities of Louisiana Economic Development; to
6 provide for the participation of certain entities; to provide for the sharing of
7 information; to provide relative to external institutional review boards; to provide for
8 reporting; to provide for rulemaking authority; to provide for funding; and to provide
9 for related matters.

10 Be it enacted by the Legislature of Louisiana:

11 Section 1. Chapter 70 of Title 51 of the Louisiana Revised Statutes of 1950,
12 comprised of R.S. 51:3301 through 3306, is hereby enacted to read as follows:

13 CHAPTER 70. LOUISIANA CLINICAL TRIAL COMPETITIVENESS AND
14 PATIENT ACCESS ACT

15 §3301. Purpose

16 A. The purpose of this Chapter is to make Louisiana more competitive for
17 clinical trials by supporting sponsor-facing readiness, speed-to-trial information,
18 external central institutional review board reliance, avoidance of unnecessary
19 duplicate institutional review board ethical review, patient access, role-based
20 collaboration, and statewide visibility of confirmed clinical-trial capabilities, while
21 preserving patient choice, institutional clinical authority, lawful local review, direct
22 sponsor relationships, confidential business information, and protected health
23 information.

1 B. Nothing in this Chapter shall be construed to designate any research
2 entity, healthcare system, academic medical center, cancer program, clinical partner,
3 affiliate, or other person as the exclusive or preferred statewide provider, gateway,
4 broker, coordinator, sponsor-facing representative, or patient-referral destination for
5 covered clinical projects.

6 C. Nothing in this Chapter shall be construed to designate, deny, confer,
7 limit, or impair any research entity's status, role, application, partnership, eligibility,
8 or recognition with respect to National Cancer Institute designation, National Cancer
9 Institute-supported networks, federal grant requirements, accreditation standards,
10 cancer-center designation standards, or other federal or private designation programs.

11 D. Nothing in this Chapter shall require or authorize any action prohibited
12 by applicable federal law, federal regulation, or a binding federal award condition.

13 §3302. Definitions

14 For purposes of this Chapter, the following terms have the following
15 meanings:

16 (1) "Confidential business information" means nonpublic trade secret,
17 proprietary, competitively sensitive, commercially sensitive, sponsor-specific,
18 contract-research-organization-specific, research-entity-specific,
19 investigator-specific, or project-specific information, including trial pipelines,
20 feasibility, recruitment, referral strategy, contracts, budgets, rates, pricing, nonpublic
21 protocols, intellectual property, commercialization strategy, site-selection strategy,
22 sponsor strategy, or market strategy.

23 (2) "Contract research organization" means an organization that provides
24 clinical research services to a sponsor or trial manager.

25 (3)(a) "Covered clinical project" means an industry-sponsored interventional
26 clinical trial, or a federally supported interventional clinical trial designated by rule
27 or voluntary written election by the research entity, involving a drug, biologic,
28 medical device, radiopharmaceutical, diagnostic, combination product, or other
29 product regulated by the United States Food and Drug Administration and conducted
30 or proposed to be conducted at a site located in this state. A Phase IV clinical trial

1 is included only if interventional and designated by rule or voluntary written election
2 by the research entity.

3 (b) The term does not include a purely observational study, retrospective
4 chart review, registry-only study, quality-improvement activity, or expanded-access
5 treatment outside a clinical trial unless voluntarily included by the research entity or
6 designated by rule for a limited implementation purpose.

7 (4) "Department" means Louisiana Economic Development.

8 (5) "Designee" means a public or private entity, organizational unit,
9 contractor, or other person lawfully designated by the department to assist with
10 administrative, technical, market-facing, or implementation functions pursuant to this
11 Chapter. A designee shall be subject to the limitations, confidentiality restrictions,
12 patient-data restrictions, no-gatekeeper provisions, no-forced-routing provisions,
13 no-steering provisions, and antitrust-related limitations of this Chapter.

14 (6) "External central institutional review board" means an institutional
15 review board that serves as the single institutional review board or institutional
16 review board of record for a covered clinical project pursuant to a federally
17 compliant reliance arrangement; is registered in accordance with applicable federal
18 requirements; is not subject to an active federal restriction, suspension,
19 disqualification, or enforcement action that prohibits or materially limits review of
20 the covered clinical project; and is not the local institutional review board of the
21 research entity conducting the covered clinical project.

22 (7) "Patient-identifying information" means information that identifies or can
23 reasonably be used to identify a patient, research participant, or potential research
24 participant, including health, biological specimen, genomic, imaging, referral,
25 eligibility, or clinical information associated with that person.

26 (8) "Protected health information" has the same meaning as provided in 45
27 CFR 160.103.

28 (9)(a) "Research entity" means a hospital, academic institution, institutional
29 healthcare provider, healthcare system, private clinical research site, research
30 organization, cancer research program, academic medical center platform,

1 community oncology program, pediatric research program, translational research
 2 program, or other institutional entity serving as a trial site or otherwise exercising
 3 institutional responsibility for a covered clinical project at a site located in this state.

4 (b) The term does not include an individual healthcare provider acting solely
 5 in an individual professional capacity and not on behalf of an institutional trial site.

6 (10) "Sponsor" means a pharmaceutical company, biotechnology developer,
 7 medical device manufacturer, diagnostic developer, radiopharmaceutical developer,
 8 academic sponsor, federal sponsor, foundation sponsor, or other entity advancing an
 9 investigational product.

10 §3303. Department role; voluntary participation; limitations

11 A. The department may administer this Chapter and may act through a
 12 designee.

13 B. The department may coordinate, verify, aggregate, and market voluntarily
 14 provided or verified Louisiana clinical-trial capabilities to sponsors, contract
 15 research organizations, federal partners, site-selection teams, and other persons
 16 involved in clinical-trial development, site selection, patient access, or
 17 economic-development activities in a neutral, nonexclusive, and capability-based
 18 manner.

19 C. Department-coordinated marketing, capability-presentation,
 20 sponsor-facing, site-identification, pilot, cooperative endeavor agreement, or other
 21 implementation activity is voluntary and nonexclusive. No research entity, sponsor,
 22 contract research organization, patient, or referring provider shall be required to use
 23 or route communications through the department or its designee, or participate in
 24 such activity, as a condition of conducting, considering, referring to, contracting for,
 25 or participating in a covered clinical project.

26 D. A research entity may voluntarily provide capability, contact,
 27 site-readiness, speed-to-trial, or role-based collaboration information to the
 28 department or its designee for statewide clinical-trial marketing.

29 E. The department may enter into confidentiality agreements and other
 30 lawful agreements to support implementation of this Chapter, to the extent permitted

1 by law. Nothing in this Chapter shall require a research entity, sponsor, or contract
2 research organization to provide the department or its designee with
3 patient-identifying information, protected health information, confidential business
4 information, feasibility information, trial-pipeline information, patient or referral
5 information, contract or budget terms, recruitment strategy, market strategy, or other
6 competitively sensitive information except pursuant to law or voluntary written
7 agreement.

8 F. Nothing in this Chapter shall authorize the department or its designee to
9 approve or disapprove a protocol, contract, budget, local operational determination,
10 site activation decision, patient referral, sponsor selection, contract research
11 organization selection, site-selection decision, clinical judgment, credentialing
12 decision, licensure determination, coverage determination, or federal research
13 determination.

14 G. Nothing in this Chapter shall transfer ownership of research programs,
15 clinical operations, faculty governance, medical judgment, licensure standards,
16 credentialing authority, contracting authority, budget authority, institutional review
17 authority, or clinical decision-making authority from a research entity to the
18 department or its designee.

19 H. A designee affiliated with a research entity, healthcare provider,
20 healthcare system, academic medical center, clinical partner, affiliate, or other
21 person that competes with a research entity shall not receive, collect, access, store,
22 transmit, or control another research entity's confidential business information,
23 patient-identifying information, protected health information, feasibility information,
24 trial-pipeline information, patient or referral information, contract or budget
25 information, recruitment strategy, market strategy, or other competitively sensitive
26 information unless each affected person provides written consent or the information
27 is otherwise lawfully available to the designee.

28 I. Coordination in accordance with this Chapter shall be nonexclusive and
29 shall not require or authorize allocation of markets, patients, sponsors, trials,
30 investigators, service lines, territories, prices, reimbursement, contract terms, budget

1 terms, referral sources, or commercial opportunities among research entities or other
2 persons.

3 §3304. Speed-to-trial and capability information

4 A. The department may establish by rule or guidance categories, formats,
5 and criteria for voluntarily provided or aggregate speed-to-trial and capability
6 information useful to sponsors, contract research organizations, and site-selection
7 teams.

8 B. Rules or guidance issued pursuant to this Section may vary by project
9 type, trial phase, therapeutic area, trial complexity, research entity type, site
10 capability, institutional infrastructure, sponsor or contract research organization
11 submission completeness, or voluntary participation in department-coordinated
12 activity.

13 C. No rule or guidance issued pursuant to this Section shall require final
14 contract execution, final budget agreement, study acceptance, site activation,
15 enrollment commitment, use of the department or its designee, or disclosure of
16 information protected by law or contract.

17 D. No research entity shall be required to route sponsor or contract research
18 organization communications, feasibility information, patient or referral information,
19 contract or budget terms, recruitment strategy, trial-pipeline information,
20 patient-access strategy, referral strategy, or other confidential business information
21 through another research entity, the department, or a designee affiliated with a
22 competing healthcare provider or research entity.

23 E. Nothing in this Chapter shall authorize the department, its designee, or
24 any research entity to require a sponsor, contract research organization, patient, or
25 referring provider to use a particular research entity, healthcare system, cancer
26 program, clinical partner, affiliate, or designee, or to route communications,
27 referrals, or confidential business information through a competing research entity,
28 except with the written consent of the affected parties and as otherwise authorized
29 by law.

1 F. Nothing in this Chapter shall prohibit voluntary collaboration,
2 consolidated feasibility responses, hub-and-spoke arrangements, decentralized trial
3 arrangements, teletrial arrangements, shared-investigator participation,
4 specialist-access planning, community-access partnerships, local follow-up support,
5 or patient-access support, where lawful, clinically appropriate, operationally feasible,
6 and consistent with patient consent, privacy law, institutional credentialing, sponsor
7 requirements, protocol requirements, and clinical judgment.

8 G. Nothing in this Chapter shall require a research entity to accept, open,
9 activate, or enroll a covered clinical project for which the research entity reasonably
10 determines that sufficient patient population, clinical expertise, investigator
11 availability, facility readiness, staffing, data capacity, credentialing, coverage
12 analysis, or operational capability is lacking.

13 §3305. External central institutional review board; local review

14 A. The requirements of this Section apply regardless of participation in
15 department-coordinated activity.

16 B. When an external central institutional review board is designated as the
17 institutional review board of record or has approved the covered clinical project, a
18 research entity shall not require separate local institutional review board approval or
19 conduct duplicate local institutional review board ethical review. Nothing in this
20 Subsection shall limit lawful local review preserved by this Section.

21 C. For a first-in-human clinical trial, Phase I clinical trial, early-feasibility
22 device trial, or dose-escalation trial, a research entity shall rely on an external central
23 institutional review board as the institutional review board of record where permitted
24 by law and where a federally compliant reliance arrangement is available, unless
25 external central institutional review board reliance is prohibited by federal law, state
26 law, or binding federal award condition, or the sponsor or its authorized
27 representative states in writing that the research entity's institutional review board
28 serve as the institutional review board of record.

1 D. A lack of a preexisting master agreement alone shall not make an external
2 central institutional review board unavailable if a lawful study-specific reliance
3 arrangement can be executed.

4 E. If an external central institutional review board has been designated as the
5 institutional review board of record, a request pursuant to Subsection C of this
6 Section or Paragraph (F)(1) of this Section is effective only if the sponsor or its
7 authorized representative withdraws that designation or confirms in writing that the
8 external central institutional review board is unavailable. If an external central
9 institutional review board has approved the covered clinical project, local
10 institutional review board ethical review shall not occur.

11 F. For a Phase II clinical trial or Phase III clinical trial, a research entity shall
12 rely on an external central institutional review board as the institutional review board
13 of record where permitted by law and where a federally compliant reliance
14 arrangement is available, unless either of the following applies:

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

18 (2) The chancellor, chief executive officer, or highest-ranking executive
19 officer of the research entity or institutional operating unit with formal legal or
20 operational responsibility for the covered clinical project approves and signs a
21 written project-specific exception based on one or more of the following:

22 (a) External central institutional review board reliance is prohibited by
23 federal law, state law, or binding federal award condition.

24 (b) Extraordinary project-specific circumstances involving project
25 feasibility, participant rights, safety, or welfare require review by the research
26 entity's own institutional review board for that covered clinical project.

27 (c) A specific federal or state legal requirement requires review by the
28 research entity's own institutional review board for that covered clinical project.

29 G.(1) Notwithstanding any provision of this Chapter to the contrary, this
30 Section shall not apply to any clinical trial, clinical investigation, or study that is a

1 Phase IV clinical trial, a Phase 4 clinical trial, or otherwise postmarketing,
2 post-approval, post-authorization, post-clearance, or post-classification, if the trial,
3 investigation, or study is conducted after approval, licensure, clearance,
4 authorization, or classification by the United States Food and Drug Administration
5 of the product for the indication or use being studied, regardless of whether the trial,
6 investigation, or study is interventional, observational, required, requested, agreed
7 to, or voluntary. No rule, guidance, pilot, cooperative endeavor agreement, written
8 agreement, or other implementation material pursuant to this Chapter shall make
9 such a trial, investigation, or study subject to this Section. Nothing in this Paragraph
10 shall prohibit the voluntary use of an external central institutional review board when
11 otherwise lawful.

12 (2) For a covered clinical project not described in Paragraph (1) of this
13 Subsection and designated by rule, pilot, cooperative endeavor agreement, or written
14 agreement of the affected parties, external central institutional review board reliance
15 standards may be established by rule, pilot, cooperative endeavor agreement, or
16 written agreement of the affected parties.

17 H. No approval required pursuant to Paragraph (F)(2) of this Section may be
18 delegated. The approving official shall be the chancellor, chief executive officer, or
19 highest-ranking executive officer of the research entity or institutional operating unit
20 with formal legal or operational responsibility for the covered clinical project. The
21 approving official shall not be the institutional review board chair, head of the local
22 institutional review board, direct supervisor of the head of the local institutional
23 review board, principal investigator, department chair, compliance officer, legal
24 counsel, or other person primarily responsible for institutional review board
25 administration or review, unless that person is also the highest-ranking executive
26 officer of the research entity or institutional operating unit with formal legal or
27 operational responsibility for the covered clinical project.

28 I. A written exception pursuant to Paragraph (F)(2) of this Section shall state
29 the basis for the exception with reasonable specificity, shall be limited to the covered
30 clinical project, and shall not establish a standing institutional exception. The

1 research entity shall transmit the written exception, or a summary sufficient to
2 identify the statutory basis for the exception, to the sponsor, contract research
3 organization if applicable, and the department or its designee in a form that does not
4 disclose patient-identifying information, protected health information, or confidential
5 business information.

6 J. An exception pursuant to Paragraph (F)(2) of this Section shall not be
7 based solely on institutional policy or preference, administrative convenience,
8 staffing limitation, customary practice, generalized concern regarding external
9 institutional review board review, preference for duplicate ethical review,
10 disagreement with the use of external institutional review boards generally, or desire
11 to control sponsor, referral, patient-access, or contracting relationships.

12 K. A research entity that relies on its own institutional review board pursuant
13 to this Section shall maintain documentation supporting such reliance and report
14 aggregate, non-identifiable information to the department on a schedule established
15 by rule or guidance, but not more frequently than semiannually. The report shall not
16 include patient-identifying information, protected health information, confidential
17 business information, sponsor-specific nonpublic information,
18 contract-research-organization-specific nonpublic information,
19 research-entity-specific nonpublic information, investigator-specific nonpublic
20 information, or project-specific nonpublic information. The department may set the
21 form and schedule for reports in accordance with this Subsection, but shall not
22 expand, narrow, waive, or modify the institutional review board requirements,
23 exceptions, prohibitions, or local-review protections established in this Section.

24 L. Nothing in this Chapter shall prohibit lawful local institutional review
25 relating to contracts, budgets, coverage analysis, investigator qualifications, conflicts
26 of interest, privacy, HIPAA, billing compliance, credentialing, pharmacy,
27 investigational-drug logistics, device logistics, radiation safety, radiopharmaceutical
28 handling, biosafety, cellular therapy readiness, BMT readiness, CAR-T readiness,
29 gene-therapy readiness, pediatric safeguards, facility readiness, site feasibility,
30 ancillary safety committees, local consent-language requirements, data security,

1 scientific review, disease-group review, Protocol Review and Monitoring System
2 review, Protocol Review and Monitoring Committee review, data and safety
3 monitoring, clinical protocol and data management, local context submissions, or
4 equivalent review required by law, applicable federal award conditions, accreditation
5 standards, cancer-center designation standards, reliance agreements, or written
6 objective institutional requirements directly related to local operational readiness,
7 participant safety, or institutional compliance.

8 M. Local institutional review preserved by this Section shall not be used to
9 duplicate institutional review board ethical review or delay a covered clinical project
10 based solely on institutional preference, generalized practice, administrative
11 convenience, staffing limitation, customary internal sequencing, or disagreement
12 with external central institutional review board reliance generally.

13 N. Nothing in this Chapter shall require a research entity to waive or
14 disregard legal requirements, safety obligations, federal research requirements,
15 federal award conditions, accreditation standards, cancer-center designation
16 requirements, reliance agreement responsibilities, or documented institutional
17 responsibilities.

18 §3306. Reporting; rulemaking; funds

19 A. The department may require only aggregate, non-identifiable information
20 reasonably necessary to evaluate implementation of this Chapter and may publish
21 aggregate reports, implementation summaries, speed-to-trial information, capability
22 information, and recommendations. Information required pursuant to this Subsection
23 shall not include patient-identifying information, protected health information,
24 confidential business information, sponsor-specific nonpublic information,
25 contract-research-organization-specific nonpublic information,
26 research-entity-specific nonpublic information, investigator-specific nonpublic
27 information, or project-specific nonpublic information unless provided pursuant to
28 law or voluntary written agreement.

29 B. Public reporting in accordance with this Chapter shall be aggregated and
30 shall not include patient-identifying information, protected health information,

1 confidential business information, sponsor-specific nonpublic information,
2 contract-research-organization-specific nonpublic information,
3 research-entity-specific nonpublic information, investigator-specific nonpublic
4 information, or project-specific nonpublic information.

5 C. Nothing in this Chapter shall be construed to do any of the following:

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

9 (2) Create a private cause of action based solely on implementation of this
10 Chapter.

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

13 (4) Require or authorize the department or its designee to receive, store,
14 transmit, access, control, collect, maintain, audit, or validate identifiable patient-level
15 data, source data, endpoint data, adverse-event data, protected health information,
16 or patient-identifying information except as authorized by federal and state law,
17 contract, protocol, consent, and applicable federal requirements.

18 (5) Create immunity from federal or state antitrust law, unfair trade practice
19 law, fraud law, abuse law, conflict-of-interest law, procurement law, or ethics law.

20 (6) Require or authorize market allocation, patient allocation, sponsor
21 allocation, trial allocation, referral-source allocation, price coordination,
22 contract-term coordination, budget-term coordination, or service-line allocation
23 among competitors.

24 D. The department may adopt rules in accordance with the Administrative
25 Procedure Act to implement this Chapter and may issue guidance, templates,
26 reporting formats, capability tools, confidentiality procedures, conflict-of-interest
27 procedures, model provisions, and other nonregulatory implementation materials, but
28 only for the department's economic-development, speed-to-trial,
29 capability-presentation, marketing, aggregate-reporting, consultation,
30 voluntary-program, funding, and implementation functions pursuant to this Chapter.

1 E. Rules or guidance may establish categories of covered clinical projects,
2 standards for voluntarily provided or aggregate speed-to-trial and capability
3 information, capability criteria, aggregate reporting formats, external central
4 institutional review board reliance procedures, exception procedures, confidentiality
5 procedures, role-based collaboration categories, hub-and-spoke models, teletrial
6 models, decentralized trial models, patient-access criteria, voluntary program
7 criteria, and phased implementation by project type, institution type, therapeutic
8 area, trial phase, site, or pilot cohort. Rules or guidance shall not authorize the
9 department or its designee to regulate clinical judgment, protocol content, site
10 activation decisions, contracting decisions, patient referrals, sponsor selection,
11 substantive institutional review board determinations, or local operational
12 determinations.

13 F. The department shall consult with research entities subject to this Chapter,
14 sponsors, contract research organizations, the Louisiana Department of Health,
15 patient-access stakeholders, privacy experts, clinical-trial operations experts, and
16 persons with relevant clinical, research, operational, contracting, regulatory,
17 academic medical center development, biomedical innovation, or
18 economic-development expertise.

19 G. Nothing in this Chapter shall be construed to require a specific
20 appropriation of funds or the creation of new positions. Subject to appropriation and
21 availability of funds, the department may seek, accept, and expend federal funds,
22 grants, gifts, donations, philanthropic contributions, private contributions,
23 cooperative endeavor funds, matching funds, and other lawful funds made available
24 for purposes of this Chapter.

25 H. Subject to appropriation, available funds, and applicable law, the
26 department may establish voluntary programs or enter into case-by-case cooperative
27 endeavor agreements or other written agreements to support this Chapter. Before
28 providing funds or other things of value, the department shall determine in writing
29 that the program or agreement serves a public purpose and reasonably advances
30 patient access, clinical-trial competitiveness, speed-to-trial, statewide capability

1 development, rural or underserved access, academic medical center development,
 2 research investment, or another purpose of this Chapter. No program or agreement
 3 shall confer market exclusivity, require use of or routing through the department or
 4 its designee, require disclosure of information protected by law or contract, or
 5 require surrender of the right to conduct, consider, refer to, contract for, or
 6 participate in a covered clinical project independently.

7 Section 2. The requirements of this Act shall apply prospectively to covered clinical
 8 projects for which the initial sponsor, contract research organization, site-selection, or
 9 feasibility submission is received on or after the effective date of this Act. Requirements
 10 established by rule, guidance, capability tool, criterion, or other implementation material
 11 apply prospectively only after the effective date of that rule, guidance, tool, criterion, or
 12 material.

13 Section 3. This Act shall become effective upon signature by the governor or, if not
 14 signed by the governor, upon expiration of the time for bills to become law without signature
 15 by the governor, as provided by Article III, Section 18 of the Constitution of Louisiana. If
 16 vetoed by the governor and subsequently approved by the legislature, this Act shall become
 17 effective on the day following such approval.

SPEAKER OF THE HOUSE OF REPRESENTATIVES

PRESIDENT OF THE SENATE

GOVERNOR OF THE STATE OF LOUISIANA

APPROVED: _____