

2026 Regular Session

HOUSE BILL NO. 1223

BY REPRESENTATIVE MCFARLAND

ECONOMIC DEVELOPMENT: Establishes the La. Early-Phase Clinical Trial Acceleration Framework

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 3310, relative to creating the Louisiana Early-Phase Clinical
4 Trial Acceleration Framework; to provide for findings and purpose; to provide for
5 definitions; to provide for responsibilities of Louisiana Economic Development; to
6 provide for participation in the framework; to provide for performance benchmarks;
7 to provide for reporting; to provide for confidentiality; to provide for rulemaking;
8 and to provide for related matters.

9 Be it enacted by the Legislature of Louisiana:

10 Section 1. Chapter 70 of Title 51 of the Louisiana Revised Statutes of 1950,
11 comprised of R.S. 51:3301 through 3310, is hereby enacted to read as follows:

12 CHAPTER 70. LOUISIANA EARLY-PHASE CLINICAL TRIAL ACCELERATION

13 FRAMEWORK

14 §3301. Legislative findings and purpose

15 The legislature hereby finds and declares all of the following:

16 (1) Biomedical innovation and clinical research are important drivers of
17 patient access to investigational therapies, improvements in public health, private
18 investment, and economic growth.

19 (2) Early-phase and first-in-human clinical trials are among the most
20 specialized and capability-intensive forms of clinical research and frequently

1 influence where long-term sponsor relationships, downstream clinical development
2 activity, and related private investment are placed.

3 (3) Louisiana's competitiveness in biomedical innovation depends not only
4 on the quality of its physicians, hospitals, and research institutions but also on
5 whether the state is responsive, coordinated, and easy for sponsors and contract
6 research organizations to navigate.

7 (4) Louisiana patients with serious or life-threatening conditions should have
8 improved opportunities to access investigational therapies and related clinical
9 research without unnecessary delay or avoidable travel burdens.

10 (5) It is therefore the purpose of this Chapter to establish a statewide
11 framework to improve the speed, predictability, and coordination of early-phase
12 clinical trials in Louisiana in order to enhance patient access, attract private
13 investment, and strengthen the state's clinical research ecosystem, all within existing
14 resources.

15 §3302. Definitions

16 For the purposes of this Chapter, the following terms have the following
17 meanings:

18 (1) "Benchmark category" means a project category established by the
19 department or its designee by rule or guidance for purposes of participation
20 expectations, pilot implementation, process standards, and public reporting for
21 admitted covered clinical projects, including categories reflecting trial phase,
22 therapeutic complexity, participant risk profile, and operational intensity.

23 (2) "Complete submission" means a submission containing the materials
24 required by the standardized checklist adopted by the department or its designee for
25 a covered clinical project, together with any research-entity-specific addendum
26 previously posted or incorporated by reference in a participation agreement.

27 (3) "Contract research organization" means an organization that provides
28 clinical research services to a sponsor or trial manager, including site identification,

1 feasibility assessment, project management, monitoring, regulatory support, data
2 management, or related services associated with the conduct of a clinical trial.

3 (4) "Covered clinical project" means an industry-sponsored, interventional
4 clinical trial involving a drug, biologic, or medical device regulated by the United
5 States Food and Drug Administration and conducted at a site located in this state,
6 including early-phase, first-in-human, dose-escalation, proof-of-concept,
7 precision-medicine, rare-disease, cell-therapy, gene-therapy, biologic, or
8 medical-device clinical investigations.

9 (5) "Department" means Louisiana Economic Development.

10 (6) "External institutional review board" means an institutional review board
11 registered with the appropriate federal authorities and operating in compliance with
12 applicable federal regulations governing human subjects research.

13 (7) "Participation agreement" means an agreement entered into pursuant to
14 this Chapter establishing expectations for coordination, benchmark performance,
15 reporting, and compliance with applicable provisions of this Chapter.

16 (8) "Patient-access support" means navigation, scheduling assistance, referral
17 coordination, eligibility pre-screening coordination, travel-support coordination,
18 remote follow-up coordination where permitted, language-access coordination, and
19 other lawful activities designed to reduce avoidable barriers to participation in a
20 covered clinical project.

21 (9) "Research entity" means a healthcare provider, hospital, academic
22 institution, research organization, or other entity that is mandated to participate in the
23 framework established by this Chapter.

24 (10) "Sponsor" means a pharmaceutical company, biotechnology developer,
25 venture-backed therapeutic developer, medical device manufacturer, academic
26 sponsor, or other entity advancing an investigational product, including a contract
27 research organization acting on behalf of such entity.

28 §3303. State coordination within existing resources

1 A. The department shall administer a clinical trial acceleration coordination
2 function within existing resources.

3 B. The department may designate existing personnel or organizational units
4 to carry out responsibilities pursuant to this Chapter.

5 C. The department may enter into cooperative endeavor agreements,
6 memoranda of understanding, or other lawful agreements with public or private
7 entities to support implementation of this Chapter, provided that nothing in this
8 Chapter shall be construed to require the creation of new positions or the expenditure
9 of state funds unless separately appropriated.

10 D. The department may coordinate with state agencies, public and private
11 postsecondary institutions, healthcare providers, research organizations, sponsors,
12 contract research organizations, and site-selection teams to support the
13 implementation of this Chapter.

14 E. Nothing in this Chapter shall be construed to transfer ownership of
15 research programs, clinical operations, faculty governance, medical judgment,
16 licensure standards, or hospital credentialing authority from any research entity to
17 the department or its designee.

18 §3304. Participation and participation agreements

19 A. Participation in the framework established by this Chapter shall be
20 mandatory for all entities implementing a covered clinical project located in this
21 state.

22 B. A research entity shall enter into a participation agreement with the
23 department or its designee.

24 C. A participation agreement shall establish expectations for all of the
25 following:

26 (1) Benchmark categories or project types for research entities.

27 (2) Primary contacts for intake, contracts, budgets, institutional review board
28 reliance, ancillary reviews, and escalation.

1 (3) Institution-specific addenda, if any, that supplement the standardized
2 checklist.

3 (4) Local review categories that remain applicable when an external
4 institutional review board is used.

5 (5) Provision of information reasonably necessary to support performance
6 evaluation and fair distinction between institution-controlled time and
7 sponsor-controlled time.

8 (6) Escalation contacts and internal accountability procedures applicable
9 when a covered clinical project becomes stalled or repeatedly misses benchmark
10 expectations.

11 (7) Any category-specific limitations, capacity constraints, or participation
12 conditions the research entity elects to disclose.

13 §3305. Process acceleration and coordination

14 A. The department or its designee shall publish standardized completeness
15 checklists and intake procedures for covered clinical projects within benchmark
16 categories.

17 B. The department or its designee may publish model clinical trial agreement
18 provisions, budget assumptions, and bounded redline guidance for benchmark
19 categories, recognizing that deviations may be necessary because of applicable law,
20 patient-safety requirements, payer or billing requirements, insurance requirements,
21 sponsor-specific regulatory obligations, or other circumstances designated by rule
22 or participation agreement.

23 C. The department or its designee may coordinate directly with sponsors,
24 contract research organizations, and site-selection teams regarding feasibility, site
25 identification, benchmark implementation, and covered clinical project issue
26 resolution.

27 D. The department or its designee may maintain a sponsor-facing,
28 contract-research-organization-facing, and site-selection-team-facing coordination
29 function with authority to coordinate across research entities for covered clinical

1 projects, obtain feasibility and routing responses, elevate stalled matters for
2 executive review, and present this state's verified capabilities in a uniform
3 market-facing manner, all within existing resources.

4 E. The department or its designee may coordinate feasibility responses
5 among research entities and may provide sponsors, contract research organizations,
6 or site-selection teams with a consolidated statewide feasibility response based on
7 information provided or confirmed by research entities.

8 F. The department or its designee may maintain, subject to applicable
9 confidentiality protections and participation agreements, a registry of research
10 investigators, sites, benchmark categories, and verified operational capabilities for
11 use in sponsor, contract research organization, and site-selection coordination. Any
12 verified capabilities presented pursuant to this Subsection shall be based on criteria
13 established by the department or its designee, including demonstrated operational
14 capacity, staffing, and prior experience appropriate to the applicable benchmark
15 category.

16 G. The department or its designee may facilitate lawful referral, navigation,
17 and patient-access support activities in coordination with research entities and
18 community providers.

19 §3306. Activation standards for covered clinical projects

20 A. For each covered clinical project, a research entity shall do all of the
21 following, unless modified by rule or guidance for a specified benchmark category:

22 (1) Acknowledgment of receipt of a sponsor, contract research organization,
23 or site-selection feasibility inquiry within two business days, provided that
24 acknowledgment of receipt shall not constitute acceptance of feasibility or
25 commitment to participate in the study.

26 (2) Completeness confirmation or a single consolidated deficiency notice not
27 later than five business days after receipt of a submission. A submission shall be
28 deemed complete on the sixth business day if no such notice is issued.

1 (3) No serial deficiency notices for items that were reasonably available to
2 be identified in the initial completeness review, except for sponsor-requested
3 changes, newly arising issues, or categories designated by rule or guidance.

4 (4) A sponsor feasibility response or engagement determination within ten
5 business days after receipt of all materials reasonably required for such
6 determination, unless a different benchmark is designated by rule or guidance for a
7 specified benchmark category.

8 (5) Concurrent review, to the maximum extent permitted by applicable law
9 and documented institutional requirements, of contracts, budgets, coverage analysis,
10 ancillary reviews, pharmacy review, operational readiness, and other nonduplicative
11 startup functions that need not await completion of another function.

12 (6) An initial contract response within ten business days after receipt of a
13 sponsor draft or applicable model agreement, unless a different benchmark is
14 designated by rule or guidance for a specified benchmark category.

15 (7) An initial budget response within ten business days after receipt of the
16 sponsor budget or budget template, unless a different benchmark is designated by
17 rule or guidance for a specified benchmark category.

18 (8) Escalation to designated research-entity and department personnel upon
19 failure to meet a benchmark, in accordance with the participation agreement, which
20 may include executive-level review. Escalation may be initiated by the department
21 or its designee, the sponsor, or the contract research organization.

22 B.(1) For a covered clinical project for which reliance on an external
23 institutional review board is permitted by applicable federal law, a research entity
24 shall rely on an external institutional review board unless the research entity
25 documents in writing one of the following:

26 (a) A specific federal or state legal requirement requires local review.

27 (b) A project-specific participant safety consideration requires nonreliance.

28 (2) Nonreliance shall not be based solely on institutional policy, preference,
29 or generalized practice.

1 C. Any written determination of nonreliance pursuant to Subsection B of this
2 Section shall be issued within ten business days after receipt of a complete
3 submission and shall state with reasonable specificity the local responsibility,
4 participant-safety consideration, or lawful project-specific condition supporting the
5 determination.

6 D. Nothing in this Chapter shall be construed to eliminate lawful local
7 review relating to investigator qualifications, conflict of interest, privacy, HIPAA,
8 billing compliance, site feasibility, ancillary safety committees, credentialing, or
9 other institutional responsibilities that do not duplicate ethical review of the protocol.

10 E. Nothing in this Chapter shall be construed to require a research entity to
11 waive or disregard legal requirements, safety obligations, or documented institutional
12 responsibilities in order to satisfy a benchmark established in accordance with this
13 Chapter.

14 §3307. Performance benchmarks and reporting

15 A. The framework outlined in this Chapter shall include benchmark
16 categories related to clinical trial startup and execution for admitted covered clinical
17 projects.

18 B. Participation agreements shall incorporate expectations aligned with
19 benchmark categories and may provide for pilot implementation by benchmark
20 category.

21 C. Benchmark categories may include but are not limited to the following:

22 (1) Acknowledgment of feasibility inquiry.

23 (2) Time to completeness confirmation.

24 (3) Time to sponsor feasibility response.

25 (4) Time to external institutional review board reliance determination.

26 (5) Contract and budget execution timelines.

27 (6) Time to site activation.

28 (7) Time to first patient enrollment.

1 D. Research entities shall provide information reasonably necessary to
2 support evaluation of performance pursuant to this Chapter.

3 E. The department or its designee shall compile aggregated, non-identifiable
4 information regarding performance benchmark categories and may publish such
5 aggregated information.

6 F. Reporting shall be implemented in a manner that avoids unnecessary
7 duplication and utilizes existing data sources to the extent practicable. The
8 department or its designee shall seek, where reasonably available, to distinguish
9 institution-controlled time, sponsor-controlled time, and total elapsed time in
10 aggregated reporting.

11 G. Public reporting shall not include patient-identifying information or
12 sponsor proprietary commercial terms and shall be designed to minimize disclosure
13 of sensitive nonpublic business information.

14 H. The department or its designee shall submit an annual report to the
15 legislature by January first of each year summarizing research entities, active
16 benchmark categories, number of admitted covered clinical projects, median
17 timelines by benchmark category to the extent practicable, barriers encountered in
18 implementation, and recommendations for statutory or administrative changes.

19 I. Participation may be modified, limited, or conditioned in accordance with
20 the participation agreement, rule, or guidance for entities that demonstrate repeated
21 failure to meet applicable benchmark expectations.

22 §3308. Confidentiality and legal effect

23 A. The department or its designee may collect only such information as is
24 reasonably necessary to administer this Chapter and may enter into confidentiality
25 agreements or rely upon confidentiality provisions in participation agreements to
26 protect nonpublic business information and other information protected by law.

27 B. Nothing in this Chapter shall be construed to do any of the following:

28 (1) Create a state warranty of site performance, patient outcome, sponsor
29 selection, enrollment success, or commercial success.

1 (2) Create a private cause of action based solely on benchmark expectations,
2 participation decisions, referrals, feasibility coordination, or public reporting in
3 accordance with this Chapter.

4 (3) Require a research entity to disclose information prohibited from
5 disclosure by federal or state law or by enforceable contractual obligation.

6 §3309. Rulemaking and implementation

7 A. The department may adopt rules in accordance with the Administrative
8 Procedure Act as necessary to implement this Chapter.

9 B. Implementation may also occur through participation agreements,
10 guidance, templates, benchmark-category publications, and other nonregulatory
11 mechanisms consistent with applicable law.

12 C. The department may phase implementation by benchmark category,
13 project type, institution type, therapeutic area, or pilot cohort in order to promote
14 operational reliability and early-phase clinical trial readiness within existing
15 resources.

16 §3310. Funding

17 Nothing in this Chapter shall be construed to require a specific appropriation
18 of funds or the creation of new positions. This Chapter shall be implemented within
19 existing resources unless otherwise provided by law.

20 Section 2. This Act shall become effective upon signature by the governor or, if not
21 signed by the governor, upon expiration of the time for bills to become law without signature
22 by the governor, as provided by Article III, Section 18 of the Constitution of Louisiana. If
23 vetoed by the governor and subsequently approved by the legislature, this Act shall become
24 effective on the day following such approval.

DIGEST

The digest printed below was prepared by House Legislative Services. It constitutes no part of the legislative instrument. The keyword, one-liner, abstract, and digest do not constitute part of the law or proof or indicia of legislative intent. [R.S. 1:13(B) and 24:177(E)]

HB 1223 Original

2026 Regular Session

McFarland

Abstract: Provides relative to the La. Early-Phase Clinical Trial Acceleration Framework.

Proposed law provides for legislative findings and purpose.

Proposed law defines "benchmark category", "complete submission", "contract research organization", "covered clinical project", "department", "external institutional review board", "research entity", "participation agreement", "patient-access support", and "sponsor".

Proposed law provides that La. Economic Development (department) shall administer a clinical trial acceleration coordination function within existing resources.

Proposed law provides for how the department may implement provisions of proposed law.

Proposed law provides that participation in the framework established by proposed law shall be mandatory for all entities implementing a covered clinical project located in this state.

Proposed law provides that a research entity shall enter into a participation agreement with the department or its designee.

Proposed law provides that a participation agreement shall establish expectations for all of the following:

- (1) Benchmark categories or project types for research entities.
- (2) Primary contacts for intake, contracts, budgets, institutional review board reliance, ancillary reviews, and escalation.
- (3) Institution-specific addenda, if any, that supplement the standardized checklist.
- (4) Local review categories that remain applicable when an external institutional review board is used.
- (5) Provision of information reasonably necessary to support performance evaluation and fair distinction between institution-controlled time and sponsor-controlled time.
- (6) Escalation contacts and internal accountability procedures applicable when a covered clinical project becomes stalled or repeatedly misses benchmark expectations.
- (7) Any category-specific limitations, capacity constraints, or participation conditions the research entity elects to disclose.

Proposed law provides that the department or its designee shall publish standardized completeness checklists and intake procedures for covered clinical projects within benchmark categories.

Proposed law provides for coordination between the department and other entities to implement the provisions of proposed law.

Proposed law provides that the department or its designee may maintain, subject to applicable confidentiality protections and participation agreements, a registry of research investigators, sites, benchmark categories, and verified operational capabilities for use in sponsor, contract research organization, and site-selection coordination.

Proposed law provides that for each covered clinical project, a research entity shall do all of the following, unless modified by rule or guidance for a specified benchmark category:

- (1) Acknowledgment of receipt of a sponsor, contract research organization, or site-selection feasibility inquiry within two business days, provided that acknowledgment of receipt shall not constitute acceptance of feasibility or commitment to participate in the study.
- (2) Completeness confirmation or a single consolidated deficiency notice not later than five business days after receipt of a submission. A submission shall be deemed complete on the sixth business day if no such notice is issued.
- (3) No serial deficiency notices for items that were reasonably available to be identified in the initial completeness review, except for sponsor-requested changes, newly arising issues, or categories designated by rule or guidance.
- (4) A sponsor feasibility response or engagement determination within 10 business days after receipt of all materials reasonably required for such determination, unless a different benchmark is designated by rule or guidance for a specified benchmark category.
- (5) Concurrent review, to the maximum extent permitted by applicable law and documented institutional requirements, of contracts, budgets, coverage analysis, ancillary reviews, pharmacy review, operational readiness, and other nonduplicative startup functions that need not await completion of another function.
- (6) An initial contract response within ten business days after receipt of a sponsor draft or applicable model agreement, unless a different benchmark is designated by rule or guidance for a specified benchmark category.
- (7) An initial budget response within 10 business days after receipt of the sponsor budget or budget template, unless a different benchmark is designated by rule or guidance for a specified benchmark category.
- (8) Escalation to designated research-entity and department personnel upon failure to meet a benchmark, in accordance with the participation agreement, which may include executive-level review. Escalation may be initiated by the department or its designee, the sponsor, or the contract research organization.

Proposed law provides that for a covered clinical project for which reliance on an external institutional review board is permitted by applicable federal law, a research entity shall rely on an external institutional review board except for circumstances provided for in proposed law.

Proposed law provides that nothing in proposed law shall be construed to eliminate lawful local review relating to investigator qualifications, conflict of interest, privacy, HIPAA, billing compliance, site feasibility, ancillary safety committees, credentialing, or other institutional responsibilities that do not duplicate ethical review of the protocol.

Proposed law further provides that nothing in proposed law shall be construed to require a research entity to waive or disregard legal requirements, safety obligations, or documented institutional responsibilities in order to satisfy a benchmark established in proposed law.

Proposed law provides that the framework outlined in proposed law shall include benchmark categories related to clinical trial startup and execution for admitted covered clinical projects.

Proposed law provides that participation agreements shall incorporate expectations aligned with benchmark categories and may provide for pilot implementation by benchmark category.

Proposed law provides for what the benchmark categories may include.

Proposed law provides relative to information from a research entity for the department to compile and publish.

Proposed law provides that public reporting shall not include patient-identifying information or sponsor proprietary commercial terms and shall be designed to minimize disclosure of sensitive nonpublic business information.

Proposed law provides relative to what the department shall report to the legislature.

Proposed law provides that participation may be modified, limited, or conditioned in accordance with the participation agreement, rule, or guidance for entities that demonstrate repeated failure to meet applicable benchmark expectations.

Proposed law provides relative to confidentiality.

Proposed law provides that nothing in proposed law shall be construed to do any of the following:

- (1) Create a state warranty of site performance, patient outcome, sponsor selection, enrollment success, or commercial success.
- (2) Create a private cause of action based solely on benchmark expectations, participation decisions, referrals, feasibility coordination, or public reporting in accordance with proposed law.
- (3) Require a research entity to disclose information prohibited from disclosure by federal or state law or by enforceable contractual obligation.

Proposed law provides for rulemaking and implementation by the department in regards to proposed law.

Proposed law provides that nothing in proposed law shall be construed to require a specific appropriation of funds or the creation of new positions. Proposed law shall be implemented within existing resources unless otherwise provided by law.

Effective upon signature of governor or lapse of time for gubernatorial action.

(Adds R.S. 51:3301-3310)