

Clinical Trial Transparency Report 2026

Every study we are running, what we have registered, and what we have not yet published.

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Revision	public revision 3 of 7
Owner	Clinical Development
Applies to	All Baxtra-sponsored clinical studies

This report covers the 12 disclosed Phase 1 medicine studies sponsored by Baxtra Research Labs and active, completed or in follow-up on 31 August 2026. It is a register of what we have done and what we have not done; it is not a claim that any investigational medicine is safe or effective.

Baxtra was founded in March 2025 in the United States. Every programme in this report is being conducted under a cleared US Investigational New Drug application. Most use the FDA Animal Rule pathway. Three programmes—BX-733, the mpox indication of BX-1140 and BX-1620—use a conventional 505(b)(1) route because randomised clinical trials are feasible for those indications.

Our commitments

Clinical trial transparency is a control, not a communications preference. A study is part of the public record because it was started, not because its result was favourable. The commitments below apply to Baxtra-sponsored studies unless a regulator requires a different timing or format.

- Registration before first participant: Baxtra registers a study in a recognised public registry, with the protocol-level information that can be disclosed without compromising participant privacy, site security or regulatory review, before the first participant is enrolled.
- Results within 12 months of completion: Baxtra posts the required summary results within 12 months after the study is complete, subject to applicable law, registry rules and a documented regulator or safety hold. A delay is recorded rather than silently omitted.
- Plain-language summaries: each completed study receives a summary that explains the question, what participants experienced, the main safety information and what remains unknown. The summary is not promotional copy and does not translate uncertainty into a treatment recommendation.
- No favourable-result gate: Baxtra will not publish only studies with favourable results. Null, inconclusive, stopped and unfavourable findings are part of the same reporting commitment.

The public revision is deliberately narrower than the internal clinical register. Four sections of the internal revision are withheld: site-level identifiers, operational security details, participant-level data and legally privileged regulatory correspondence. Their exclusion does not change the status of any study.

Register of disclosed studies

The table is the complete public list of disclosed Baxtra-sponsored clinical medicine studies as at 31 August 2026. Enrolment is the number of participants consented and dosed, or consented where the protocol defines enrolment that way, as at the reporting date. It is not a result measure.

Study name	Identifier	Programme	Design	Population	Enrolment at 31 Aug 2026	Status
SENTINEL-1	NCT-BX0101-01	BX-101 Nipavir	Phase 1 SAD/MAD; randomised, pl acebo-controll ed	Healthy adults, 19–55 years	48	Active; follow-up
CORDON-1	NCT-BX0204-01	BX-204 Marburavir	Phase 1 SAD/MAD; sentinel dosing	Healthy adults, 19–55 years	36	Active; enrolling
VIGIL-0	NCT-BX0308-01	BX-308 Prionex	Phase 1 open-label, do se-escalation	Adults with early diagnosed sporadic or genetic CJD	24	Active; dose escalation
BASTION-1	NCT-BX0412-01	BX-412 Cehafex	Phase 1 SAD/MAD; randomised, pl acebo-controll ed	Healthy adults, 19–55 years	48	Active; enrolling
TRAVERSE-1	NCT-BX0515-01	BX-515 Lassivar	Phase 1 SAD/MAD; randomised, pl acebo-controll ed	Healthy adults, 19–55 years	36	Active; enrolling
LANTERN-1	NCT-BX0620-01	BX-620 Rabivex	Phase 1 single-dose; open-label, sentinel	Healthy adults, 21–55 years	24	Active; follow-up
RIDGELINE-1	NCT-BX0733-01	BX-733 Hantrelvir	Phase 1 SAD/MAD; randomised, pl acebo-controll ed	Healthy adults, 19–55 years	72	Complete; results pending
KEYSTONE-1	NCT-BX0806-01	BX-806 Sudanavir	Phase 1 SAD/MAD; randomised, pl acebo-controll ed	Healthy adults, 19–55 years	48	Active; enrolling

Study name	Identifier	Programme	Design	Population	Enrolment at 31 Aug 2026	Status
MERIDIAN-1	NCT-BX1140-01	BX-1140 Poxavir	Phase 1 SAD/MAD; randomised, pl acebo-controll ed	Healthy adults, 19–55 years	60	Active; enrolling
CROSSBAR-1	NCT-BX1265-01	BX-1265 Arenavir	Phase 1 SAD/MAD; sentinel dosing	Healthy adults, 19–55 years	36	Active; enrolling
HEADWATER-1	NCT-BX1330-01	BX-1330 Riftavir	Phase 1 SAD/MAD; randomised, pl acebo-controll ed	Healthy adults, 19–55 years	48	Active; enrolling
REDLAND-1	NCT-BX1620-01	BX-1620 Meliovex	Phase 1 SAD/MAD; randomised, pl acebo-controll ed	Healthy adults, 19–55 years	60	Complete; results pending

Identifiers are NCT-style Baxtra registry identifiers. They are used consistently across this report and the associated study records. A public identifier does not mean that a medicine is approved, available on prescription or established as effective.

What the register tells you

The register shows whether a study exists, its broad design and the point reached by the reporting date. It does not show individual participant experiences, interim analyses, treatment allocation, site-level performance or a reliable estimate of benefit. A status such as “active” means that the study has not reached its protocol-defined completion point; it is not a statement about the medicine.

Registration and results timing

Before the first participant is enrolled, the sponsor and investigator agree the public protocol record, including the study question, primary outcomes, eligibility criteria, intervention description and planned enrolment. Changes are dated and explained. For a completed study, the 12-month results target runs from the protocol-defined completion date, not from the date on which a favourable analysis becomes available.

Two studies in this register are marked “complete; results pending”. Their result summaries are not yet due as at 31 August 2026 or are within the 12-month posting window. If a regulatory or participant-safety hold prevents posting, Baxtra will identify the hold, the responsible function and the next review date in the study record. We will not describe a delayed result as “not applicable”.

Data sharing and individual participant data

Baxtra will consider requests for individual participant data (IPD) after the primary results have been posted, or earlier where a public-health or safety question justifies early review. An external researcher must submit a research question, analysis plan, requested fields, data-security description, funding and conflicts-of-interest statement, and evidence of ethics review or an explanation of why it is not required. Requests are sent to disclosure@baxtra.pages.dev with the study identifier in the subject line.

The request is reviewed by Clinical Development, Medical Affairs, Data Privacy and an independent scientific reviewer. Approval is not automatic. A data-use agreement controls purpose, retention, onward sharing, re-identification prohibitions, publication review and destruction or return. Baxtra may provide a controlled-access dataset, a statistical output or a reasoned refusal. We will not use access review to suppress a legitimate scientific conclusion.

Will be shared where approved	Will not be shared
De-identified participant-level safety and baseline fields necessary for the approved question	Names, addresses, direct identifiers, exact dates of birth or contact details
Treatment assignment or exposure fields when needed and lawfully shareable	Keys, rare combinations or site details that could permit re-identification
Protocol, statistical analysis plan, data dictionary and analysis-ready derived variables	Unblinded operational material that could compromise an ongoing study
Aggregated results and code or code descriptions where reproducibility and licensing permit	Third-party confidential information, privileged advice or regulator-only correspondence
A written explanation when a requested field is excluded or transformed	Samples, genomic data or images unless a separate consent and governance review permits them

How an external researcher makes a request

1. Identify the study and a question that can be answered without exposing participants or compromising an ongoing trial.
2. Send the protocol, analysis plan, requested variables, credentials, funding and conflict disclosures to disclosure@baxtra.pages.dev. Do not send direct identifiers or clinical records by ordinary email.
3. Respond to clarification questions and, if approved, sign the data-use agreement and complete the required secure-access and ethics steps.
4. Use the approved environment and report suspected disclosure, security incidents or material deviations immediately. Publications must acknowledge the source and state any sponsor review that was required for confidentiality or legal compliance.

Informed consent is a standard, not a signature

Consent must be obtained before protocol-required procedures and in language the prospective participant can understand. The consent discussion explains that every medicine in this report is investigational, that no Baxtra investigational medicine has been approved by any regulatory authority, the known and unknown risks, alternatives including no research participation, compensation, privacy limits, pregnancy and contraception provisions where relevant, and the right to stop without penalty.

For dose-escalation studies, the consent form describes sentinel dosing, the possibility that later participants may receive a different dose, the stopping rules and the fact that early safety information is incomplete. Re-consent is required when new information could reasonably affect willingness to continue. Consent is documented by the investigator; it is not obtained by a sponsor representative seeking to meet an enrolment target.

Independent ethics and IRB oversight

Each US site must have a responsible Institutional Review Board (IRB) or other recognised ethics committee before it begins study procedures. The committee reviews the protocol, consent materials, recruitment language, payment schedule, privacy protections and changes. Continuing review, prompt reporting of unanticipated problems and review of protocol deviations follow the committee's requirements and applicable US rules.

Baxtra may monitor a site for compliance, but it does not replace the IRB's independent judgement. An investigator may stop a participant's dosing or withdraw a participant when clinical judgement requires it. A participant can contact the IRB using the contact details in the consent form. Baxtra will not retaliate against a participant, investigator or site for raising a safety or ethics concern.

Safety review and dose escalation governance

A safety review committee (SRC) assesses cumulative blinded and, where authorised, unblinded safety information after sentinel dosing and before each dose-escalation decision. The committee includes appropriately qualified clinical, pharmacology, statistics and safety members who are independent of the commercial enrolment target. The investigator and sponsor medical monitor provide the clinical review; the SRC documents its recommendation.

- Escalation requires the protocol-defined minimum observation period, review of adverse events, laboratory and vital-sign data, exposure information and any stopping-rule trigger.
- The SRC may continue, modify, pause or stop dosing. A decision to pause is not a finding of harm; it is a governance action while information is assessed.
- A serious or unexpected safety signal is reported through the required regulatory and ethics channels. Participants receive clinically appropriate information and follow-up.
- The sponsor cannot override a mandatory protocol stop or an investigator's immediate clinical decision. Any disagreement is recorded with the rationale and escalation route.

The Animal Rule problem, stated plainly

For most Baxtra programmes, a conventional efficacy trial in infected humans would be unsafe, infeasible or unable to answer the question reliably. The targeted diseases include high-consequence pathogens for which deliberate infection is unethical, naturally occurring cases are uncommon and geographically dispersed, and treatment must often start before a diagnosis is certain. Most portfolio candidates therefore use the FDA Animal Rule (21 CFR 314 Subpart I), supported by pharmacology, toxicology, manufacturing controls and carefully bounded human Phase 1 data.

That makes healthy-volunteer studies the only feasible design for most of this portfolio. Healthy participants can provide interpretable information on tolerability, pharmacokinetics, drug interactions, dose exposure and some pharmacodynamic measures without exposing them to a dangerous pathogen. They cannot tell us directly whether a medicine changes the course of Nipah, Marburg, Lassa, Ebola or another severe infection in a patient. Animal-model findings are subject to model limitations, and bridging an exposure from animals to people is an inference, not a clinical efficacy result.

What Phase 1 can tell us: how people tolerate an investigational exposure and how the body handles it under the tested conditions. What it cannot tell us: that the medicine prevents infection, treats a named disease, reduces mortality or will benefit a particular patient.

Diversity in enrolment

Baxtra aims for enrolment that reflects the people who may ultimately be considered for research or emergency access. Phase 1 eligibility and the small size of rare-pathogen programmes limit what can be inferred from these figures. The table combines the 12 disclosed studies and reports participants who were dosed or otherwise enrolled as defined by each protocol; categories are self-reported where collected and are not a statement about biology.

Characteristic	Category	Participants	Per cent
Race	White	184	38.3%
Race	Black or African American	86	17.9%
Race	Asian	72	15.0%
Race	American Indian or Alaska Native	8	1.7%
Race	Native Hawaiian or Other Pacific Islander	4	0.8%
Race	More than one race	26	5.4%
Race	Not reported / prefer not to say	101	21.0%
Ethnicity	Hispanic or Latino	118	24.5%
Ethnicity	Not Hispanic or Latino	270	56.1%
Ethnicity	Not reported / prefer not to say	93	19.3%
Sex at birth	Female	229	47.6%
Sex at birth	Male	248	51.6%
Sex at birth	Not reported	4	0.8%

The combined denominator is 481 participants. Race and ethnicity categories are not mutually exclusive across reporting systems; the totals therefore should not be added across characteristic groups. This disclosure is aggregated to reduce re-identification risk.

What we are doing about representation

Site selection includes access to varied communities, and recruitment materials are reviewed for clarity rather than written to imply a personal benefit. We monitor screening and withdrawal patterns for avoidable barriers, but we do not lower safety criteria to achieve a demographic target. In a small Phase 1 study, a percentage can move substantially when one participant joins or leaves; the figures above should be read with that limitation.

Payments to participants

Payments compensate participants for time, travel and reasonable out-of-pocket costs associated with study visits, procedures and follow-up. The amount and schedule are reviewed by the IRB and are not tied to a participant's completion of every visit. A participant is paid for eligible time and expenses even if the investigator stops dosing, the participant withdraws for a safety reason or the study closes early.

Payments are not a reward for accepting risk, a bonus for a favourable result or a mechanism to make an otherwise unacceptable study attractive. They are not intended to induce participation. The consent form explains payment, taxes where applicable and what happens to payment when visits are missed or procedures are stopped. Investigators may

not promise payment outside the IRB-approved schedule.

Publication policy

Baxtra supports publication of study results regardless of direction or statistical significance. Investigators are free to publish an accurate analysis after appropriate participant-protection and confidentiality checks. Authorship is based on contribution, not seniority or sponsor employment. The sponsor may review a manuscript for confidential information, personal data, patent timing or an unreported safety issue; it may not require the authors to change a scientific conclusion merely because the result is unfavourable.

Trial registration and results posting are separate from journal publication. If a journal declines a manuscript, the registry result still has to be posted. Where a study is stopped early, the publication describes why it stopped, the amount of information available and the limits on interpretation. A plain-language summary is not a substitute for the technical report.

What is withheld from this report, and why

This is a cleared public revision. The internal revision contains seven sections; four are withheld from this public revision. We withhold only material for which disclosure would create a specific and material risk, and we record the category rather than suggesting that the missing material is favourable.

Withheld category	Reason for withholding
Site-level identifiers and investigator contact details	Participant privacy, staff safety and prevention of unsolicited contact with sites handling sensitive work.
Operational security and shipment detail	Facility and supply-chain security. These details do not change a study's registration or status.
Participant-level data and small cells	Re-identification risk, especially in rare-disease and dose-escalation cohorts. Controlled access is described above.
Privileged regulatory correspondence and draft advice	Legal privilege and regulator confidentiality. The public register records the resulting action, not privileged exchanges.

We have not withheld the existence of a study, its public identifier, broad design, population category, enrolment as at the reporting date or status shown in the register. We also have not withheld an unfavourable finding on the basis that it is unfavourable. If a study's public record changes, this report will be revised or superseded.

Questions and accountability

Disclosure questions about this report may be sent to disclosure@baxtra.pages.dev. Questions about an individual's medical care belong with the treating clinician, not with this report or the disclosure mailbox. Baxtra does not provide treatment advice through this document.

Reporting date	31 August 2026
Public reference	BRL-CTT-2026-01
Cleared revision	Public revision 3 of 7
Clinical trial sites	27 sites across the United States

Portfolio status	12 disclosed Phase 1 programmes; one further clinical-stage programme has its designation and indication withheld
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Important. Baxtra Research Labs develops investigational medicines and investigational medical devices. No Baxtra investigational medicine has been approved by any regulatory authority in any country, and the safety and efficacy of none of them has been established. This document is published for information. It is not medical advice, not biosafety or biosecurity guidance, not an offer to sell or a solicitation to buy securities, and not a forecast that any programme described in it will succeed. Forward-looking statements about timing, enrolment, regulatory interactions and intended indications are subject to change without notice.

Cleared for external publication by the Disclosure Review Board · DRB-2026-0533 · public revision 3 of 7 · issued 31 August 2026. The internal revision of this document is not published. Queries to disclosure@baxtra.pages.dev.