

Toward a Breast Cancer Prevention Vaccine

The evidence we need to build

A summary of recent works and a proposed data agenda for Tesserie

11 September 2026

Our ultimate goal is to develop a vaccine that prevents breast cancer before a first diagnosis. Our immediate task is to determine which early biological changes could be targeted safely, and what evidence would justify developing a candidate.

This edition starts with that goal and works backward: from a future prevention claim, to target validation, to the tissue, immune and longitudinal clinical data needed today. It replaces the website's broader vaccine data map as the current reading edition.

Tesserie is at the research-planning stage. It does not yet have a vaccine candidate, an approved study, a linked research dataset or an institutional partnership. No medical-data collection or trial enrollment is offered by this summary.

AI-assisted literature summary. Not peer reviewed or medical advice. No original patient analysis or experiments are reported. The proposed priorities are a research-planning interpretation, not a consensus ranking or an experimental protocol.

Reading map

- Define the prevention goal and the first population.
- Separate existing evidence from what remains unproven.
- Map eight data domains to development decisions.
- Plan a clinic-linked research cohort and staged collection.
- Identify collaborators, resources and development gates.

1. Start with the claim we eventually need to test

A successful preventive vaccine would need to reduce first breast cancer diagnoses in its intended population with an acceptable benefit-risk balance. Detectable antibodies or vaccine-responsive T cells would be important mechanistic observations, but not sufficient evidence of that clinical claim. The route to human investigation also requires a defensible preclinical, manufacturing and regulatory package. [1,2,10]

Three settings must remain separate

Setting	People being studied	What the evidence can establish
Primary prevention	People without a previous breast cancer diagnosis	Whether an intervention reduces first diagnoses, with adequate safety and follow-up
Prevention of recurrence	People previously treated for breast cancer	Whether disease returns less often; not automatically protection before a first cancer
Treatment or interception	Existing invasive cancer or a defined lesion such as DCIS	Activity in established disease or a lesion; not equivalent to a cancer-free population

Recommended first decision: evaluate a defined high-risk population with a clinical investigator, rather than announcing a universal vaccine for all women. BRCA1 and BRCA2 pathogenic-variant carriers are plausible populations to assess, but they should not be assumed to have identical biology, risks or target requirements. This is a proposal for feasibility assessment, not an eligibility rule or personal risk recommendation. The NCI-funded MD Anderson program illustrates why studying antigens before invasive cancer is relevant to this setting. [1]

The first target-product brief should define intended population, cancer subtype or spectrum, first-cancer endpoint, acceptable safety profile, duration of protection to evaluate and interaction with existing screening and risk-reducing care. Exact eligibility, sample size, follow-up schedule and endpoints require scientific, statistical, clinical and regulatory review.

Tesserie should not select an mRNA, protein or peptide platform solely because it is fashionable. Target biology, immune mechanism, rights, manufacturability and safety should determine which platform deserves evaluation. A preventive product cannot simply reuse a personalized tumor-vaccine workflow when the intended recipient has no tumor to sequence.

2. What current research contributes

The evidence below motivates questions and measurements. None is a Tesserie result, a partnership announcement or proof that Tesserie can prevent breast cancer.

Evidence	Relevant finding or approach	Implication and limit
NCI-funded MD Anderson program; FY2025 [1]	Investigates chimeric-RNA-derived antigens in BRCA1/2-related prevention	Seek targets in preneoplastic tissue. A funded research aim is not a demonstrated human benefit
Cleveland Clinic Phase 1 announcement; December 2025 [2]	35 participants; four were cancer-free high-risk participants planning preventive mastectomy	Safety and immune-response observations support further study. The reported 74% immune-response figure is not a prevention rate
Individualized mRNA TNBC study; Nature, 2026 [3]	Studied vaccination after surgery and other treatment in 14 patients	Informs immune persistence and linked follow-up. Small adjuvant study, not a randomized primary-prevention trial
Parity and lactation study; Nature, 2026 issue [4]	Human observations and mouse experiments connect reproductive history with tissue immunity	Record physiological context and local immunity. This is not a preventive-vaccine trial or reproductive advice
Breast immunopeptidomics; JCI, 2024 issue [5]	Directly characterized HLA-presented peptides in 26 primary tumors	Measure actual presentation, not expression alone. Tumor findings require validation in earlier lesions and normal tissues

Normal breast atlases and benign HLA-ligand references add essential context. They do not establish that a candidate absent from a particular dataset is absent from every healthy tissue or physiological state. Cell atlases, conventional proteomics and immunopeptidomics measure different things and should not be treated as interchangeable. [6,7]

Search scope: targeted rechecking of selected primary publications, official research programs, resource providers and regulatory pages on 11 September 2026, building on the earlier review. This is not a systematic review, exhaustive pipeline census or claim to cover unpublished data. Dates distinguish publication or announcement dates from this edition's review date. Future company milestones are not treated as completed trials.

3. Data for target discovery

The useful research unit is not a file. It is a permissioned link between a participant, clinical event, specimen, assay, candidate target and subsequent outcome. The priorities below are proposed for Tesserie's primary-prevention goal; feasibility and study design may change the order.

Domain	Minimum research information	Development decision it supports
1. Provenance and permissions	Coded participant/event/specimen identifiers; source; dates; consent version; allowed uses; processing and quality metadata	Can evidence be linked reliably and used for this project? Required for every domain
2. Tissue before cancer	Normal, high-risk and defined precursor tissue; pathology review; anatomical site; appropriate tumor and non-cancer comparisons	Does the candidate appear early enough to matter? Does it distinguish risky changes from normal biology?
3. Antigen expression and presentation	Relevant DNA/RNA/protein findings; HLA typing; direct peptide-presentation evidence where feasible; assay confidence	Is the candidate expressed and displayed in the intended setting, rather than merely predicted?
4. Normal-tissue safety context	Tissue distribution; cell type; reproductive and hormonal context; benign presentation references; cross-reactivity evidence	Is there a plausible safety margin, and which normal-tissue uncertainties still require testing?

The rationale for domains 2-4 comes from research into preneoplastic antigens, breast immuno-peptidomics, tissue immunity and normal-reference atlases. These are complementary approaches, not a proven recipe for a vaccine. [1,4-7]

Preserve distinctions that change interpretation

- A pathology PDF describes tissue; it does not provide the tissue itself.
- Histologically normal tissue next to a tumor may differ from tissue in a person without cancer. Preserve the source category rather than pooling them automatically.
- RNA expression is not proof of protein abundance, HLA presentation or immune recognition.
- An unmeasured antigen is not a negative result. Retain assay sensitivity, quality and reasons for missingness.
- A high-risk genotype is not permission to obtain additional tissue. Use clinically justified or ethically approved collection routes.

Initial deliverable: a source-linked candidate evidence table with knowns, unknowns and exclusion reasons, not a list labeled "validated vaccine targets."

4. Data for validation and outcomes

Domain	Minimum research information	Development decision it supports
5. Functional immunity	Antigen-linked immune assays; HLA context; local and circulating immune measurements; controls; failures and negative findings	Does recognition translate into relevant biological activity, and is healthy tissue spared?
6. Population and clinical context	Verified risk context; genetics where authorized; age and physiological state; screening, pathology and relevant interventions	For whom might a target be relevant? Which confounders and safety contexts need accounting for?
7. Longitudinal outcomes	First diagnosis and pathology; last confirmed cancer-free assessment; follow-up completeness; risk-reducing treatments/surgery; adverse outcomes	Can target biology be related to natural history? Later, can a trial assess actual prevention and harm?
8. Candidate, product and trial data	Candidate/version, manufacturing and quality records; exposure; trial assignment; safety; immune measurements; adjudicated outcomes	Does a reproducible product have a favorable benefit-risk profile? This belongs to later regulated development

Immune measurements should be tied to their antigen, specimen, timepoint and experimental conditions. Favor retention of informative failures over selective collection of positive responses. The published adjuvant vaccine study illustrates the value of longitudinal immune observations, but its patient setting does not establish a correlate of protection for cancer-free recipients. [3]

The highest-value missing connection

For this project, the proposed priority is **prediagnostic tissue biology linked to immune recognition and reliable longitudinal outcomes**, with suitable normal controls. A large archive of unrelated reports or wearable measurements does not create this connection. Records remain valuable for reconstructing events and locating specimens, but molecular and functional questions need laboratory evidence.

Long-term outcomes must include participants who remain cancer-free as well as those who develop disease. Record the observation period and ascertainment method. An absent diagnosis in an incomplete record is not a negative outcome. Observational association can guide discovery; it does not prove that vaccinating against the associated target prevents cancer.

This data agenda cannot establish vaccine efficacy by itself. Later human evaluation requires the relevant development and regulatory pathway, with safety and clinically meaningful outcomes appropriate to the intended population. [10]

5. Design the first research project, not the final trial

Proposed first project: assess whether existing, appropriately authorized breast specimens and their clinical context can support a study of candidate antigens before cancer. Begin with a tissue and data feasibility audit rather than promising a large prospective vaccine trial.

A clinic-linked starting structure

- **High-risk group:** a clinically defined population without prior breast cancer, considered with a high-risk clinic and genetics expertise. Confirm classifications rather than treating self-reported risk or a variant of uncertain significance as equivalent to a pathogenic variant.
- **Reference group:** appropriate non-cancer controls with source, age and physiological context retained. Match or adjust according to a prespecified scientific question, not convenience alone.
- **Lesion comparison:** separately classified precursor and invasive disease specimens, when authorized. A cross-sectional sequence of tissue states is not longitudinal proof that one person's lesion progressed.
- **Follow-up:** first diagnoses, remaining cancer-free, last contact and clinically relevant interventions. Loss to follow-up and preventive surgery must remain visible in analysis.

The investigator and statistician should set the cohort definition, sampling plan and analysis before results are examined. The first cohort size should follow specimen availability, assay feasibility, effect assumptions and precision needs; a round number chosen for a pitch deck is not a statistical justification.

First project's success criteria

1. A scientific lead and clinical investigator agree on a bounded question and an interpretable comparison.
2. A specimen inventory shows that the required data can actually be linked under applicable permissions.
3. The study has the necessary institutional review, agreements and qualified laboratory support.
4. Candidate evidence is evaluated with prespecified uncertainty, negative findings and independent validation plans.
5. The team can decide whether to advance, change population/target strategy, or stop.

No vaccine is administered in this proposed initial data-and-specimen feasibility project. Do not request extra biopsies merely to make a dataset more complete. An observational or retrospective study and a future interventional vaccine trial have different approvals, responsibilities and evidence needs. [8,10,11]

6. What Tesserie can collect, and when

Now: an evidence map and a contact community

The current website can collect ordinary account information and an email-only waitlist with its existing notices. It should not collect diagnoses, genetic results, DICOM, medical PDFs or samples. Registration is a request for future contact, not consent to research or clinical-trial enrollment.

Tesserie can now maintain a versioned literature evidence table, assess appropriately licensed public resources, interview potential collaborators about research workflows and use synthetic records to develop a data dictionary. Avoid soliciting individual health histories through informal interviews or general email. Any proposed human-subjects research needs the relevant institutional determination before it starts.

After a qualified partner and governance are in place

Source	Targeted collection	Important boundary
Participants / authorized clinical records	Necessary imaging and pathology reports, screening timeline and relevant clinical history	Patient permission must match the use; self-report and source-verified facts remain distinguishable
Hospitals and imaging departments	Original DICOM with study/series identifiers, acquisition context and corresponding report	Collect only if the research question needs images; a PDF is not DICOM
Pathology and tissue banks	Specimen identifiers, pathology classification, processing details and authorized material	Digital slides, reports and physical specimens are separate assets
Qualified laboratories	Molecular, HLA and functional immune measurements linked to specimens	Patient uploads cannot substitute for missing laboratory evidence

Prefer a small, purpose-defined set of information to broad intake. For each field, specify why it is needed, who supplies it, how it is verified, who can access it and when it is deleted or retained. Research data may initially remain in the partner's approved environment instead of being copied into Tesserie.

Wearables are not an initial priority unless a defined hypothesis requires them. They do not measure breast-tissue antigen presentation. Patient contributions can help connect the longitudinal story, but a contact list is not a clinical cohort and uploads are not a biobank.

7. Governance and analysis are part of the dataset

Permissions must travel with the evidence

Record whether a specific use is allowed: primary research, future research contact, sample linkage, commercial development, AI training or evaluation, and onward sharing. These are not interchangeable permissions. The legal and ethical basis must be assessed for the actual project; not every lawful research use relies on the same consent or authorization mechanism. HHS describes authorization and other permitted research pathways where HIPAA applies. [11]

Data access is not ownership of a vaccine invention. Materials transfer, sponsored research, data-use and intellectual-property terms should specify permitted analyses, publication, inventions, commercialization, recipients and obligations after withdrawal or termination. A downloadable dataset does not automatically allow every commercial use. GDC, for example, distinguishes open and controlled access. [8,9]

Minimum quality and security plan

- Separate direct identifiers from coded research data; retain a controlled linkage mechanism only where justified and authorized.
- Define least-privilege access, audit records, encrypted storage/transfer, retention, deletion and incident response before medical intake.
- Keep original source provenance, document versions, extraction confidence, corrections and reviewer decisions.
- Distinguish not tested, assay failed, below detection, confirmed negative and missing follow-up.
- Prevent leakage by separating participants, and where appropriate sites or time periods, between discovery and validation; do not split tiles or repeated specimens as if they were independent people.
- Assess selection bias: people volunteering online, receiving surgery or donating tissue may not represent the intended population.

These are proposed controls, not a statement that Tesserie already operates a compliant medical portal. The applicability of HIPAA and other US privacy, consumer-protection and research rules depends on the service and relationships, not simply on accepting US users. Qualified review is needed.

AI may assist extraction, provenance checks and analysis after permitted access, but important research labels require accountable validation. This summary does not authorize patient records to be uploaded to general-purpose AI services. AI capability is a supporting tool, not the company's vaccine asset or proof of benefit.

8. Build a focused collaboration network

Need	Potential entry point	First concrete request
Primary-prevention scientific direction	MD Anderson / Isabelle Bedrosian research program [1]	Discuss population, early-antigen hypotheses and a bounded collaboration or licensing opportunity
Clinical cohort and follow-up	A high-risk breast clinic; Vanderbilt-Ingram's breast research program is one possible introduction [12]	Identify an accountable PI and assess whether the proposed cohort and record/specimen links are feasible
Normal comparison tissue	IU Susan G. Komen Tissue Bank [8]	Request an inventory and feasibility discussion; apply through its scientific review and material-transfer process
Vaccine immunology and translation	University of Washington Cancer Vaccine Institute [13]	Seek scientific input on immune validation and future development requirements
Existing breast vaccine program	Cleveland Clinic and Anixa Biosciences [2]	Explore a specific research or business opportunity; Anixa already holds the exclusive worldwide license to the reported technology

These organizations are potential contacts, not Tesserie partners. Investigators' interest does not itself grant institutional approval, access, an endorsement or rights to an existing vaccine.

Resources for starting the evidence work

- **Human Breast Cell Atlas:** normal cell-state and spatial context; not a prospective prevention cohort or direct HLA-ligand assay. [6]
- **HLA Ligand Atlas:** benign tissue peptide-presentation reference; retain tissue/HLA coverage and non-detection limits. [7]
- **GDC / TCGA-BRCA:** tumor molecular and clinical resources with separate access tiers; not a vaccine-exposed cancer-free cohort. [9]
- **Published breast immunoepitomics:** evidence of presented tumor antigens, requiring earlier-tissue and functional validation for this goal. [5]

Start with one clinic, one sample-access route and one scientific leader. The availability, cost, commercial-use terms and completeness of any resource must be confirmed directly. No number of institution logos substitutes for those commitments.

9. Milestones to a vaccine candidate

Gate	What Tesserie needs to establish	Reason not to advance yet
Foundation	Accountable scientific leadership; first population and question; feasible specimen access and rights	No suitable tissue, unresolved permissions or no investigator ownership
Discovery	Early target evidence with normal controls and traceable assay support	Target appears only after invasive disease, insufficient presentation evidence or safety concerns
Validation	Relevant functional evidence, reproducibility and independent confirmation	Activity cannot be reproduced, poor coverage or unacceptable normal-tissue effects
Development	A defensible candidate, IP path, appropriate preclinical package and manufacturing/quality plan	Biology, safety, scalability or rights do not justify human exposure
Human evaluation	Appropriate regulatory and ethical pathway, qualified sponsor/sites, safety and later prevention endpoints	Immune signals are being used as a substitute for demonstrating clinical benefit

The FDA IND framework describes the need for preclinical, manufacturing and clinical information before investigational human use. It is not a guarantee of approval or a substitute for product-specific regulatory advice. Tesserie is currently before candidate selection, not at clinical-trial launch. [10]

The next 90 days: proposed work, not promised completion

- **Weeks 1-2:** prepare a two-page prevention hypothesis and a source-linked evidence table; identify a scientific cofounder or substantive lead.
- **Weeks 3-4:** obtain clinic and tissue-bank feasibility feedback; document which specimens and outcomes are actually available.
- **Month 2:** co-develop a bounded research concept, data dictionary, validation strategy, permissions/IP path and budget based on real quotations.
- **Month 3:** decide whether the evidence and access justify proceeding. Start only work that has the necessary agreements and approvals; revise the plan when they are missing.

The first financing milestone should be a decision-quality research package, not a claim that signup volume proves vaccine feasibility. Data collection supports discovery, but developing a vaccine still requires scientific leadership, experimental validation, product development and clinical evidence. Prevention remains the goal; proof must determine the path.

References

Selected sources checked for this revision on 11 September 2026. Sources describe their own work, not Tesserie. Numbered citations distinguish original research, an institutional announcement, a funded-project description and operational guidance.

[1] National Cancer Institute, Division of Cancer Prevention. Chimeric RNA driven neoepitope vaccine for prevention of breast cancer in germline BRCA1/2 carriers. Funded project UG3CA290454; PI Isabelle Bedrosian; FY2025. Research proposal, not trial results. [Project](#)

[2] Cleveland Clinic. Cleveland Clinic Presents Final Results of Phase 1 Clinical Trial of Preventive Breast Cancer Vaccine Study. 11 December 2025. Institutional announcement of Phase 1 findings; includes cohort composition and Anixa license disclosure. [Announcement](#)

[3] Individualized mRNA vaccines evoke durable T cell immunity in adjuvant TNBC. Nature. 2026;651:1088-1096. Published online 18 February 2026. DOI: 10.1038/s41586-025-10004-2. Adjuvant clinical research, not primary prevention. [Article](#)

[4] Virassamy B, Caramia F, Savas P, et al. Parity and lactation induce T-cell-mediated breast cancer protection. Nature. 2026;649:449-459. Published online 20 October 2025. Human observations and mouse experiments. [Article](#)

[5] Kina E, Laverdure JP, Durette C, et al. Breast cancer immunopeptidomes contain numerous shared tumor antigens. Journal of Clinical Investigation. 2024;134:e166740. Human tumor antigen-presentation and functional research. [Article](#)

[6] Kumar T, Nee K, Wei R, et al. A spatially resolved single-cell genomic atlas of the adult human breast. Nature. 2023;620:181-191. Normal breast reference resource. [Article](#)

References and use of this edition

- [7] Marcu A, Bichmann L, Kuchenbecker L, et al. HLA Ligand Atlas: a benign reference of HLA-presented peptides to improve T-cell-based cancer immunotherapy. *Journal for ImmunoTherapy of Cancer*. 2021;9:e002071. [Publication](#) / [Resource](#)
- [8] Indiana University, Susan G. Komen Tissue Bank. Sample Acquisition FAQ. Resource access, sample types, review and material-transfer terms. [Provider guidance](#)
- [9] National Cancer Institute, Genomic Data Commons. Data Access Processes and Tools. Open and controlled access are distinct. [Access guidance](#)
- [10] US Food and Drug Administration. Investigational New Drug (IND) Application. Regulatory overview, including preclinical, manufacturing and clinical information. [FDA](#)
- [11] US Department of Health and Human Services. Research. HIPAA Privacy Rule research uses, authorizations and other applicable pathways. [HHS](#)
- [12] Vanderbilt-Ingram Cancer Center. Breast Cancer Research Program. Institutional capabilities; not an agreement with Tesserie. [Program](#)
- [13] University of Washington Medicine. Cancer Vaccine Institute. Institutional research and translational capabilities; not evidence of a universally effective preventive vaccine. [Institute](#)

Revision and limitations

This is a focused rewrite of the prior website summary. Its purpose is to connect Tesserie's long-term primary-prevention goal to concrete evidence requirements and staged collection. It is intentionally not a catalog of every cancer vaccine program. Prior tumor/recurrence findings are retained only where they inform a clearly labeled question; they are not relabeled as primary-prevention results.

No candidate antigen sequence, formulation, dosing schedule or experimental procedure is proposed. No institution listed has endorsed this plan. Scientific, clinical, ethical and regulatory review must precede the relevant research or development work. The earlier broad data-map source remains in the project history for reference.

The central proposal is a research direction: connect the biology before cancer to immune function and reliable outcomes, then let the evidence decide whether a prevention candidate should advance.