

Closing the Gap:

Extending E-witnessing into Off-site Storage

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Disclosures

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Objectives

- **Identify** where traceability weakens when specimens move into off-site storage
- **Examine** how e-witnessing principles and tools can support the full lifecycle of IVF specimens
- **Describe** a practical design for extending traceability into off-site storage and transport
- **Advocate** for digital chain-of-custody systems that complement workflows

What's at Stake?

- A single mistake can be devastating
- Significant emotional toll
- Loss of trust
- Legal and reputational damage¹

FIRST OPINION

A fertility clinic failure destroyed my chance at motherhood

NIGHTLY NEWS

NBC News tracks errors at fertility clinics nationwide

WOMEN'S HEALTH

After IVF nightmares, patients have few protections

An NBC News analysis found hundreds of lawsuits over five years alleging that embryos were lost, destroyed or swapped by fertility clinics or companies.

US woman sues after carrying wrong baby in IVF error

19 February 2025

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How Do Errors Occur?

Active Errors^{2,3}:

- Automaticity
- Inattention blindness
- Distractions
- Stress/fatigue
- High workload

Latent Errors⁴:

- Ambiguous accountability
- Manual handoffs
- Documentation gaps
- Flawed redundancy
- Systemic weakness

2. Rienzi L, Bariani F, Dalla Zorza M, Romano S, Scarica C, Maggiulli R, Ubaldi FM, et al. Failure mode and effects analysis of witnessing protocols for ensuring traceability during IVF. *Reprod Biomed Online*. 2015 Oct;31(4):516–522.

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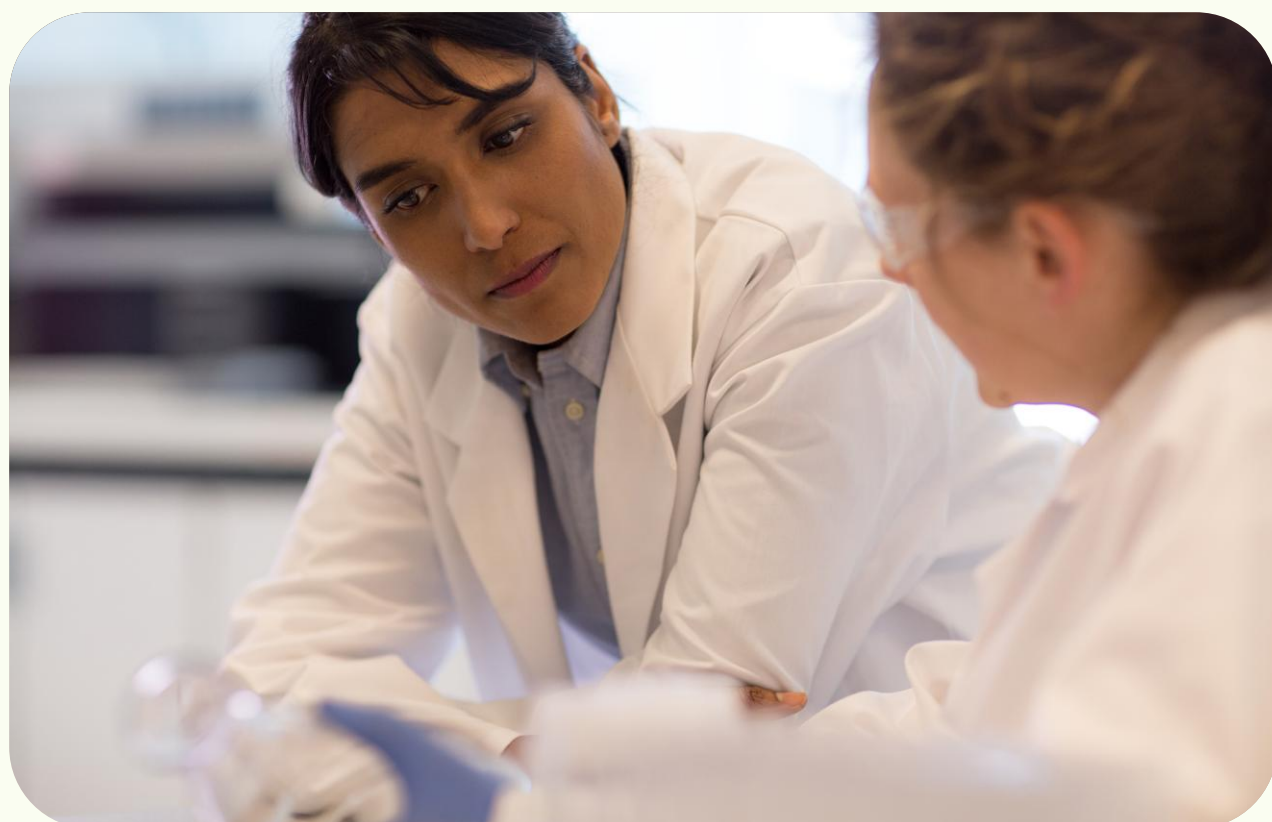
4. Forbrig M, Peirce K, Copeland C, Natalwala J, Chapple V, Liu Y. Risk factors for mismatches in the ART laboratory: an analysis of 73,719 electronic witnessing points. *Reprod Biomed Online*. 2025 May;50(5):104500. doi:10.1016/j.rbmo.2024.104500.

Patient and Clinical Perspective

- 90% of patients expressed concerns with sample mix up⁵
 - 92% of those patients felt highly comfortable with EWS present⁵
 - 85% of embryologists reported feeling more confident with EWS⁶
-

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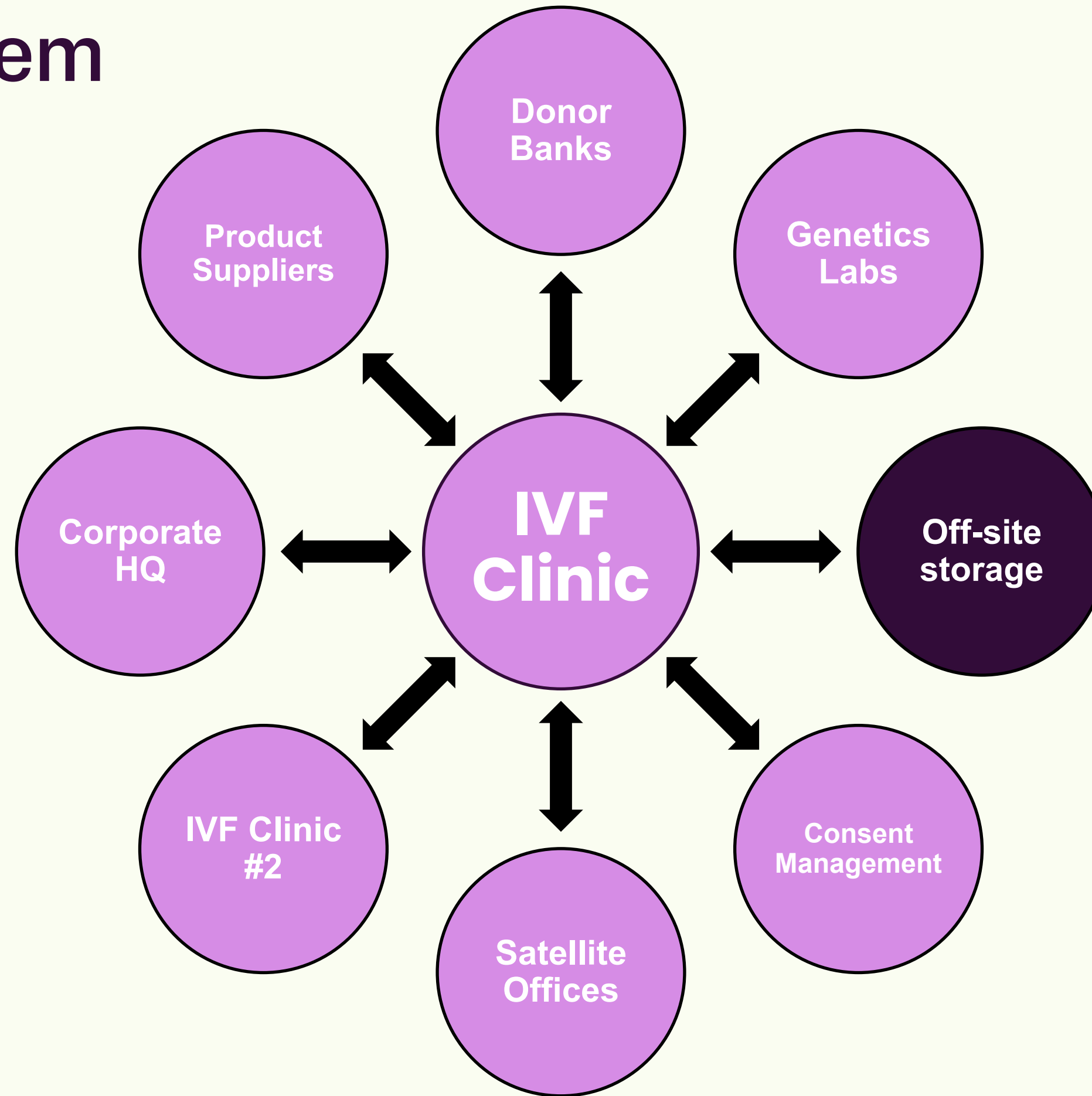


The Role of Digital Witnessing in the Lab



- Risk mitigation
- Reduces manual double witnessing
- Uses 1D/2D Codes, RFID, scanners and cameras
- Creates a real-time auditable chain of custody

IVF Ecosystem



Witnessing vs Traceability

Witnessing:

Verifying the right patient, sample, and procedure at a specific step (manual or electronic).

Traceability:

Being able to answer *who/what/where/when/how* for each specimen across its entire lifecycle.

Limitations

- Some dependence on double witnessing
 - Staff over-reliance
 - Manual handoffs around storage and shipping
 - Traceability beyond the clinic remains inconsistent
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Embryo Witnessing Lifecycle

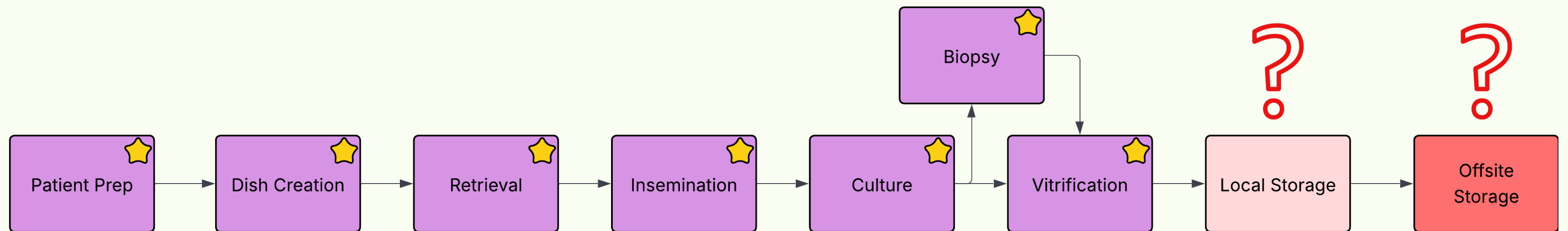


Figure 1. Generic embryo lifecycle and e-witnessed procedures (Stars).

Off-Site Storage: Long Horizons, Limited Visibility

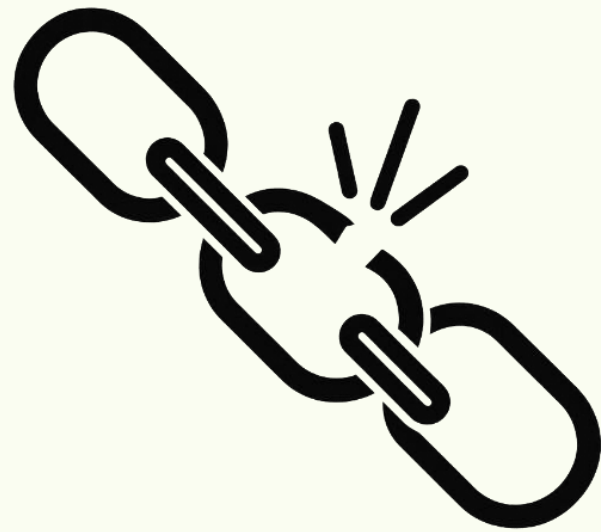
- Treatment volumes and cryopreservation continues to increase^{7,8}
 - Duration of cryostorage is increasing⁹
 - Data often lives in siloed databases
 - Limited integration between EMR, e-witnessing, and off-site storage systems
-

7. Pomeroy KO, Comizzoli P, Rushing JS, Lersten IL, Nel-Themaat L. The ART of cryopreservation and its changing landscape. *Fertil Steril*. 2022 Mar;117(3):469–476. doi:10.1016/j.fertnstert.2022.01.018.

8. Society for Assisted Reproductive Technology. National summary report. Available at: https://www.sartcorsonline.com/rptCSR_PublicMultYear.aspx. Accessed December 2, 2025.

9. Lee MB, Siavoshi M, Kwan L, Kroener L. Elective fertility preservation: a national database study on trends in oocyte cryopreservation and oocyte utilization over a 5- to 7-year follow-up period. *Am J Obstet Gynecol*. 2025 Aug 29:S0002-9378(25)00589-7. doi:10.1016/j.ajog.2025.08.032.

Framing the Problem



“A broken audit trail is a broken promise.”

A Closed Loop Model

- Specimen-level traceability
- Centralized, continuous audit trail
- Reuse existing specimen identifiers
- Designed for future automation and analytics

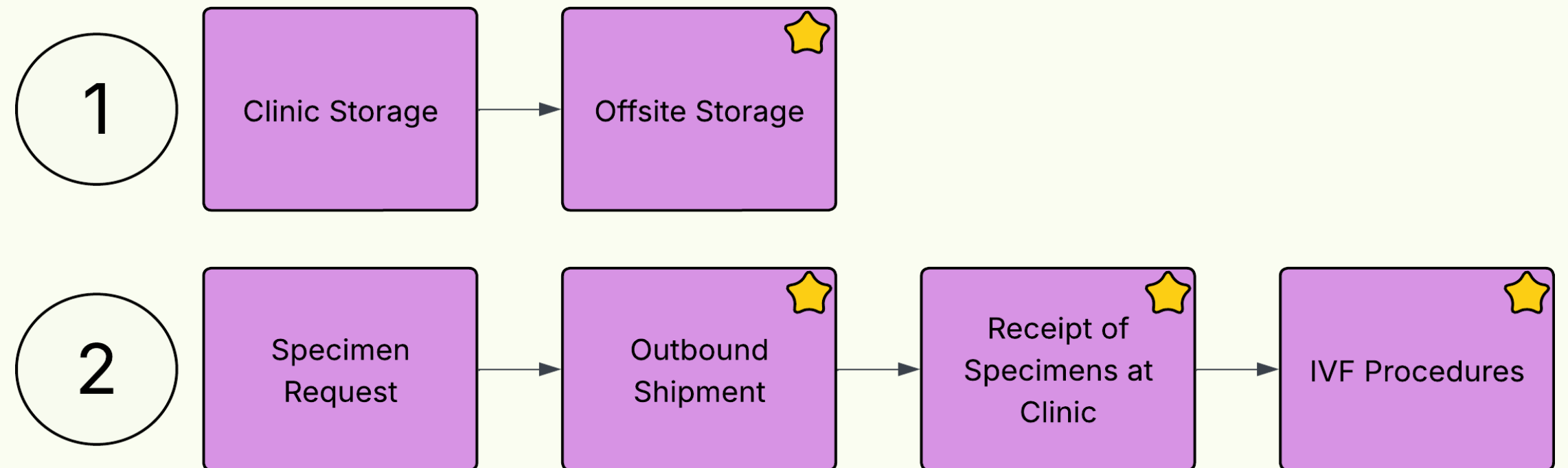


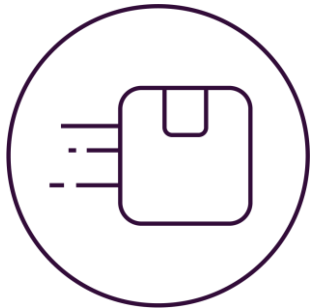
Figure 2. EWS model for off-site storage and e-witnessed procedures (Stars).

Critical Checkpoints



Outbound

Cane, Devices
& Shipper



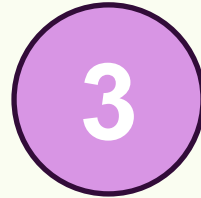
Inbound

Cane & Shipper



Storage

Cane & Storage
Tank Canister





Technology

- 1D/2D codes for unique identification
- RFID for location tracking and recovery
- Image capture scanners
- Cane level visibility

Error Prevention Beyond the Lab

- Catch outbound errors before shipment
 - Use scans at outbound, inbound, and storage movements
 - RFID-assisted recovery without unnecessary handling
-

Questions for Off-site Storage Providers

- How are specimens uniquely identified?
 - How is each specimen movement logged?
 - How do you handle a specimen request?
 - Can our EMR or EWS data be used to reduce manual data entry and mismatch risk?
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Looking Ahead

- Increasing patient expectations for transparency and safety
 - Opportunity for deeper EMR integration
 - Transparent access to traceability for clinics
 - Clinic to off-site storage traceability as a standard of care
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Thank you!

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Q&A