

Research Considerations for Informatics: Designing Solutions with Scientific Integrity

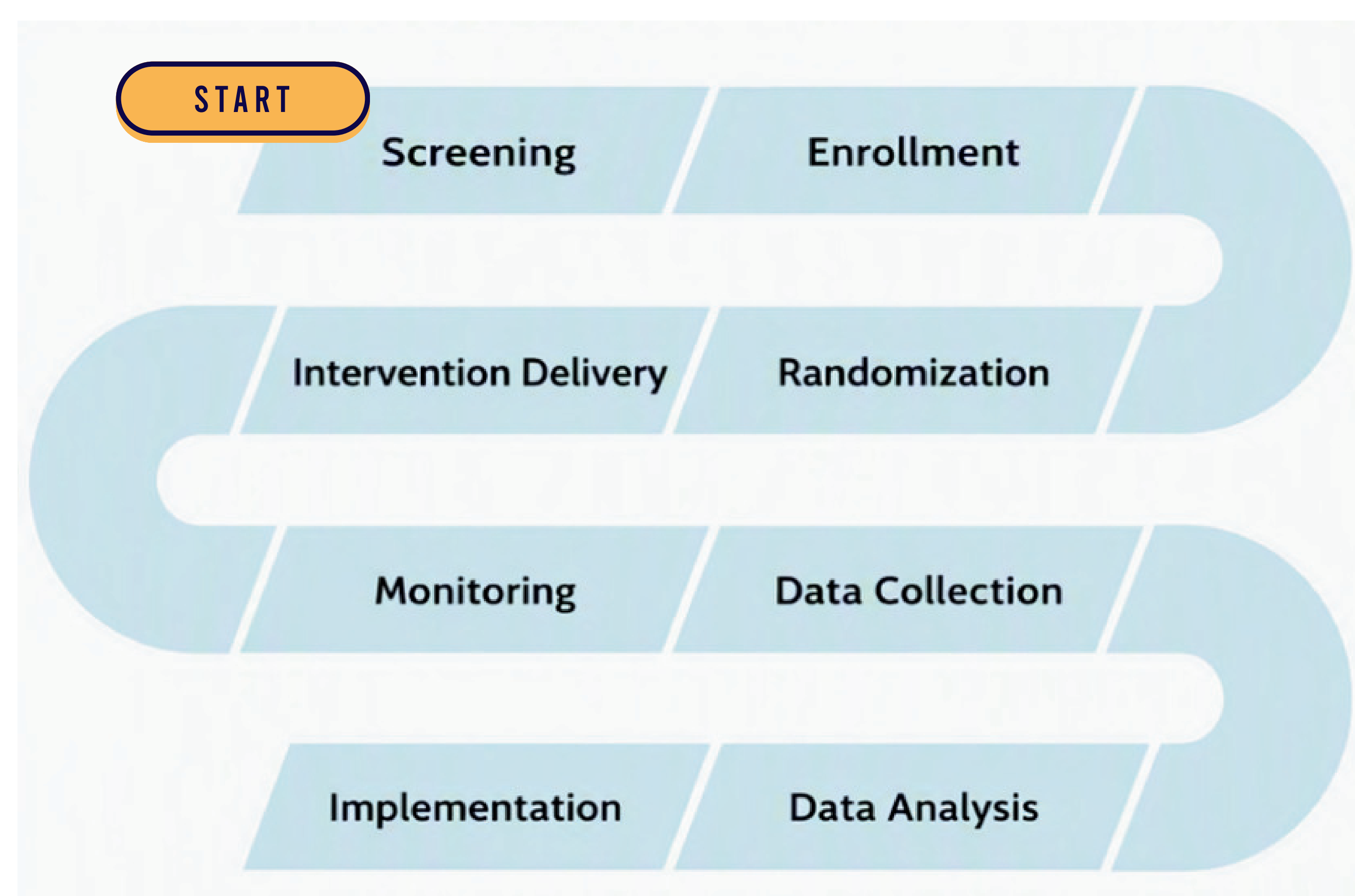
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Abstract

Research informatics requires balancing **what is technically possible** with **what is scientifically optimal**. Using examples from embedded pragmatic trials conducted by the Center for Learning Healthcare, this presentation highlights key considerations for designing informatics solutions that support research while preserving study integrity and minimizing bias.

Clinical Trial Roadmap



Example Trial

Research Question: Does providing clinicians with a model-driven recommendation improve patient outcomes compared with usual care?

- **Intervention group:** Providers treat patients according to the recommendation.
- **Usual care group:** Providers do not receive a recommendation, and provide care as usual.

Participant Screening

Potential Option

Build a report of potentially eligible patients for providers to review and enroll

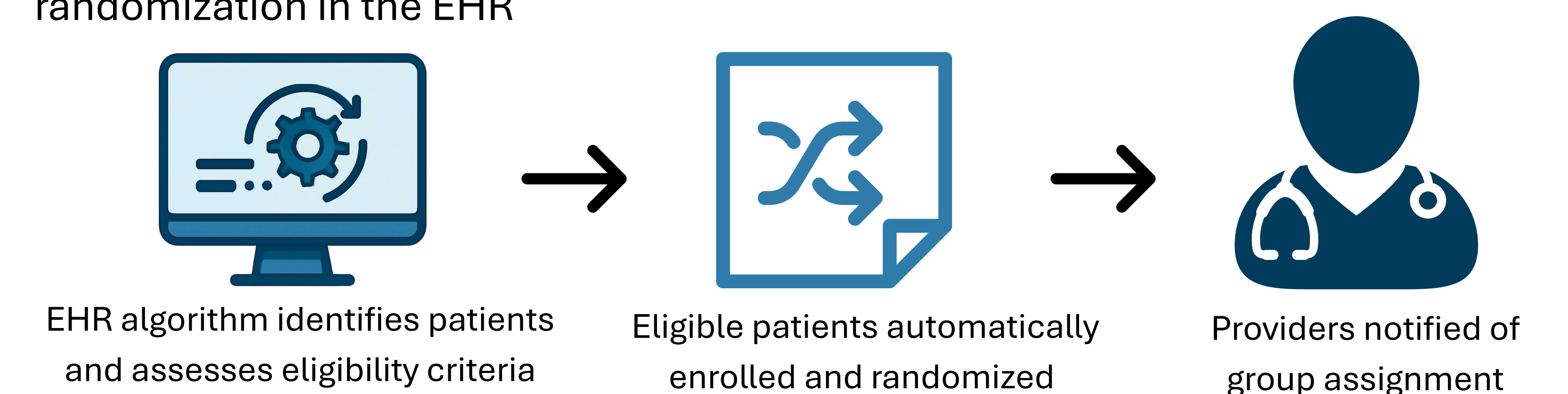


Research Concerns

- Knowledge of eligibility criteria may change provider behavior before randomization
- Selective enrollment may reduce representativeness

Research-Informed Option

Automate assessment of inclusion and exclusion criteria, enrollment, and randomization in the EHR



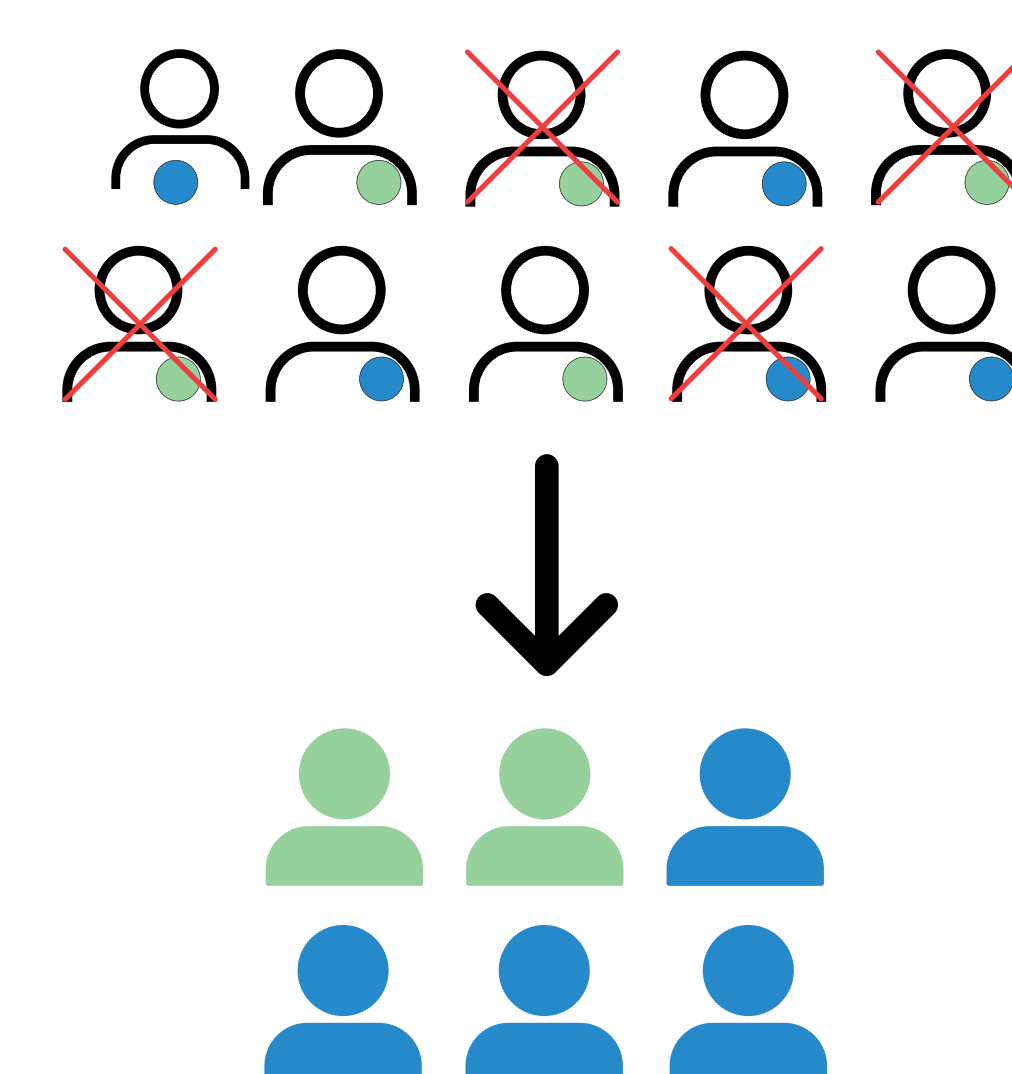
Research Advantages

- Applies eligibility criteria consistently, reducing discretionary enrollment
- Minimizes influence on provider behavior prior to enrollment
- Supports generalizability and representativeness of study cohort

Randomization Timing

Potential Option

Assign potential patients to a group before they are enrolled

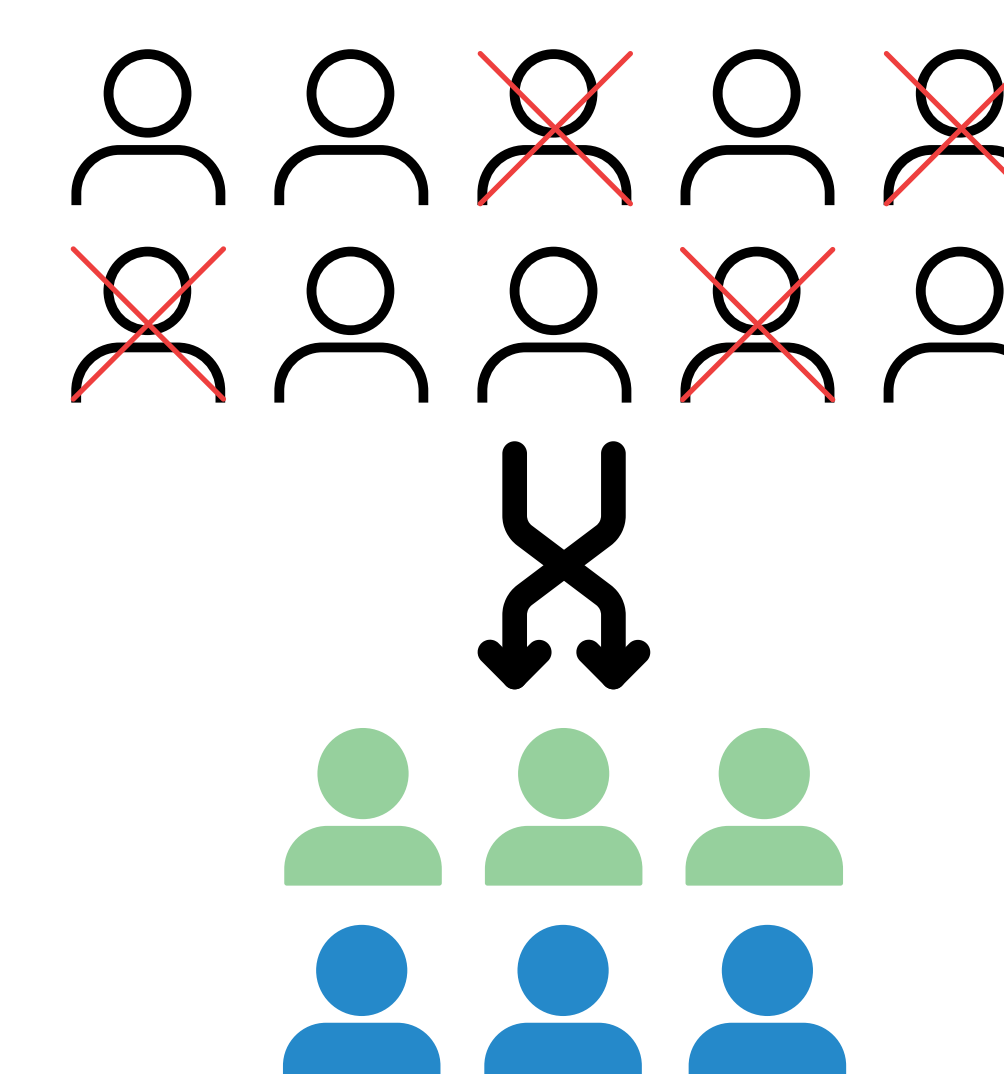


Research Concerns

- Imbalanced groups
- Potential bias in arm assignment

Research-Informed Option

Randomize patients after they have been screened and enrolled



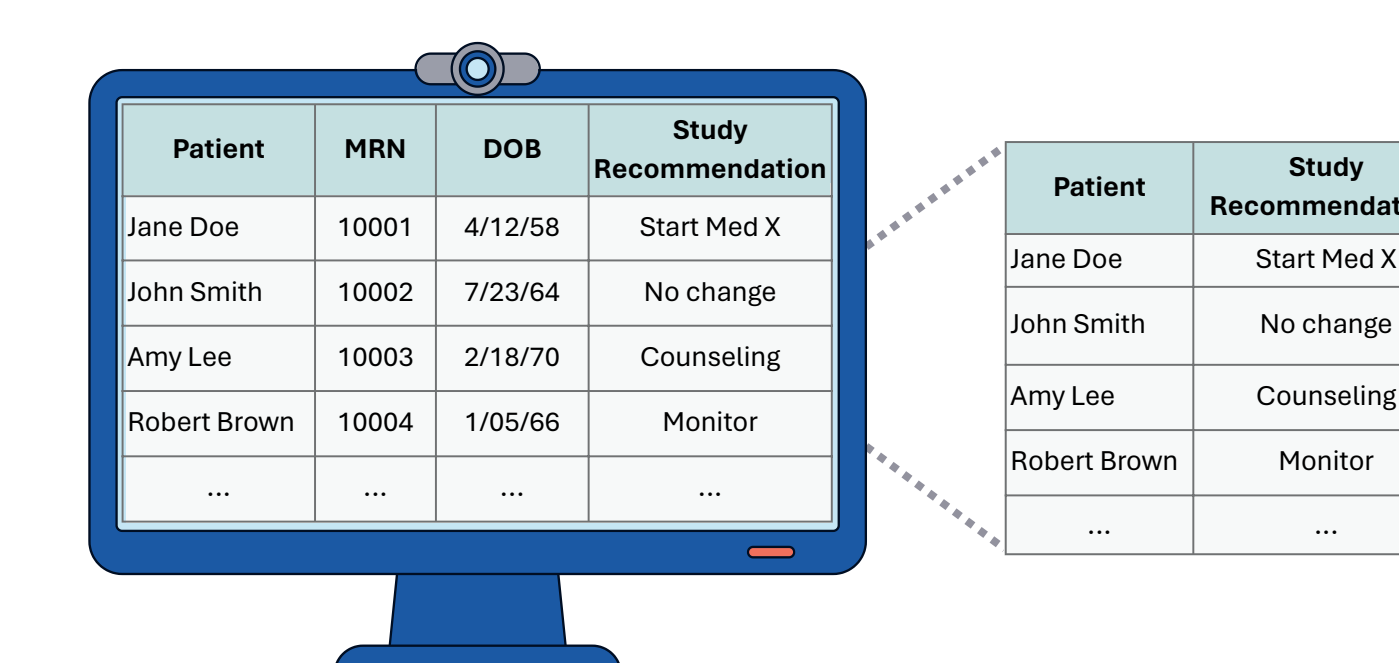
Research Advantages

- Balanced groups
- Unbiased arm assignment

Intervention Delivery

Potential Option

Recommendation displayed in a Patient List column

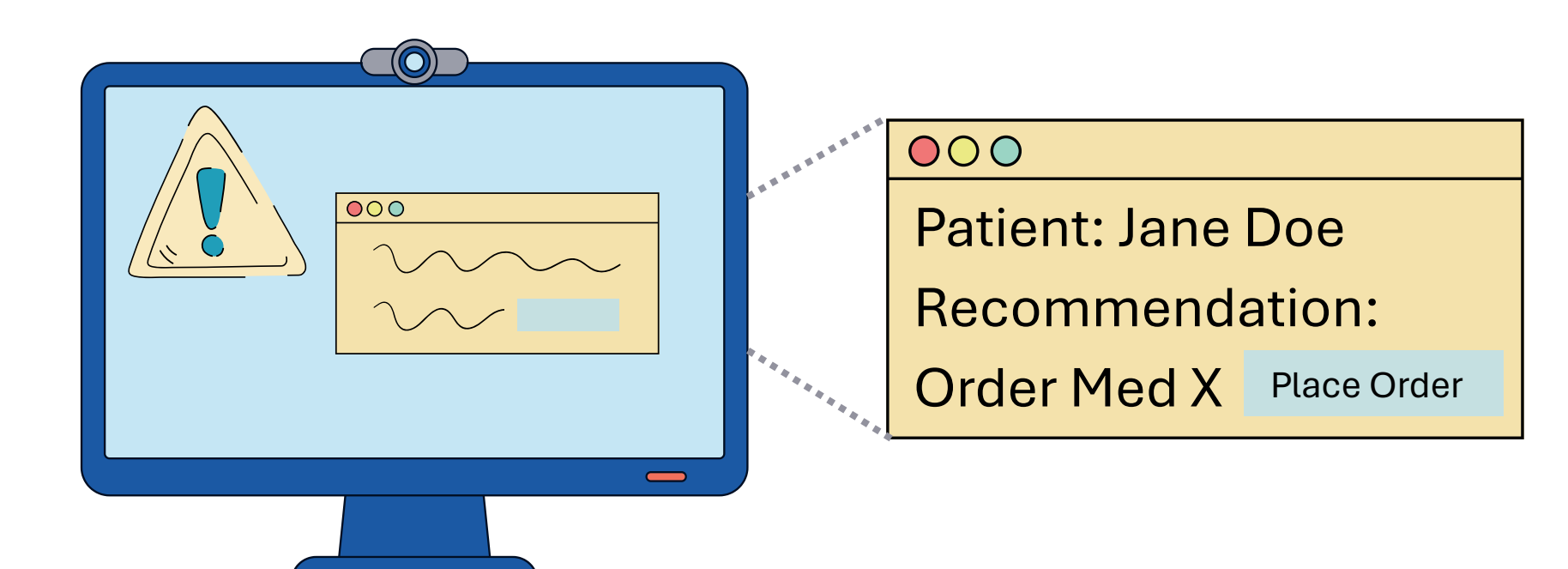


Research Concerns

- Recommendation not actionable at time of delivery
- Not acting on recommendation → less separation between groups

Research-Informed Option

Recommendation alert when the provider opens the patient's chart



Research Advantages

- Actionable recommendation delivered within workflow
- Recommendation only seen by relevant providers → less risk of contamination

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