



Predictive Analytics Framework for Diversity-focused Trial Enrolment : Synergistic Role of Registry Data, Lived Experiences, and Programming Power

RE03

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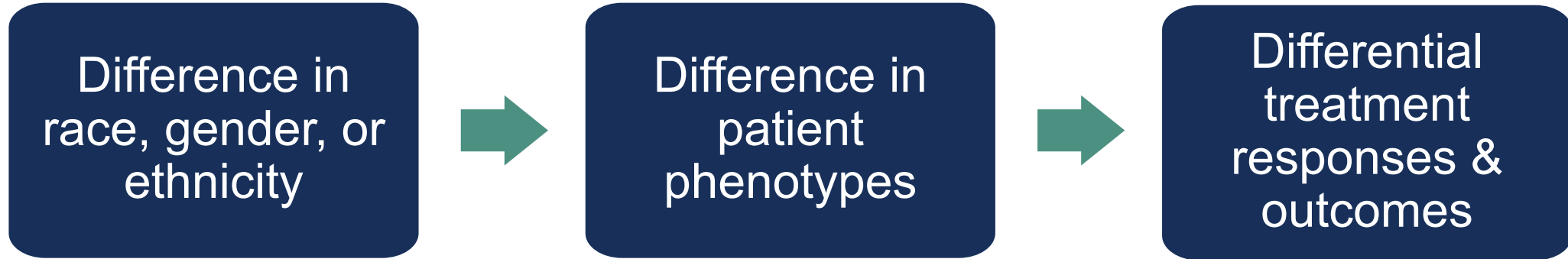
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DISCLAIMER

The views presented are authors' current opinions only. It does not reflect the opinion of any organization nor provides any recommendation for its implementation without contextual applicability.

Overview - Unmet Need



- Overestimated oxygen saturation during hypoxia in communities of color¹
- Lower survival in Multiple Sclerosis (MS) patients with dark skin and hispanics²
- Lower odds of having responses in CoC compared to its counterpart in multiple myeloma US FDA drug approval trials³

Overview – Negative Consequences

Poor participation of minority target population

Great loss (financial and patient trust) due to missed clinical insights

Need for re-visiting the study design



Solution : Three “V”s of RWE – Future...

Variety



Volume



Velocity

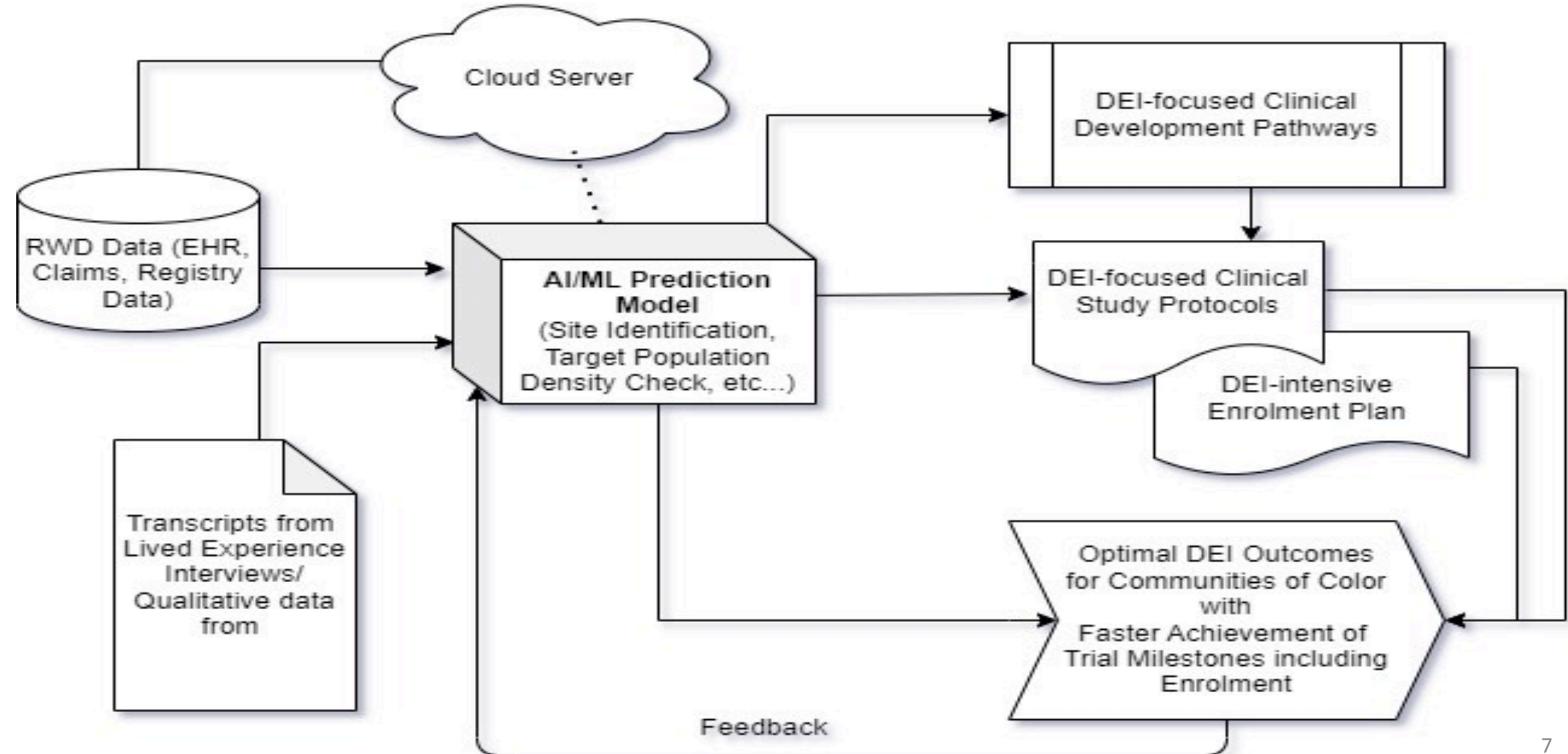


Is RWE for REAL? What Regulatory Says

- Recent accelerated use of RWD
- Regulatory interest → Data Quality does matter!
- Recent guidance documents by EMA on
 - RWD quality
 - Use of metadata catalogue of RWD sources



Prediction Model Framework At-A-Glance



Unique Inputs to the AI/ML Prediction Model

- Unlike CT data, RWD provide pragmatic insights because of several factors: uncontrolled study environment, positive and negative treatment outcomes unlike trial findings with selective reporting, data collection by patients via medical wearables in some cases, patient journey touchpoints in real-time on continual basis.

Clinical Data
Registries,
Patient-
Reported
Outcome
Registries



Prediction Model
Input A
(Quantitative)

URL for ML technology :

<https://www.appliedclinicaltrials.com/view/how-nlp-ocr-and-social-graphs-accelerate-subject-recruitment-for-clinical-trials>

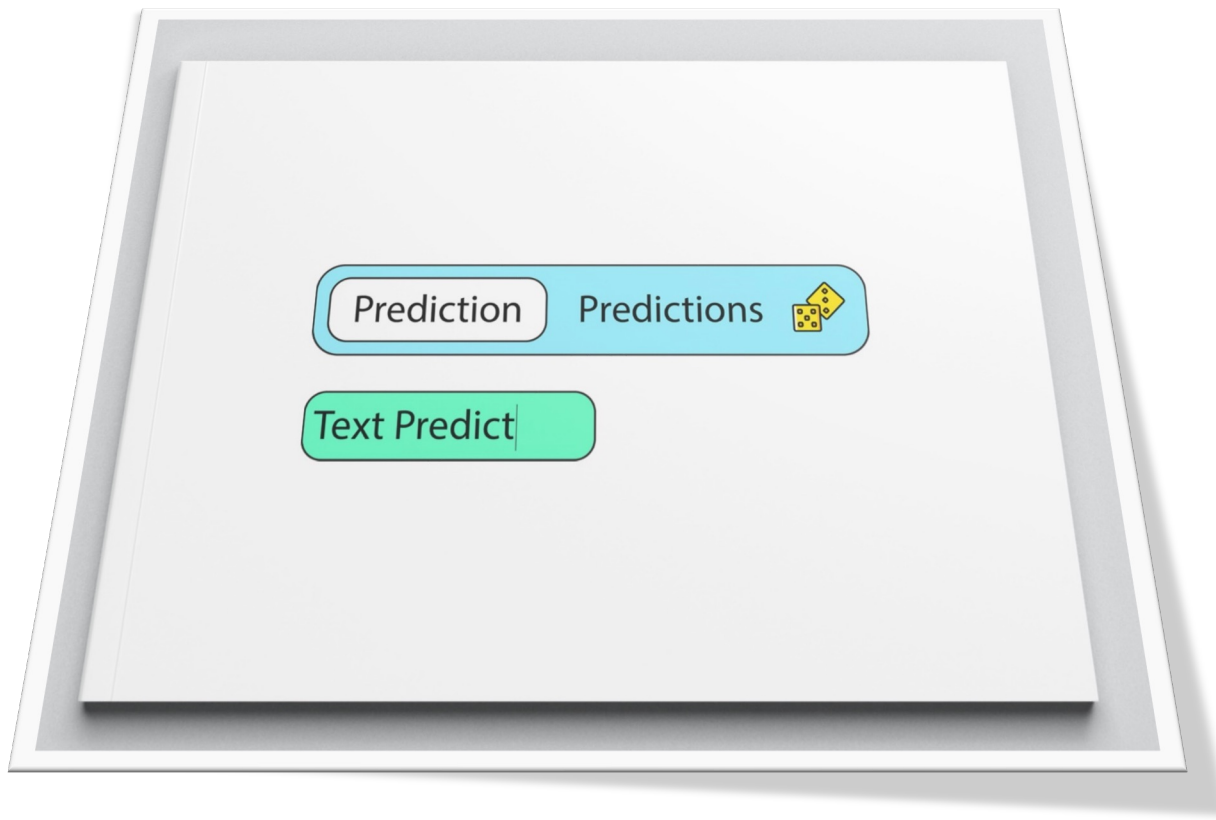


Prediction Model
Input B
(Qualitative)

Experiential
Systems
Opinion Surveys
and
Other
experiential
systems

Potential Applications of Predictive Analytics Framework

Document Development with DEI-specific Auto-Suggestions



Data-driven Prediction with DEI focus



Auto-identification and auto-invite for minority forums for their enrolment inputs

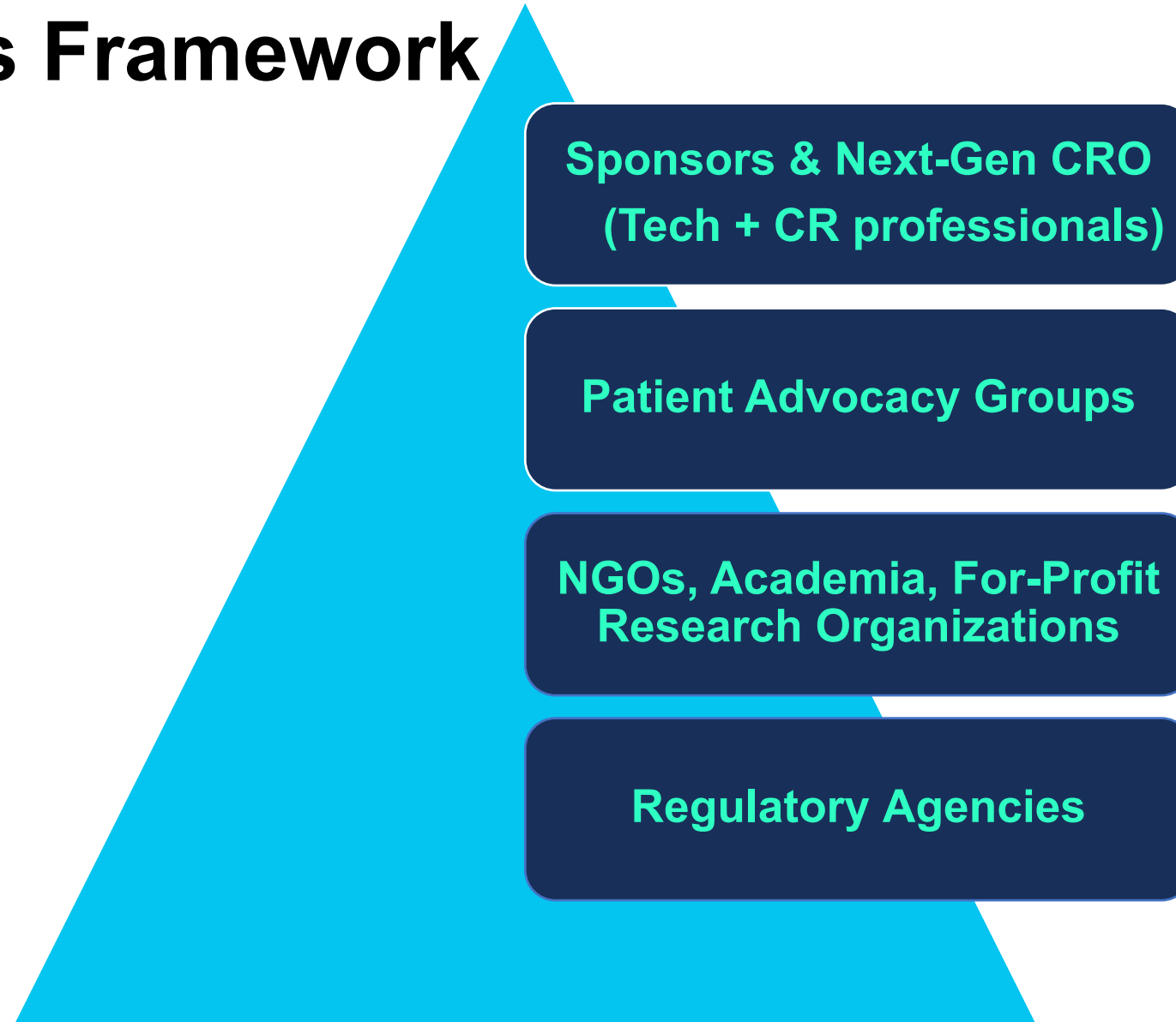


Auto-alerts against potential diversity gap(s) in enrolment plan



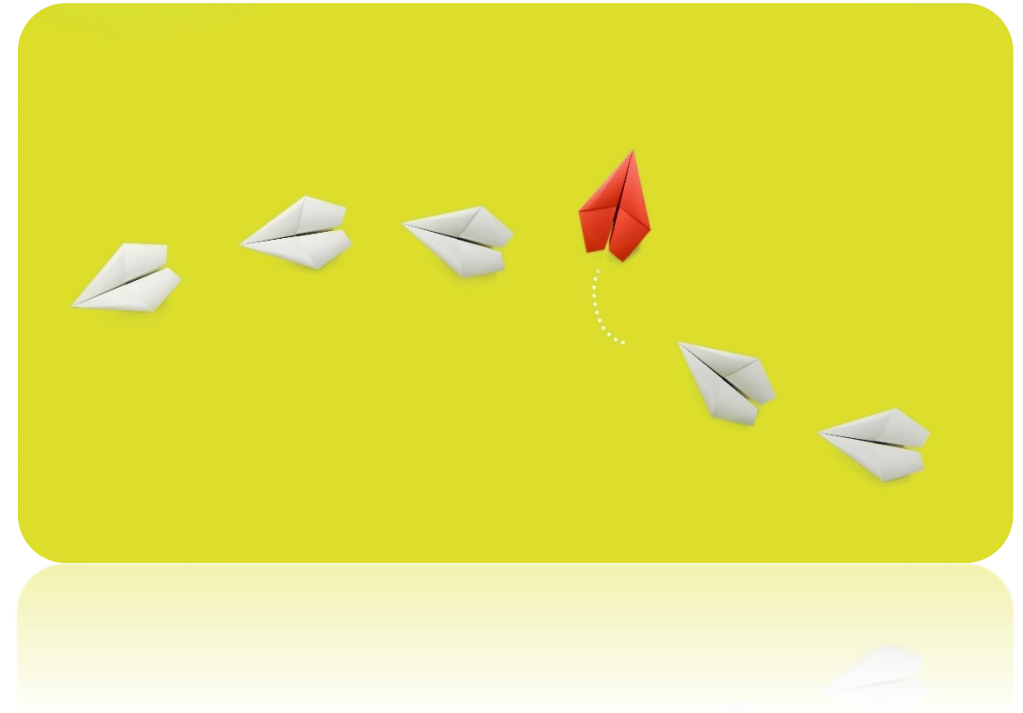
Early knowledge where more minority target population resides

Stakeholders for DEI-focused Predictive Analytics Framework



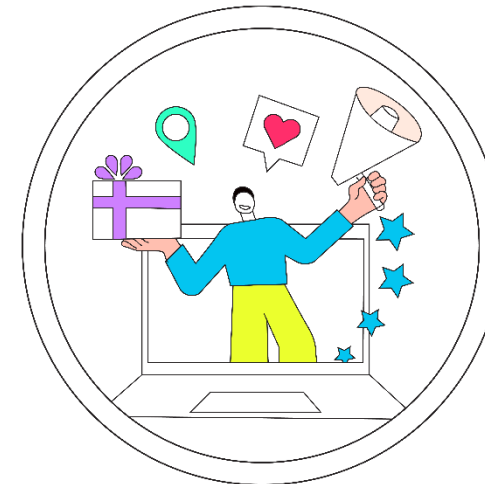
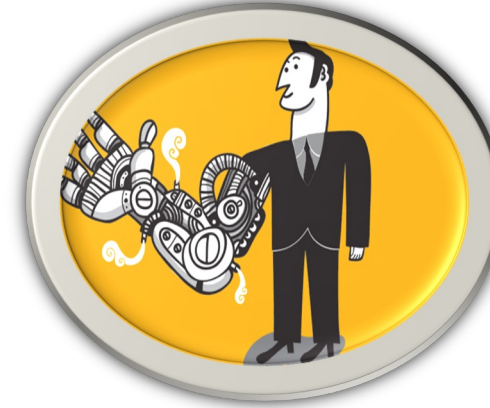
Challenges

- Know-do gap
- Paradigm shift
- Stigma and lack of active participation from minority groups



Action Roadmap

- **3 “E”s** : Integration of Human + Tech - Education , Engagement, and Execution
- Promotion of Interdisciplinary Research
- Minority/Underserved patients as Clinical Trial Diversity Ambassadors
- DEI-focused algorithms and platforms
 - ✓ Tech Development
 - ✓ Tech Validation
 - ✓ Tech Implementation



Take Home Messages

DE&I is crucial consideration for next-gen trial planning & recruitment.

RWD possesses a great potential to revolutionize the existing trial enrollment landscape.

Human-driven, Tech-enhanced, prediction models may envisage DE&I-compliant enrolment outcomes.

Paradigm shift from conventional to prediction-driven
DEI-focused enrolment is difficult
but possible with interdisciplinary efforts.

Reference URLs

1. <https://pubmed.ncbi.nlm.nih.gov/15791098/>
2. <https://pubmed.ncbi.nlm.nih.gov/34536772/>
3. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8941450/>



Thank You

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