SYNERGY-AI: Artificial intelligence based precision oncology clinical trial matching and registry

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Background

- Precision oncology encompasses the implementation of high level of evidence disease-specific and biomarker-driven diagnostic and treatment recommendations for optimized cancer care. Artificial Intelligence (AI), telemedicine and value-based care may optimize clinical trial enrollment (CTE) and cost-benefit.
- The SYNERGY-AI (NCT03452774) protocol and algorithm is an ongoing, international registry for cancer patients evaluates the feasibility and clinical utility of an AI-based precision oncology clinical trial matching tool, powered by a Virtual Tumor Boards (VTB) program, and its clinical impact on patients with advanced cancer to facilitate CTE, as well as the financial impact, and potential outcomes of the intervention.

Approach

- The SYNERGY-AI Registry is an international prospective, observational cohort study of eligible adult and pediatric patients with advanced solid and hematological malignancies, for whom the decision to consider CTE has already been made by their primary providers (PP).
- Using a proprietary application programming interface (API) linked to existing electronic health records (EHR), individual clinical data is extracted, and matched to a parametric database of existing institutional and non-institutional CTs. Machine learning algorithms allow for dynamic matching based on CT allocation and availability for optimized matching.
- Patients voluntarily enroll into registry, which is non-interventional with no protocol-mandated tests/procedures
- All treatment decisions are made at the discretion of PP in consultation with their patients, based on the AI CT matching report, and VTB support.
- CTE will be assessed on variables including biomarkers, barriers to enrollment. Study duration anticipated as approximately 36 months (estimated 24-month enrollment period, followed by 12 months of data collection, to occur every 3 months).
- The primary analysis will be performed 12 months after last subject is enrolled. The impact time to initiation of CTE on Progression Free Survival (PFS) and Overall Survival (OS) will be estimated by Kaplan-Meier and Cox multivariable survival analysis. Enrollment is ongoing, with a target of over 1,500 patients.
- Study start date: January 2018; Estimated primary completion date: December 2021

Eligibility Criteria

- **Study Population:** Observational cohort study of eligible adult and pediatric pts with advanced solid and hematological malignancies, for whom the decision to consider clinical trial enrollment (CTE) has already been made by their primary providers (PP).

Inclusion Criteria:

- Pts with solid and hematological malignancies;
- Pts cancer-related biomarkers (e.g. EGFR, ALK, TRK, ERBB2, ROS-1, MSI, BRAF, BRCA, TMB, PD-L1, Claudin 18.2, POLE) determined by CLIA-certified local laboratory, or next generation sequencing
- Decision to consider clinical trial pre-screening enrollment (CTE) by provider and/or patient

Exclusion Criteria:

- ECOG PS > 2;
- Abnormal organ function unlikely to improve;
- Hospice enrollment

Outcome Measures

Primary Outcome Measures:

- Proportion of patients Eligible for CTE versus Actual CTE

Secondary Outcome Measures:

- Impact of CTE on Overall Survival (OS), estimated by Kaplan-Meier and Cox survival analysis
- Impact of CTE on Progression-Free Survival (PFS)
- Identification of Barriers to CTE: To identify barriers to accruals to clinical trials, as measured and reported by a questionnaire
- Real World Data Analytics: To Analyze Individual Standard of Care Chemotherapy Utilization (nominal), across treatment lines (numeric); data will be combined and aggregated to report chemotherapy utilization rate (%).
- Virtual Tumor Board Utilization
- Time from Intervention to Actual CTE (months)

Patient Workflow

Identification

Pre-screening

NIH U.S. National Library of Medicine

ClinicalTrials.gov

Enrollment

NCT03452774

SYNERGY-AI: Artificial Intelligence Based Precision Oncology Clinical Trial Matching and Registry

Sponsor: Massive Bio

ClinicalTrials.gov Identifier: NCT03452774

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Outcomes

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