The majority of oncology patients receive care outside of large, academic settings. We demonstrate an innovative paradigm for identifying patients with rare genomic findings. Infrastructure and algorithms developed at Foundation Medicine provide comprehensive genomic sequencing for ~1000 cancer patients weekly across the country (the majority in community settings), identifying driver mutations potentially targetable through clinical trials. In many instances, trials may offer the best or only therapeutic options for patients with rare findings. However, conducting clinical trials of novel therapeutics targeting rare molecular variants is challenging. These challenges increase costs of drug development and approval, delaying patient access.

A novel approach is required to enable patients with rare genomic findings to participate in clinical trials. One approach would be to identify patients with relevant genomic drivers identified by CGP, e.g., NTRK1/2/3, ROS1, and ALK fusions broadly across tumor types, adult and pediatric patients, new or treated patients.

In these settings, patients and providers may not routinely consider clinical trial options for relevant genomic drivers identified by CGP, e.g., FoundationOne. In these scenarios, it is challenging for oncologists to develop local networks for potential activation (symbolic representation only, specific activation sites may vary).

Extension of this approach could improve drug development timelines and patient access, advancing precision medicine.

**BACKGROUND**

MODERN CLINICAL TRIALS: OPPORTUNITIES AND CHALLENGES

- In many instances, trials may offer the best or only therapeutic option for oncology patients with rare findings.
- Conducting clinical trials of novel therapeutics targeting rare molecular variants is challenging.
- 80% of cancer patients are treated in community settings, where clinical trials may be less common.
- In these settings, patients and providers may not routinely consider clinical trial options.
- These challenges increase costs of drug development and approval, delaying patient access.

**ELEMENTS OF A SOLUTION**

1. Comprehensive genomic profiling: Foundation Medicine
   - Foundation Medicine provides comprehensive genomic sequencing for ~1000 cancer patients weekly across the country (the majority in community settings), identifying driver mutations potentially targetable through clinical trials.

2. Innovative targeted trial sponsor: Ignyta
   - Ignyta is a precision oncology company developing entrectinib, an orally available, CNS-active TKI targeting NTRK1/2/3, ROS1, and ALK fusions broadly across tumor types, adult and pediatric patients, new or treated patients.

3. Novel clinical trial network: Pharmatech
   - Pharmatech is a just-in-time CRO/SMO which manages an oncology network of more than 340 pre-contracted sites with 2,200 investigators.

**METHODS**

SMART TRIALS ENGINE: ENABLING PATIENT AWARENESS

- Infrastructure and algorithms developed at Foundation Medicine match patients with specific mutations to relevant clinical trials.
- Oncologists at Foundation Medicine, through peer-to-peer outreach, facilitate access by providing trial and site information to helping providers.

JUST IN TIME NETWORKS: ENABLING PATIENT ACCESS

Map representing variable density of clinical trial sites and wide geographic distribution of eligible patients (for example, patients with a targetable genomic driver in a rare tumor type).

**RESULTS**

“LIGHTNING FAST” ENROLLMENT: UNPRECEDENTED ACCESS AND SPEED

- 107 treatment-eligible patients with NTRK, ROS1, or ALK fusions were matched by the SmartTrials Engine.
- 36 (33%) expressed interest in trial participation.
- One patient with NSCLC and CD74-ROS1 fusion was unable to participate at an open trial site due to inability to travel.

Nearby “Just-In-Time” network site identified.
- IRB and contract pre-approval, followed by activation, within 3 days. Total time from patient identification to initiation of therapy was 7 days.

107 treatment-eligible patients identified 36 (33%) expressed interest

**CONCLUSIONS**

- The majority of oncology patients receive care outside of large, academic centers.
- A novel approach is required to enable patients with rare genomic findings to access clinical trials, especially in these community settings.
- We demonstrate an innovative paradigm for identifying patients with rare variants, and through collaborative industry partnerships, facilitate rapid local site activation for patient enrollment.
- Extension of this approach could improve drug development timelines and patient access, advancing precision medicine.

**GENOMIC ENGINE**

- All genomic findings from patients are annotated in a landscape to enable rapid local site activation (symbolic representation only, specific activation sites may vary).

**SMART TRIALS ENGINE**

- Foundation Medicine connects patients to clinical trials.

**PATIENT + PROVIDER OUTREACH & AWARENESS**

- Designing effective outreach for patient and provider connection (Pharmatech).

**GENOMIC RESULTS**

- 1000s of patients
- 1000s of providers
- 1000s of sites

**SMART TRIALS ENGINE**

- Patient / Provider
- Outreach & Awareness

**SCIENTIFIC EXPERTISE**

- Team of scientific / genomic experts
- annotating clinical knowledge & trials

**PARTNERSHIPS**

- Dozens of trial sponsors, institutions, networks, national organizations

**GENOMIC KNOWLEDGE**

- Multiple genomic data sources
- annotating clinical knowledge & trials

**SMART TRIALS ENGINE**

- Foundation Medicine connects patients to clinical trials.

**OUTREACH**

- Foundation Medicine connects patients to clinical trials.

**ONCOLOGY PATIENTS**

- All genomic findings from patients are annotated in a landscape to enable rapid local site activation (symbolic representation only, specific activation sites may vary).

**CONCLUSIONS**

- The majority of oncology patients receive care outside of large, academic centers.
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