

Process Improvement of the Precision Medicine program at Sylvester Comprehensive Cancer Center

An exploration of different models to increase awareness and clinical trial enrollment



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Background

Next-Generation Sequencing (NGS) tests have mushroomed in type and number of genes assayed with a parallel expansion of reported results. Additionally, Precision Medicine (PM) clinical trials have very specific, detailed mutation eligibility requirements.

The Sylvester Comprehensive Cancer Center (SCCC) PM program implemented different models to provide interpretive scientific support and recommendations on mutation-based clinical trial matching. We will describe lessons learned from a Referral PM review and a Virtual PM clinic.

Methods

The PM group comprises of an oncologist, a molecular scientist, and research coordinators.

Referral PM Review:

- Starting May 2021, we publicized an Inbox account for providers to refer NGS tests
- PM group reviewed for matching to ASCO-TAPUR (7), NCI-MATCH (9), mutation target trials (13) or basket trials (5).
- When matched to a clinical trial, PM emails the provider and, if in agreement, the research coordinators are contacted.

Virtual PM Review Clinic:

- Starting December 2021, PM added a Virtual PM (VPM) clinic where all SCCC patients' NGS tests are reviewed.
- Data transfer agreements between SCCC and NGS vendors allows for the VPM clinic to have access to web portal results.
- PM group reviewed for matching to ASCO-TAPUR (7), NCI-MATCH (9), mutation target trials (13) or basket trials (5).
- When matched to a clinical trial, PM emails the ordering provider and, if in agreement, the research coordinators are contacted.

Data:

- PM digitalized all information from Referral and VPM cases in a RedCap database allowing for analyses of the processes implemented.
- Metrics reviewed include the number of clinical trial matches, number consented, enrolled, and the providers' responses to emails.

Results

From May to November 2021, the Referral PM received 116 NGS requests. 42 patients matched to clinical trials (36%); seven enrolled and one was at consent status (total 8 consented) (Table 1).

Tumor Site	Referrals (Percent of Total Referrals)	Clinical Trial Match (Percent of Tumor Site Referrals / Percent of Total Matches)
Breast	68 (59%)	28 (41% / 67%)
Thoracic	11 (9%)	10 (91% / 24%)
Pancreas	5 (4%)	1 (20% / 2%)
GYO	4 (3%)	1 (25% / 2%)
Skin	2 (2%)	1 (50% / 2%)
Myeloma	1 (1%)	1 (100% / 2%)
Colorectal, Head and Neck	17 (15%)	0
Biliary, GE, Sarcoma	7 (7%)	0
Total	116	42 of 116 (36%)
	Consent for Screening	8 of 42 (19%)
	Enrolled on Trial	7

From December 2021 to February 2022, the Referral PM received 52 requests. 14 patients matched to clinical trials (27%); one enrolled (Table 2)

Tumor Site	Referrals (Percent of Total Referrals)	Clinical Trial Match (Percent of Tumor Site Referrals / Percent of Total Matches)
Breast	28 (54%)	7 (25% / 50%)
Thoracic	8 (15%)	4 (50% / 29%)
Gastroesophageal	2 (4%)	1 (50% / 7%)
GYO	1 (2%)	1 (100% / 7%)
Head and Neck	1 (2%)	1 (100% / 7%)
Colorectal, Prostate	8 (15%)	0
Sarcoma, Intestine, Thyroid	4 (8%)	0
Total	52	14 of 52 (27%)
	Consent for Screening	1 of 14 (3%)
	Enrolled on Trial	1

From December 2021 to February 2022, the Virtual PM clinic reviewed 384 NGS tests with 38 patients matched to clinical trials (10%); one patient consented, one patient declined, and five providers were interested. For seven patients, the providers would consider PM clinical trials at progression (Table 3).

Tumor Site	Cases (Percent of Total)	Trial Match Emails (Percent of Site Cases)	Email Responses
Thoracic	63 (16%)	6 (10%)	2 (At progression)
Colorectal	56 (15%)	2 (4%)	1 (Interested)
Breast	42 (11%)	5 (12%)	4 (2 Interested, 2 At progression)
Sarcoma	38 (10%)	4 (11%)	0
GYO	35 (9%)	4 (11%)	2 (1 Pt declined, 1 on therapy)
GU	29 (8%)	6 (21%)	1 (Interested)
Pancreas	21 (5%)	2 (10%)	1 (At progression)
Head and Neck	20 (5%)	5 (25%)	4 (1 consent, 2 on therapy, 1 at progression)
GE	10 (3%)	2 (20%)	2 (1 Interested, 1 on therapy)
Melanoma	9 (2%)	1 (11%)	1 (At progression)
Thyroid	7 (2%)	1 (14%)	0
Neuro; Biliary; Liver	41 (11%); 10 (3%); 3 (1%)	0	0
Total	384	38 of 384 (10%)	20
		Consent	1 of 20 (5%)
		Interested	5 (25%)
		Patient declined	1 (5%)
		Already on therapy	4 (20%)
		At progression	7 (35%)
		Deceased	2 (10%)

Discussion and Conclusion

The better model to continue is the Referral PM Review. The greater enrollment rate is likely because this is a pre-selected group of patients who need clinical trial options. With the VPM clinic, much effort was expended for a lower matching rate, likely due to the wider mixture of various disease stages and treatment history. However, without the VPM, seven patients would not have been asked about a clinical trial and seven patients will not have the clinical trial considered for subsequent treatment.

Future Efforts

If we continue the VPM clinic review, we will focus on tumor sites mutations with enrolling arms (ex: there are no brain PM trials, so those NGS tests should not be reviewed).

The PM program will host an all-site monthly Molecular Tumor Board (MTB) meeting to discuss patient cases which will increase awareness of open and enrolling PM trials. Subsequently, PM will invite community SCCC affiliated providers to the MTB to enhance scientific dialog, awareness of clinical trials, and logistics of enrollment. We will continue to capture data and frequently review for process success.