

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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1. 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.

2. Goals

Metrics reviewed include the number of clinical trial matches, number enrolled, and the providers' responses to emails.

3. Solutions and Methods

The PM group is comprised of an oncologist, a molecular scientist, and research coordinators. Starting in May 2021, we publicized an inbox account for providers to refer NGS tests 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. Starting in December 2021, PM added a virtual PM (VPM) clinic where all SCCC patients' NGS tests are reviewed with ordering providers emailed clinical trial matches. Data transfer agreements between SCCC and NGS vendors allows for the VPM clinic to have access to web portal results. PM digitalized all information from Referral and VPM cases in a REDCap database, allowing for analyses of the processes implemented.

4. Outcomes

From May to November 2021, the referral PM received 116 NGS requests with 42 patients having clinical trial matches (36 percent); seven enrolled and one consented (Table 1). From December 2021 to February 2022, the referral PM received 52 requests with 14 patients having clinical trial matches (27 percent); one enrolled (Table 2). From December 2021 to February 2022, the virtual PM clinic reviewed 384 NGS tests with 38 having clinical trial matches (10 percent); one patient enrolled, one patient declined, and five providers were interested. For seven patients, the providers would consider PM clinical trials at progression (Table 3).

5. Lessons Learned and Future Directions

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 patient 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. Our modification of the VPM clinic will be to focus on tumor sites mutations with enrolling arms (example: there are no primary brain PM trials, so those NGS tests should not be reviewed in depth). In the future, the PM program will host an all-site disease group monthly molecular tumor board (MTB) meeting to discuss patient cases. Subsequently, PM will invite community SCCC affiliated providers to the MTB to

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enhance scientific dialog, awareness of clinical trials, and logistics of enrollment. We will continue to capture data and frequently review for process success.

Figure:

Table 1:

Referral PM (May - November 2021)		
Tumor Site	Referrals (Percent of Total Referrals)	(Percent of Tumor Site Referrals / Percent of Total Referrals)
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 (14%)	0
Biliary, Gastroesoph, Sarcoma	7 (7%)	0
Total	116	42 of 116 (36%)
Referral PM Clinical Trial Match (May - Nov 2021)	Consent for Screening	8 of 42 (19%)
	Enrolled on Trial	7

Table 2:

Referral PM (December 2021 - February 2022)		
Tumor Site	Referrals (Percent of Total Referrals)	(Percent of Tumor Site Referrals / Percent of Total Referrals)
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 (16%)	0
Sarcoma, Intestine, Thyroid	4 (8%)	0
Total	52	14 of 52 (27%)
Referral PM Clinical Trial Match (Dec 2021 - Feb 2022)	Consent for Screening	1 of 14 (3%)
	Enrolled on Trial	1

Table 3:

Virtual PM Clinic December 2021 - February 2022 (Not in Referral PM Group)			
Tumor Site	Cases (Percent of Total Referrals)	Clinical Trial Match Emails (Percent of Tumor 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 said no, 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 Interested, 2 on therapy, 1 at progression)
Gastroesophageal	10 (3%)	2 (20%)	2 (1 Interested, 1 on therapy)
Melanoma	9 (2%)	1 (11%)	1 (At progression)
Thyroid	7 (2%)	1 (11%)	0
Neuro; Biliary; Liver	41; 10; 3 (11%; 3%; 1%)	0	0
Total	384	38 of 384 (10%)	20
VPM Clinic Clinical Trial Match (Dec 2021 - Feb 2022)		Consent for Screening	1 of 20 (5%)
		Interested or asking patient	5 (25%)
		Patient said no	1 (5%)
		Already on therapy	4 (20%)
		At progression	7 (35%)
		Deceased	2 (10%)