The Oncologist
The official journal of the Society for Translational Oncology

Supplemental Tables for:
Academic Cancer Center Phase 1 Program Development
Arthur Frankel et al.

Table 1. Phase 1 Organization*

Site	Properties				
	Structure	Leader	Leader Reports	Manager	Meeting with leadership
1	B	3	6	0	A
2	T	1	2	1	A
3	B	5	1	5	W
4	T	1	1	1	W
5	B	1	1	0	Q
6	T	2	1	1	A
7	B	1	2	1	Q
8	T	1	1	1	M
9	B	1	1	2	A
10	B	1	1	2	T
11	T	1	1	1	W
12	B	1	2	0	Q
13	B	2	2	0	N
14	T	1	2	3	M
15	I	0	1	1	M
16	I	1	1	0	W

*B, basket; T, total; I, integrated; A, annual; W, weekly; M, monthly; T, every two weeks; N, none.

The Oncologist
The official journal of the Society for Translational Oncology

Supplemental Tables for:
Academic Cancer Center Phase 1 Program Development
Arthur Frankel et al.

Table 2. Phase 1 Personnel*

Site	PIs	Coord†	Nurse	Pts/Coord-Nurse	Percent turnover	Acuity index	Reg	Contr	Finan	Pharm tech	Nav	Pharm	Admin
1	42	30	4	7	18	Y	0.25	0	0	5	1	1	0
2	11	12	1	6	44	Y	1	1	0	2	0	1	1
3	59	28	23	10	2	Y	3	0	1	2	2	1	4
4	5	6	3	7	2	N	1	3	1	1	1	1	1
5	8	3	0.5	30	70	N	1	0.06	0	0.125	0.5	0.25	0
6	17	16	0	28	25	Y	4	2	3	0.5	0	0.8	1
7	15	15.5	2	10	33	N	1.5	0.2	0.2	0	0	0.3	0
8	11	20	4	8	30	NA	6	0	0	2	1	1	0
9	35	10	0	35	0	N	2.9	0.5	1.8	0.5	0	1	1
10	18	2	2	26	0	N	1	1	1	1	1	1	1
11	30	3	3	50***	33	Y	1.5	0	0	2	1	1	2**
12	13	5	2	57	14	N	5	1	0.3	0.7	0	1	1
13	18	3	0	57	0	N	2	1	0	2	0	1	1
14	59	20	13	27	25	N	3	2.7	0.3	3	1	3	2
15	18	4	3	14	0	N	1.5	0.2	0.2	1	0	1	0.2
16	13	0.5	2	47	NA	N	0.75	NA	0.5	0	0	1	0

*PI, principal investigator; Coord, coordinator; Pt, patient; Reg, regulatory; Contr, contracts; Finan, financial-spreadsheets & budgets; Pharm tech, pharmacology technician; Nav, navigator; Pharm, pharmacist; Admin, administrative assistant; Y,yes;N,no; NA, not available.

†Includes data entry technicians.

**Admin at site #11 has PhDs help with preparation of LOIs, protocols, grants.

***Site #11 transferred patients after initial intense PK/toxicity assessment period to disease-oriented teams. Further, breast phase 1 studies managed by breast disease-oriented team at remote site. So patients/coordinator-nurse lower in practice than 50.

The Oncologist
The official journal of the Society for Translational Oncology

Supplemental Tables for:
Academic Cancer Center Phase 1 Program Development
Arthur Frankel et al.

Table 3. Institutional Commitments to Phase 1*

Site	Adjacent facilities	Philanthropy /yr	Marketing	Startup fees/ indirects	Travel/ lodging	Unique resources
1	0	5 million	Y	13K, 35%	0	GMP
2	L	0	N	16K, 30%	0	ARI
3	L	0	N	20K, 39%	R	GMP, PK
4	F, E, I, L	0	Y	13K, 26%	R	EMR, Molecular Imaging
5	E, I, L	0	Y	10-15K, 30%	0	Tissue Bank
6	L	0	N	20K, 27%	R	CT
7	L	0	Y, web/email	NA	0	Growth, Geography
8	E,I,L	0	N	15K,32%	T	Health care network
9	0	0	N	13K or 20K,36%	0	FAST track startup,
10	F,E,I,L	0	Y	NA	R, T	Molecular profiling
11	E,I	0	N	15K, 29%	0	Correlative science
12	E,I,L	0	N	NA	0	First-in-human, Minority recruitment
13	L	0	N	15K,29%	0	NGS
14	E,I,L	2.5 million	Y	10K,27%	0	Serial tumor bx, rapid autopsy
15	F,E,I,L	0	N	8.5K,35%	0	Community outreach
16	0	0.2 million	N	NA, 26%	0	Well integrated, low cost, correlative science

*L, laboratory; ind, indirect costs; GMP, Good Manufacturing practice facilities; ARI, advanced research imaging; R, room; PK, pharmacokinetics.; EMR, phase 1-specific electronic medical record; NGS, next generation sequencing of tumorsF, office; E, exam room; I, infusion room; L, laboratory; CT, cell transplant; NA, not available; T, travel; 0, none.

The Oncologist
The official journal of the Society for Translational Oncology

Supplemental Tables for:
Academic Cancer Center Phase 1 Program Development
Arthur Frankel et al.

Table 4. Phase 1 regulatory issues*

Site	Deviations	Meeting with PRMC, DSMC, IRB	Q/A reviews	Q/C reviews/yr	Phase 1 meeting	Mean time to trial opening (mos)
1	Y	N	C	222	W	5
2	N	N	P	3/trial	W	8
3	Y	PRMC, IRB	P	1/trial	W	3.5
4	Y	DSMC, PRMC	P	4/trial	W	3.5
5	Y	N	P	2-4/trial	W	5
6	Y	DSMC, Western IRB	P	1/trial	Biweekly	4 industry and 6 IST
7	N	DSMC, PRMC, IRB	P	1/trial	W	3
8	N	DSMC, PRMC, IRB	P	4/IST	W	4.5
9	Y	PRMC	P	1/trial	W	2 FAST and 3.5 industry
10	Y	PRMC	W	1/trial	W	2.5
11	N	PRMC	P	2-4/trial	W	4.5
12	N	DSMC, PRMC, IRB	C	4/trial	W	3
13	Y	N	A	4/trial	W	8
14	Y	DSMC,PRMC,IRB	M	1/trial	W	2.5
15	Y	DSMC	P	2/trial	M	6
16	Y	DSMC, PRMC, IRB	P	1-4/trial	W	4

*Y, yes; N, no; C continuous; P, periodic; W, weekly; NA, not available; FAST, fast track startup; A, annual; M, monthly.

The Oncologist
The official journal of the Society for Translational Oncology

Supplemental Tables for:
Academic Cancer Center Phase 1 Program Development
Arthur Frankel et al.

Table 5. Phase 1 study properties

Site	Trials	Median sites/trial	"Basket" trials	Heme trials	ISTs	Patients /yr*	IST patients /yr*	Avg no patients /trial	Ratio IST /total trials	Ratio phase 1 pts/total new pts	Avg no patients/ IST
1	105	5	21	58	23	222	81	2.1	0.22	.05	3.5
2	32	6	8	10	8	75	40	2.3	0.25	.02	4.3
3	122	14	49	21	24	711	169	10	0.20	.10	7
4	12	7	7	3	0	60	0	5.4	0	.01	0
5	24	8	23	1	5	89	17	3.7	0.21	.05	3.4
6	40	10	22	6	2	441	26	11	0.05	.02	13
7	29	8	13	13	3	170	23	5.9	0.10	.03	8
8	81	8	23	1	2	166	12	2.0	0.02	.03	6
9	156	7	53	52	28	576	204	3.7	0.18	.07	7.3
10	29	16	7	10	5	105	37	3.7	0.17	.01	7.4
11	91	10	35	24	10	304	46	3.3	0.11	.05	4.6
12	58	7	27	8	10	400	100	6.9	0.17	.12	10
13	56	12	24	23	3	173	13	3.1	0.05	.03	4.3
14	262	7	91	61	39	962	203	3.7	0.15	.10	5.2
15	38	9	4	27	5	96	31	2.5	0.13	.03	11
16	29	6	4	5	10	118	46	4.0	0.35	.03	4.6

*Includes months in 2015 and 2016

[1] DSMC documents at www.nidcr.nih.gov/Research/ToolsforResearchers/Toolkit/DSMBGuidelines.htm and cancercenters.cancer.gov website and Documents in search bar.
†Phase 1A trials are first-in-human dose escalation studies. Phase 1B trials expand the number of patients treated at the MTD in a novel disease cohort or combine the drug with a second therapy in a limited dose escalation schema. Correlative science phase 1 trials employ institutional experimental laboratory or imaging biomarkers. ISTs are based on investigator science or clinical research and may use locally generated agents.