Clinical Science

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Agenda

- Clinical Trial Accrual & Activation Time Lines
- Clinical Research Growth at Moffitt
- Changes in PRMS
- ORIEN Clinical Research
- Clinical Research Retreats

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Clinical Intervention Trial Accrual by Sponsor Type

CY	Institutional	Industry	Externally Peer Reviewed	National	Total
2016	229	569	20	82	**900**
2017	336	620	26	63	**1045**
2018	**426**	629	**60**	76	**1191**

Diversity Accrual: All Intervention Trials

CY	African American/ Black		Hispanic/Latino		Women	
2016	152	7.8%	222	11.4%	997	51.1%
2017	116	6.7%	149	8.6%	883	51.2%
2018	88	4.9%	253	14.0%	944	52.2%

- AA/Black patients are 6.0% of cancer cases in our catchment area and 5.2% of patients seen at Moffitt
- H/L patients are 5.0% of cancer cases in our catchment area and 7.3% of patients seen at Moffitt
- Women are 47.0% of cancer cases in our catchment area and 47.5% of patients seen at Moffitt

Diversity Accrual: Clinical Intervention Trials

CY	African American/ Black		Hispanic/Latino		Women	
2016	45	5.0%	67	7.4%	424	47.1%
2017	62	5.9%	78	7.5%	477	45.6%
2018	57	4.8%	103	8.7%	595	50.0%

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Minority Clinical Research Committee

- Sub-Committees
  - Catchment Area Research (Vadaparampil, Springer, Green)
  - Moffitt Clinical Research Education (Moffett, Soliman)
  - Clinical Research (Sullivan, Gray)
- Support of Intervention Trials Addressing Minority Disparities
  - Prostate cancer
    - Two trials: validation of Decipher test and intervention trial with predictive biomarkers (Yamoah)
    - Adaptive clinical intervention trial (Zhang)
  - Allogeneic HSCT (Pidala, Bajanyan, Elmariah)
  - Supportive care: In-patient glucose control (Pabbathi)
- VAH Partnerships for Trials

Clinical Intervention Accrual By Federal Sponsors

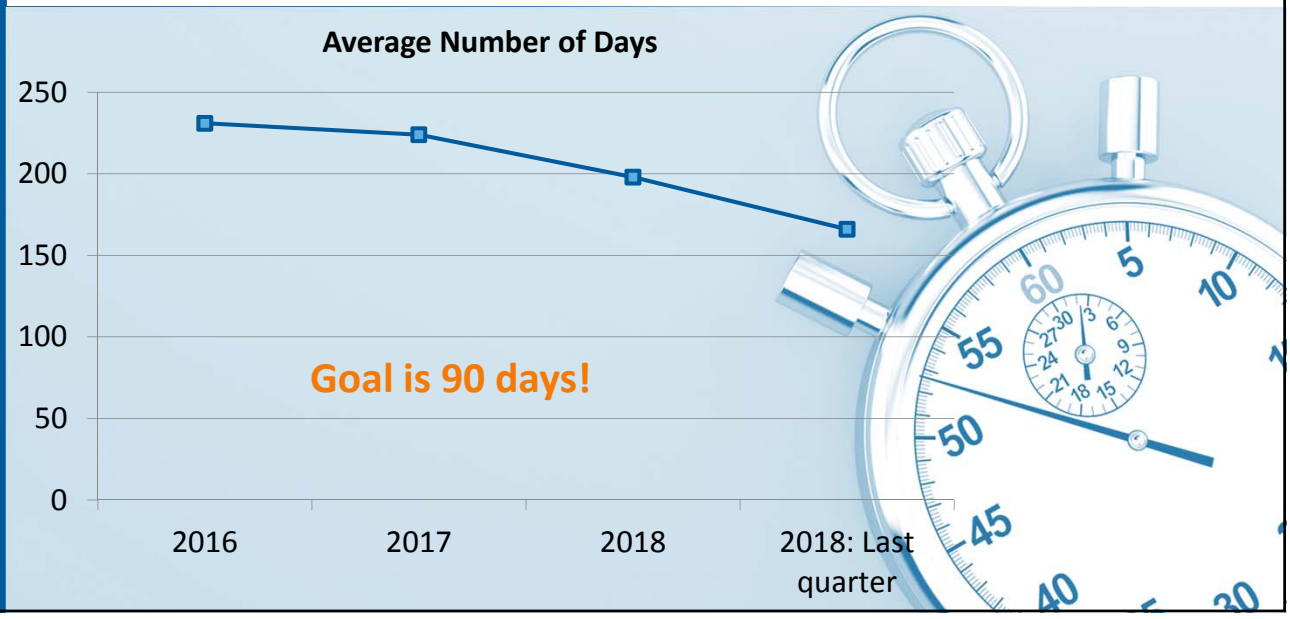
NCI National Clinical Trials Network
a National Cancer Institute program

	NCTN								Total	
	SWOG	NRG	ECOG-ACRIN	Alliance	BMT CTN	CITN	NCIC	UM1	#	%
2016	38	23	4	4	11	1	5	20	106	(11.8%)
2017	30	9	3	6	12	3	0	26	89	(8.5%)
2018	24	6	11	16	20	0	0	**58**	135	(11.4%)

All Intervention Trial Accrual by Program (CY 2018)

	Treatment	Supportive Care	Prevention	Total
CBMM	944	6	23	973
IMM	208	0	16	224
CBE	9	0	0	9
HOB	4	81	52	137
CE	26	0	439	465
Total	1,191	87	530	1,808

Clinical Intervention Trial Activation Trends: 2016 - 2018



Activation Timeline Strategies

- Task Forces in focused areas
  - Regulatory: Increased startup support (3.0 FTEs)
  - Calendar/Pharmacy:
    - Realigned calendar build with CT Finance Office (outsourced to Oncore)
    - FTE for pharmacy order sets.
  - Trial Operations
    - Expectations checklist rolled out to sponsors
    - Increased start-up support (3.0 FTEs)
- Dashboard tool in process for better tracking of trials (Insights-Forte)

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Clinical Research on Moffitt Campuses

- Magnolia Campus
  - CRU 4,100sf
  - 16 Rx stations (9 chairs + 7 beds)
  - IDS to 3rd floor hospital
  - Solmaz Sahebjam, MD, Leader Phase 1 Program
- Shultz Outpatient Clinic on the McKinley Campus
  - CRU (5 chairs + 3 beds)
  - Hung Khong, MD, Medical Director
- Moffitt at International Plaza
  - 40,000sf
  - 24 SOC infusion chairs
  - Pharmacy update


Magnolia Campus

Moffitt at International Plaza


Shultz Outpatient Clinic

Clinical Research Growth Plans: Infrastructure

- Clinical Research Units
  - Expand CRU space at Magnolia & extend hours (16 → 21 Rx stations)
  - Expand capacity at McKinley (ACLS facility)
  - Extend research capabilities to MIP (~50% Magnolia capacity)
- Investigational Drug Services space & FTE expansion (all CRUs)
- Outsourcing services
  - EmergingMed.com (clinical trial navigator)

Clinical Research Growth Plans: Partnerships

- Memorial Hospital West (malignant heme & cellular therapy)
- VAHs
  - James Haley VA
  - Bay Pines VA
- BayCare (radiation oncology trials)
- Advent Health

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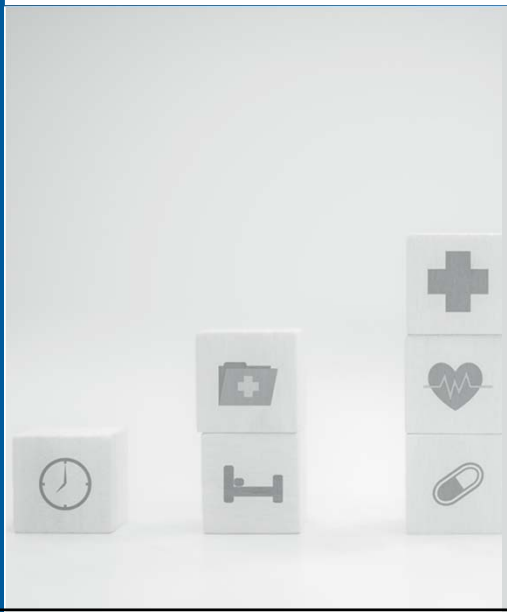
Major Changes for PRMS



- **Scientific Review Committee**
  - First ever multi-institutional SRC (ORIEN)
  - Modified definition of quorum to >50% of members present
  - Added members with specific expertise
- **Protocol Monitoring Committee**
  - Expanded membership and role of PMC to include the review of all monitoring reports & audit reports
- **Feasibility Review of Clinical Intervention Trials**

PMC & SRC Membership

	PMC	SRC Holly	SRC Magnolia
Members	**12**	**18**	**20**
Senior	4	7	1
Associate	4	3	14
Assistant	2	7	4
N/A	2	1	1
Expertise			
Med Onc/Heme	3	5	6
Surgeon	2	3	2
Radiation Oncologist	**1**	**2**	**3**
Radiologist	0	1	1
Biostatistician	3	2	2
Pharmacist	1	1	1
Pathologist	**0**	**2**	**2**
BMT	1	0	2
Basic Scientist	**0**	**2**	**2**
Nurse	1	0	0

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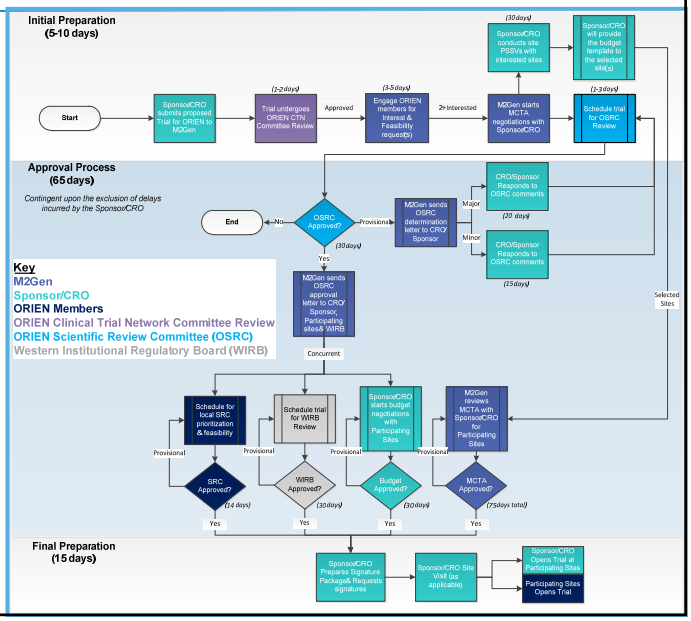
ORIEN Clinical Trials Network: Commitment to Expedited Trial Activation

IRB, scientific review, contracting and budget discussions are being centralized and harmonized across ORIEN Member sites to ensure rapid activation of trials

Item	Description
Single IRB ✓	▪ ORIEN Members using single IRB (WIRB)
Single SRC ✓	▪ ORIEN operates a single SRC, approved by NCI and hosted at Moffitt
Single Trial Budget	▪ ORIEN goal to centralize budgets for clinical trials
Single Master Trial Agreement ✓	▪ ORIEN & M2Gen developed a Master Clinical Trials agreement

ORIEN Clinical Trials Network Workflow

- Detailed process in place
- Goal for trial activation is 90 days



ORIEN Clinical Trials

Trial Status	Number
Open	3 (2 IIT)
Pending/In Development	6 (1 IIT)
Moffitt Participation	2 (open) 4 (pending)

- Using ORIEN Avatar data to enrich for eligible patients
- For example:
  - BRCA 1/2 mutations in OC
  - HRAS mutations in H&N Ca
  - PDL-1 in NSCLC umbrella trial
  - WT TP53 in NHL trial
  - CD19+ B-cell NHL trial

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Clinical Research Retreat (July 20, 2018)

Building on Success and Best Practices

- Jeff Lancet: **Heme Program**
- Fred Locke: **ICE-T Program**
- Brian Czerniecki: **Multi-D Breast Program**
- Lou Harrison: **Radiation Oncology**
- Bob Gatenby: **Evolution and Cancer Treatment**
- Scott Antonia: **Thoracic Program & Trial Lead**
- Solmaz Sahebjam: **Phase 1 Trials**

- **Optimizing Clinical Trial Portfolio**
- **Maximizing Impactful Trials**

✓ **3 actionable strategies**
✓ **Deployable in 6-12 months**
✓ **Focus on strategies that are within our control**

Work Groups Developed Strategies

One Highest Priority Strategy at Each Level

Faculty	Program	Institutional
Educator/Investigator Expectations	Optimize Clinical Trial Lead	Optimize Trials Across Moffitt Locations
McIver	Lancet	Sullivan
Czerniecki/Khushalani	Gray/Sahebjam	Soliman/Locke

Exec Sponsor

Strategy Leads

Phase 1 Program Retreat (September 28, 2018)

- 25 attendees
- 3 work groups
  - Develop Phase 1 core leadership team
  - Reformat Phase 1 meeting
    - Integrate CBMM meeting & medical oncology grand rounds
  - Phase 1 clinical trial activation
- Phase 1 fellowship program

Comprehensive Summary

	Campus Specific			Trial Activation	CR Retreat	Phase 1 Retreat	Trial Expansion
	Magnolia	McKinley	MIP				
Short Term (≤ 6 m)	Complete space plans	Code team active	Complete space plans	(170 d)	Final output WG 1 & 2	Reformat meeting	At MHS, Bay Care
Intermediate (6 m – 1 yr)	Expansion complete (+ IDS)	Pharmacy complete	Limited accrual on trials; pharmacy	Average 140 d	Ongoing WR 3	Core team operational	At VA, (Advent Health)
Long term (1 – 2 yr)	Extend hours?		Open CRU	Average ~90d	Ongoing WR 3	Activation 90 d	

Questions

- Is target of 10% intervention trial accrual on Federally sponsored trials adequate?
- Is target of >40% intervention trial accrual on IITs appropriate?
- Is 90 days average for clinical intervention trial accrual realistic?
- Concerns about prioritizing Phase 1 trial activation?