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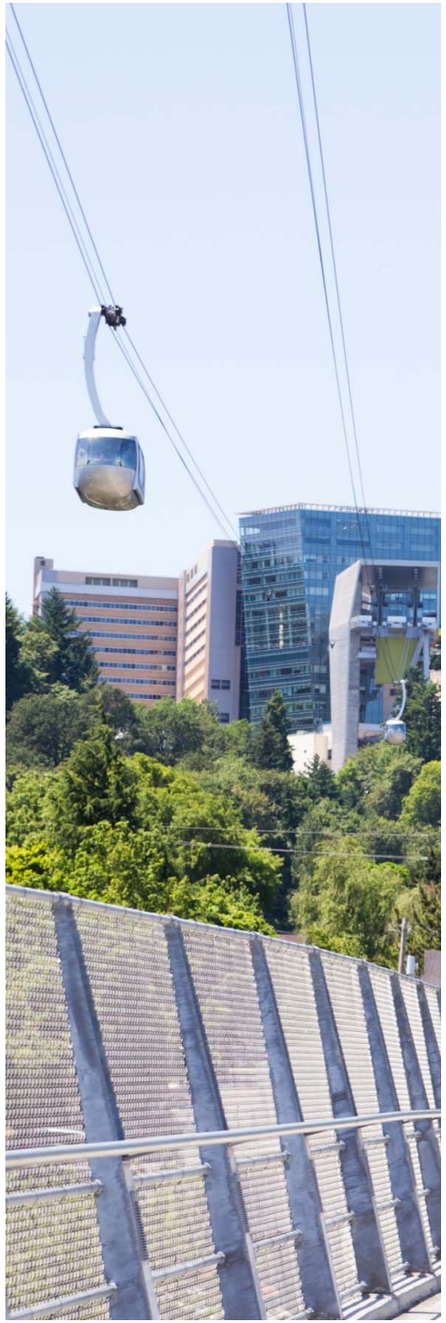
Transitioning from Local IRB to CIRB Oversight: A Case Study

Date: October 12th, 2017

Presented by: Lindsay Chandler**,** Regulatory Project Manager
OHSU Knight Cancer Institute



Overview

- Background
- Challenges to Implementation
    - eIRB system
    - Consent form
    - Conflict of Interest
- Lessons Learned
- Bonus: OHSU Regulatory Project Manager Dashboard

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Background

- The Oregon Health and Science University (OHSU) Institutional Review Board (IRB) oversees all human subjects research at OHSU, the Knight Cancer Institute, and the Portland VA hospital.

- In 2014, National Cancer Trials Network (NCTN) released a mandate that gave participating institutions the option to have study oversight change over to Central IRB (CIRB) for the National Cancer Institute.

- Following an internal audit of OHSU cooperative trials in 2015, the decision was made to transfer all NCTN studies to CIRB, with the intention of streamlining submission and approval processes.

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Challenges to Implementation
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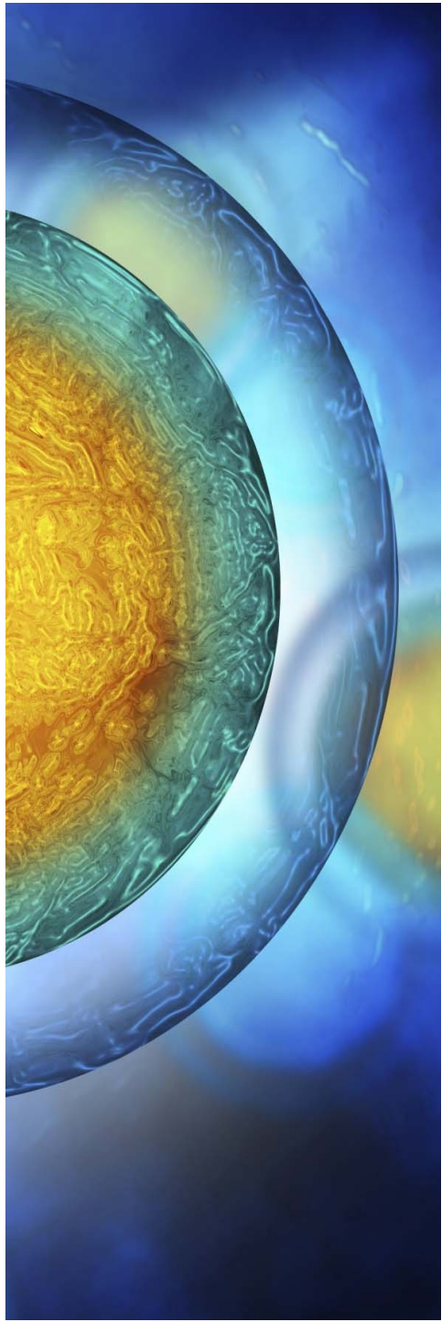

eIRB system

- **<u>Challenge:</u> Distinguishing between CIRB and local IRB submissions in eIRB**
  - **IRB reviewers unaware of need for expedited review**
    - CIRB requires 30 day approval and implementation

- **<u>Solution:</u> Refined communication**
  - **Naming conventions were put in place to call attention to reviewers that the study was under CIRB oversight and therefore, required expedited review**
    - Example: NCI CIRB protocol S2333_v03June2016
    - High-level title designation “[NCI CIRB]” in eIRB

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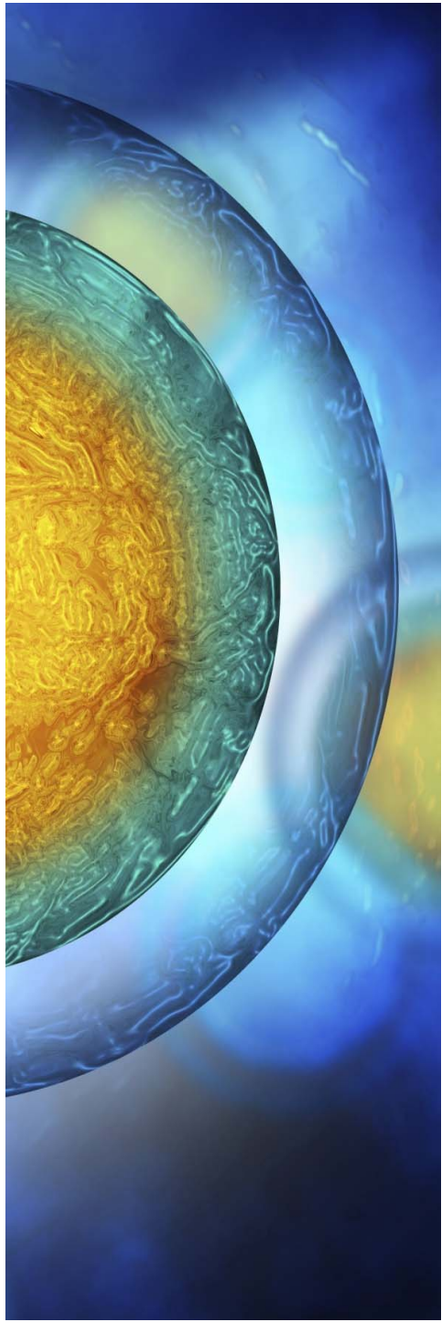

eIRB system

- **<u>Challenge:</u> Tracking documentation of approval**
  - **The eIRB system does not allow for modifications to be named**
  - **Inability to reflect which approved documents are associated with individual modifications**
    - Documents not listed in study-specific submission list
    - Approval memos do not include list of associated documents

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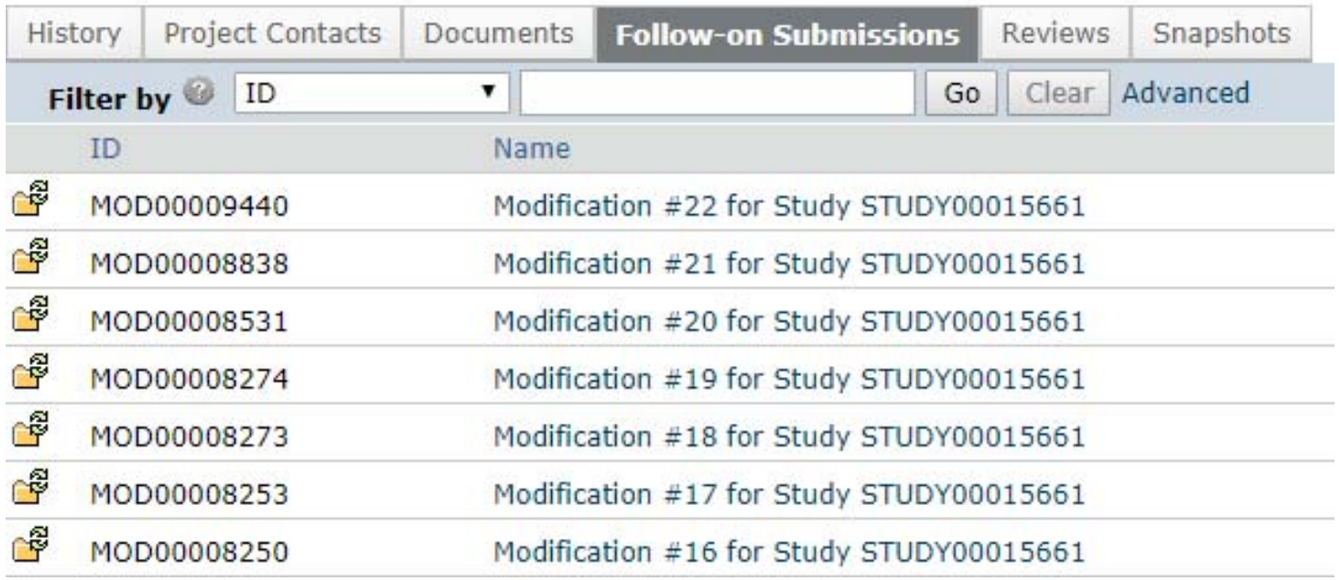
Sample eIRB modification list



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August 7, 2017

Dear Investigator:

On 8/7/2017, the IRB reviewed the following submission:

Type of Review:	Modification
Title of Study:	[NCI CIRB] S1404: A Phase III Randomized Trial Comparing Physician/Patient Choice of Either High Dose Interferon or Ipilimumab to MK-3475 (Pembrolizumab) in Patients with High Risk Resected Melanoma
Principal Investigator:	Matthew Taylor
IRB ID:	STUDY00015661
Funding:	Name: SWOG-CTI, PPQ #: n/a
IND, IDE, or HDE:	IND #125133

Your request that the Oregon Health & Science University (OHSU) IRB continue to rely on the review of NCI CIRB for the study referenced above was approved by the OHSU IRB.

The OHSU IRB expects that review of this study will occur according to all applicable federal, state, and local laws and regulations, and per any applicable agreements.

Any documents that require an IRB signature (e.g. IIAs and IAAs) will be posted to the study's Official Documents list in eIRB when signed. If this applies to your study, you will receive a notification when these documents are available.

Requirements under HIPAA:

If your study involves the collection, use, or disclosure of Protected Health Information (PHI), you must comply with all applicable requirements under HIPAA. See the HIPAA and Research website and the Information Privacy and Security website for more information.

Sincerely,
The OHSU IRB Office

Sample eIRB approval memo

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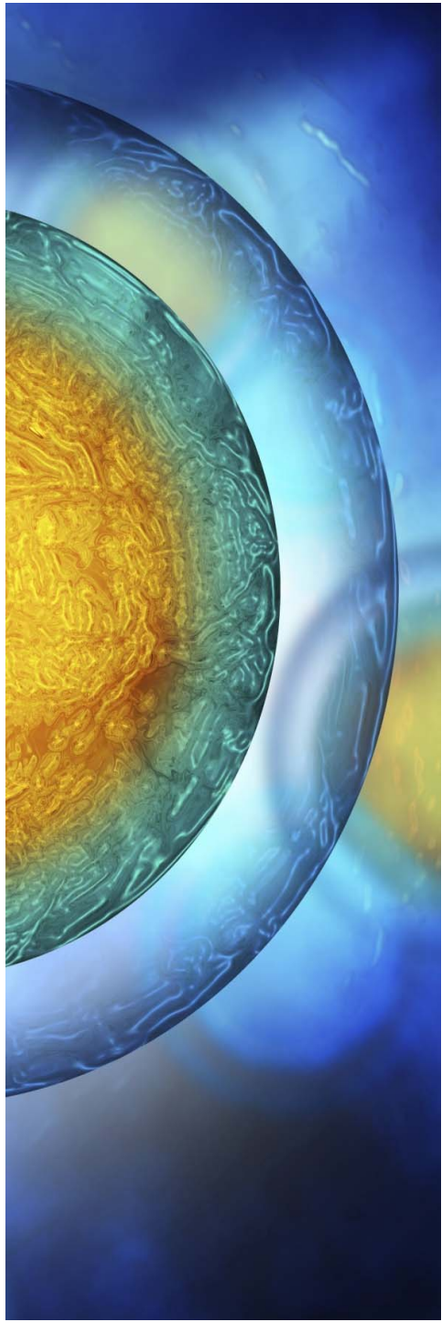

eIRB system

- **<u>Solution:</u> Separate tracking tool for documentation of approval**
  - Links modification number with approvals and documents, includes notes
  - Utilized recently for ECOG-ACRIN/SWOG audits with success

- **<u>Solution:</u> Work with the IRB to revamp approval memos in order to capture more details**
  - Goal is to have approval memos provide a list of associated documents and/or modification titles

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Sample submission tracker

Document Title	Version Date *(if appl)*	Due date	IRB Approval Date	within 90 days	Expiration Date (if applicable)	IRB Action # (IRQ/MR/CRQ/PD/UP)	Summary of Changes
Initial IRB Approval Date: 6/29/16							
Protocols							
Protocol v. 1	2/19/2016	n/a	6/29/2016	n/a	n/a	STUDY00015661	*Initial version*
Protocol v. Revision #2	6/17/2016	9/15/2016	7/26/2016	Yes	n/a	MOD00002870	
Protocol v. Revision #3	9/28/2016	12/27/2016	11/14/2016	Yes	n/a	MOD00004901	
Protocol v. Revision #4	1/19/2017	2/18/2017	2/9/2017	Yes	n/a	MOD00006069	
Protocol v. Revision #5	5/8/2017	7/2/2017	6/21/2017	Yes	n/a	MOD00007836	
Consents							
Consent v. 1	2/19/2016	n/a	6/29/2016	n/a	3/16/2017	STUDY00015661	*Initial version*
Consent v. 2	6/17/2016	n/a	7/26/2016	n/a	3/16/2017	MOD00002870	
Consent v. 2 - corrected	6/17/2016	n/a	8/12/2016	n/a	3/16/2017	MOD00003572	
Consent v. 3	6/17/2016	n/a	10/25/2016	n/a	3/16/2017	MOD00004726	
Consent v. 4	9/28/2016	n/a	11/14/2016	n/a	3/16/2017	MOD00004901	
Consent v. 5	1/12/2017	n/a	2/6/2017	n/a	1/4/2018	MODCR00002253	
Consent v. 6	2/6/2017	n/a	2/9/2017	n/a	1/4/2018	MOD00006069	
Consent v. 7	6/12/2017	n/a	6/21/2017	n/a	1/4/2018	MOD00007836	
Modifications							
Revision #2 (v. 17 June 2016) and action letter, revised ICF	n/a	n/a	7/26/2016	n/a	n/a	MOD00002870	Revision #2 (v. 17 June 2016) has been released and ICF has been updated.
ICF correction	n/a	n/a	8/12/2016	n/a	n/a	MOD00003572	Errors: All pages should note that this ICF is version 2.0, protocol amendment 02, dated 6/17/2016. As of page 21, the footnote reverts to ICF version 1.0, amendment 01. Accrual number should be 10 instead of 5.

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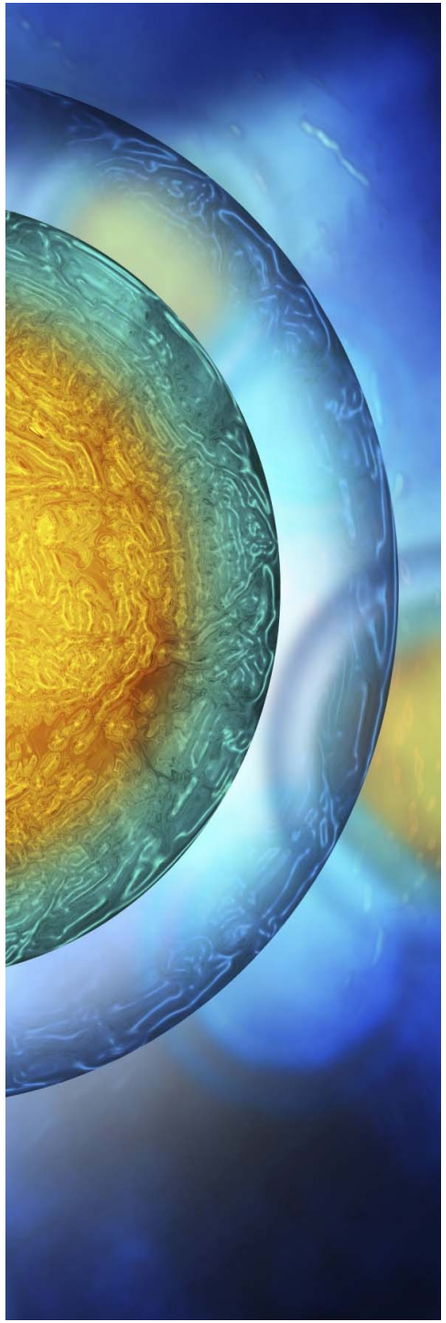

Consent form

- **<u>Challenge:</u> Discrepancies between CIRB-approved and OHSU-approved consent form boilerplates**
  - The CIRB-approved boilerplate did not capture the standard OHSU IRB consent features (approval stamp, barcode) and language

- **<u>Solution:</u> Revision and resubmission of consent form boilerplate for CIRB and OHSU approval**
  - Consent boilerplate underwent several revisions and resubmissions to account for formatting and content issues

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Sample consent form header

IRB Approved: 9/14/2017
Approval Expires: 1/4/2018

OREGON HEALTH & SCIENCE UNIVERSITY

MED. REC. NO._____

NAME_____

BIRTHDATE_____

OHSU IRB#: 15661

OHSU CIRB Knight Cancer Institute Consent and Authorization Form

Study Title for Study Participants: **Testing MK-3475 (Pembrolizumab) Compared to Standard Treatment for High Risk Resected Melanoma**

Official Study Title for Internet Search on http://www.ClinicalTrials.gov:
S1404 *A Phase III Randomized Trial Comparing Physician/Patient Choice of Either High Dose Interferon or Ipilimumab to MK-3475 (Pembrolizumab) in Patients with High Risk Resected Melanoma.*

Funded by: SWOG

Supported by: National Cancer Institute (NCI)

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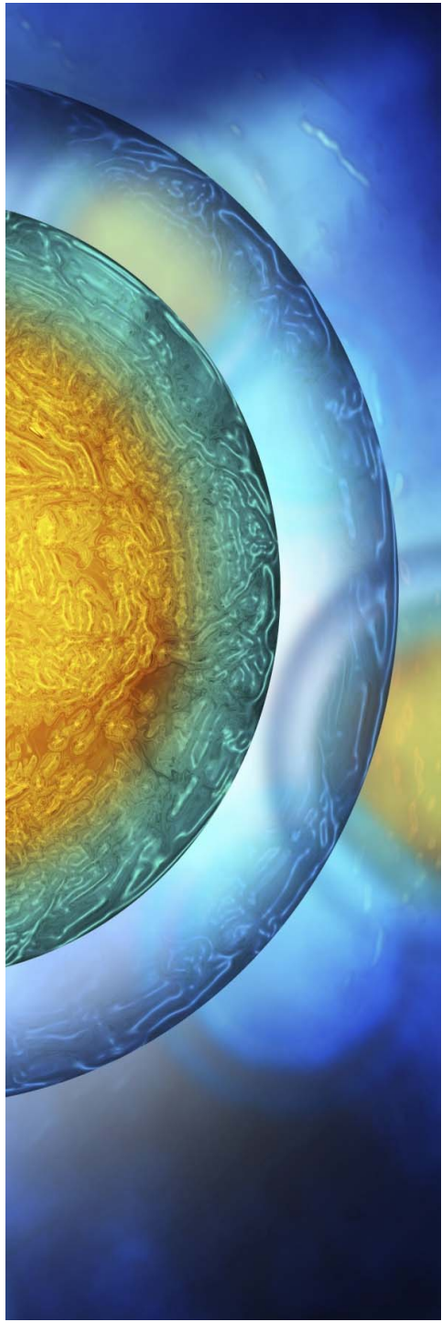

Conflict of Interest

- **<u>Challenge:</u> Conflict of Interest (CoI) status for study PI changed**
  - CoI statements not accounted for in the consent form boilerplate or in CIRB internal documents

- **<u>Solution:</u> CIRB and OHSU document revisions**
  - Updated the CIRB PI Worksheet and submitted the OHSU-approved CoI management plan
  - Revised the CIRB Study Specific Worksheet and provided updated consent language pertaining to the CoI
  - Once both worksheets were CIRB-approved, local consent form could be updated and submitted for local IRB review and implementation

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Lessons Learned
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- **Get the whole picture**
  - **Review local IRB practices and documentation to assess how they might fall in line with CIRB.**

- **Learn to adapt**
  - **Recognize where there are roadblocks or limitations to optimal study management and develop new tools to help reach solutions.**

- **Keep the lines of communication open**
  - **CIRB transition is most successful when local IRB, CIRB, and study teams communicate and work effectively together.**

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OHSU Regulatory Project Manager Dashboard
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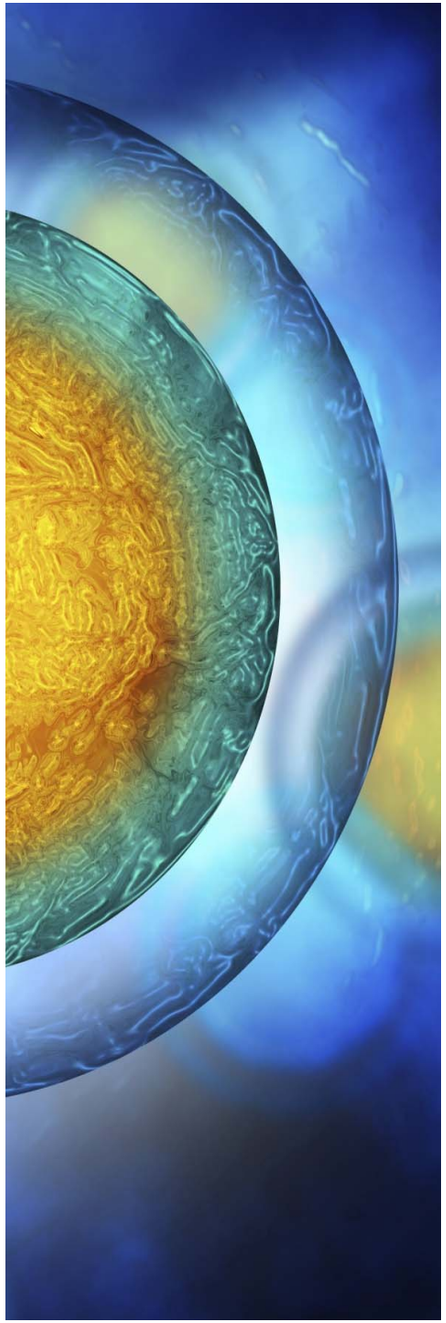

RPM Dashboard Project Background

- **Regulatory Project Manager (RPM) role launched in 2015 across solid tumor and hematologic malignancy disease groups.**

- **RPM team identified the need to standardize:**
  - Regulatory Process
  - Daily Work Management
  - Reporting

<u>Goal:</u>

- **Launch a centralized study tracking system on the Bridge for the RPM team to use for all Knight clinical trials (Industry, NCTN, and IIT)**

- **Tracker to act as a resource for PI, study team, and other stakeholders to have study status information readily available for reference.**

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Home Page

- View total number of Knight clinical trials
- Broken down by *Disease Group*
- Further organized into four separate pages
  - *Start Up, Active Trials, Mods, Close Out*

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Disease Group Main Page

- Includes specific information about each study
- View a detailed list of disease group-specific studies

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Stakeholder Views

Sponsor | Principal Investigator | Contracts | Research Pharmacy Services | Study Teams

Reg PM | Beacon Build Team | Finance | Clinical Research Manager | Satellite Site

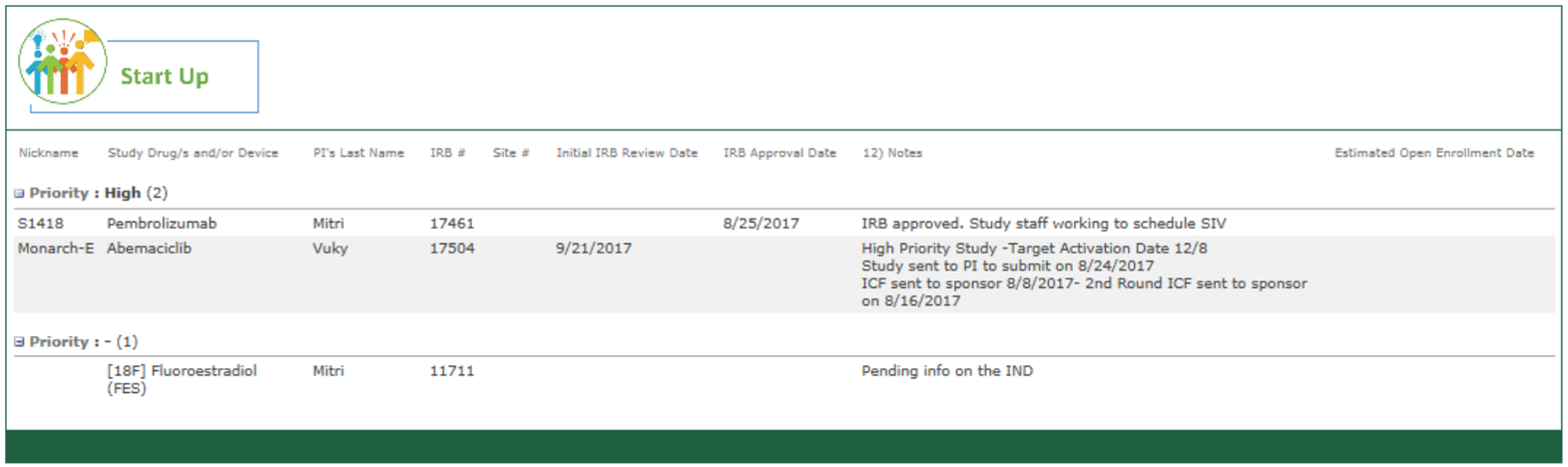
Beacon Build Team

Feedback Portal

Tips:
Bridge pages are best viewed using Internet Explorer.
To view the Bridge page in full, press on Ctrl and the minus (-) sign at the same time.
Scroll to the right to see other columns.

Data Tracked Since 04/17/17
Audited and updated weekly (Fridays at 12:00 pm)

For questions or concerns, please contact Reg PM: Wendy Stitzel



Start Up

Nickname	Study Drug/s and/or Device	PI's Last Name	IRB #	Site #	Initial IRB Review Date	IRB Approval Date	12) Notes	Estimated Open Enrollment Date
Priority : High (2)								
S1418	Pembrolizumab	Mitri	17461			8/25/2017	IRB approved. Study staff working to schedule SIV	
Monarch-E	Abemaciclib	Vuky	17504		9/21/2017		High Priority Study -Target Activation Date 12/8 Study sent to PI to submit on 8/24/2017 ICF sent to sponsor 8/8/2017- 2nd Round ICF sent to sponsor on 8/16/2017	
Priority : - (1)								
	[18F] Fluoroestradiol (FES)	Mitri	11711				Pending info on the IND	

- **Captures most relevant study information associated with each role**
- **Use Feedback Portal to request additional study information**

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Acknowledgements

- Kristien Lewis, Clinical Research Network Manager, for her continued support and guidance
- Eliana Turk, Director of Clinical Research at OHSU Knight Cancer Institute, for her encouragement and inspiration
- OHSU Institutional Review Board for their assistance and collaboration

For the RPM Dashboard:

- OHSU Regulatory Project Managers for their dedication and character: Nicholas Anderson, David Boody-Alter, Vicky Cheng, Lei-Ann Greeneltch, Lauren Hayashi, Takumi Suzuki, Wendy Stitzel, Carrie Medina, and Mai-Lee Yap
- Grace Ty, Joshuah Cobbs, and Debbie Garcia for their hard work and commitment to the project

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