

Next Steps for LesionTracker: Integration with a Clinical Trials Workflow Informatics System



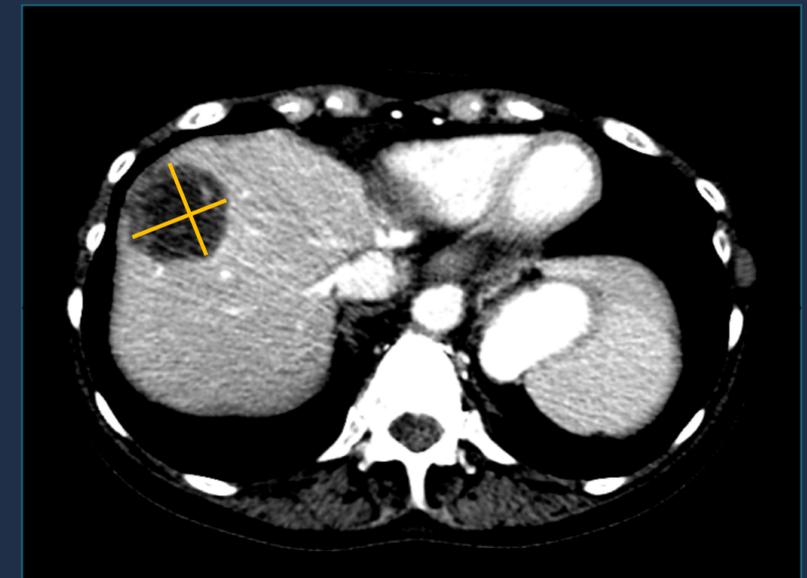
Trinity Urban
Mass General Hospital

June 1, 2017

Introduction

Background

- Oncology clinical trials rely on imaging to help determine patient eligibility and treatment efficacy



Challenges

- Progressively more varied and complex tumor metrics criteria
- Increasing demand for same day turnaround of tumor metrics
- Rising expectations for consistent and controlled results reporting

Solution

- Advanced cancer imaging informatics tools to promote protocol-compliant image evaluation and reviewer efficiency

LesionTracker

- Quantitative imaging package built on Open Health Imaging Foundation's (OHIF) open-source web viewer and optimized for oncology clinical trials workflow
- LesionTracker is funded by PAR-13-294 grant for Advanced Development of Informatics Technology (U24)
- Vendor-neutral, extensible zero-footprint image viewer for display and analysis of DICOM images
- LesionTracker will be integrated with the Precision Imaging Metrics clinical trials informatics platform (available 2018)

LesionTracker



Open Source

Commercially permissive software license (MIT) developed on GitHub and Jira



State-of-the-art

Performance and functionality expected in modern imaging viewers



Extensible

Framework for building imaging applications or integrating with 3rd-party software



Reliable

Implement software best practices and QMS



Secure

Roadmap for HIPAA and 21CFR Part 11



Zero-footprint

Web-based viewer using HTML5/CSS3/Modern JavaScript

Download the source code at: <http://github.com/OHIF/Viewers> or visit <http://lesiontracker.ohif.org> to test drive the application

LesionTracker



1

PACS Connection Protocols

- Supports DICOM message service elements (DIMSE) and DICOMweb protocols (WADO, QIDO)
- Tested against Orthanc and dcm4che

2

Architecture

- Cornerstone <https://github.com/chafey/cornerstone>
- dicomParser <https://github.com/chafey/dicomParser>
- Meteor <https://www.meteor.com>
- MongoDB <https://www.mongodb.com>

3

User Support

- Community web meetings (next on June 15, 2017)
- Public Jira instance: <https://ohiforg.atlassian.net>
- Cornerstone mailing list:
<https://groups.google.com/forum/#!forum/cornerstone-platform>

LesionTracker



Usage and Contributions

- Commercial vendors such as NucleusHealth
<http://www.nucleushealth.io>
- Students such as MGH/IACS Capstone's Saké Viewer <http://sakeviewer.com>
- Hospital research groups such as Precision Imaging Metrics
<https://www.precisionmetrics.org>

Download the source code at: <http://github.com/OHIF/Viewers> or visit <http://lesiontracker.ohif.org> to test drive the application

LesionTracker

Image Analysis

The screenshot shows the 'Image Analysis' interface of the LesionTracker application. The main window displays a CT scan of the abdomen with a yellow box highlighting a lesion labeled 'Target 4' with dimensions 'L 28.9 mm' and 'W 14.4 mm'. A context menu is open over the lesion, listing various anatomical regions for labeling. The right sidebar shows a list of targets and non-targets.

Open Health Imaging Foundation | Study list | Demo U. | Save

Series | Study

Studies | Zoom | Levels | Pan | Link | Target | Non-Target | Temp | More

Trial | HUD | Measurements

Venus 0000005 Baseline

BWH CT ABDOMEN PELVIS W CONTRAST CT192 May 10, 2014 16:43:46

COMPARISON | KEY TIMEPOINTS

Baseline 22-May-14

+ Targets MAX 5 4

Label	Dimensions
1 Mediastinum/Hilum	67.4 x 57.3
2 Lymph Node	25.7 x 18.3
3 Peritoneum/Omentum	86.5 x 43.4
4 (No description)	28.9 x 14.4

+ Non-Targets 2

1 Mediastinum/Hilum	Present
2 Retroperitoneum	Present

Generate Report

Assign label

Common	Assign label
Abdomen/Chest Wall	Adrenal
Lung	Bladder
Lymph Node	Bone
Liver	Brain
Mediastinum/Hilum	Breast
Pelvis	Colon
Peritoneum/Omentum	Esophagus
Retroperitoneum	Extremities
	Gallbladder
	Kidney
	Muscle
	Neck
	Other Soft Tissue
	Ovary
	Pancreas
	Prostate
	Small Bowel
	Spleen
	Stomach
	Subcutaneous

Results Reporting

The screenshot shows the 'Results Reporting' interface of the LesionTracker application. It displays a grid of four CT scan slices with target regions highlighted in green. The interface includes a header with patient information and a 'Generate Report' button.

Open Health Imaging Foundation

RECIST 1.1 Venus 0000005

BASELINE

1 TARGET 2 TARGET

Mediastinum/Hilum 67.4 x 57.3 mm (S:5, I:33)

Lymph Node 25.7 x 18.3 mm (S:5, I:34)

3 TARGET 4 TARGET

Retroperitoneum 86.5 x 43.4 mm (S:2, I:15)

Retroperitoneum 28.9 x 14.4 mm (S:2, I:35)

Generate Report

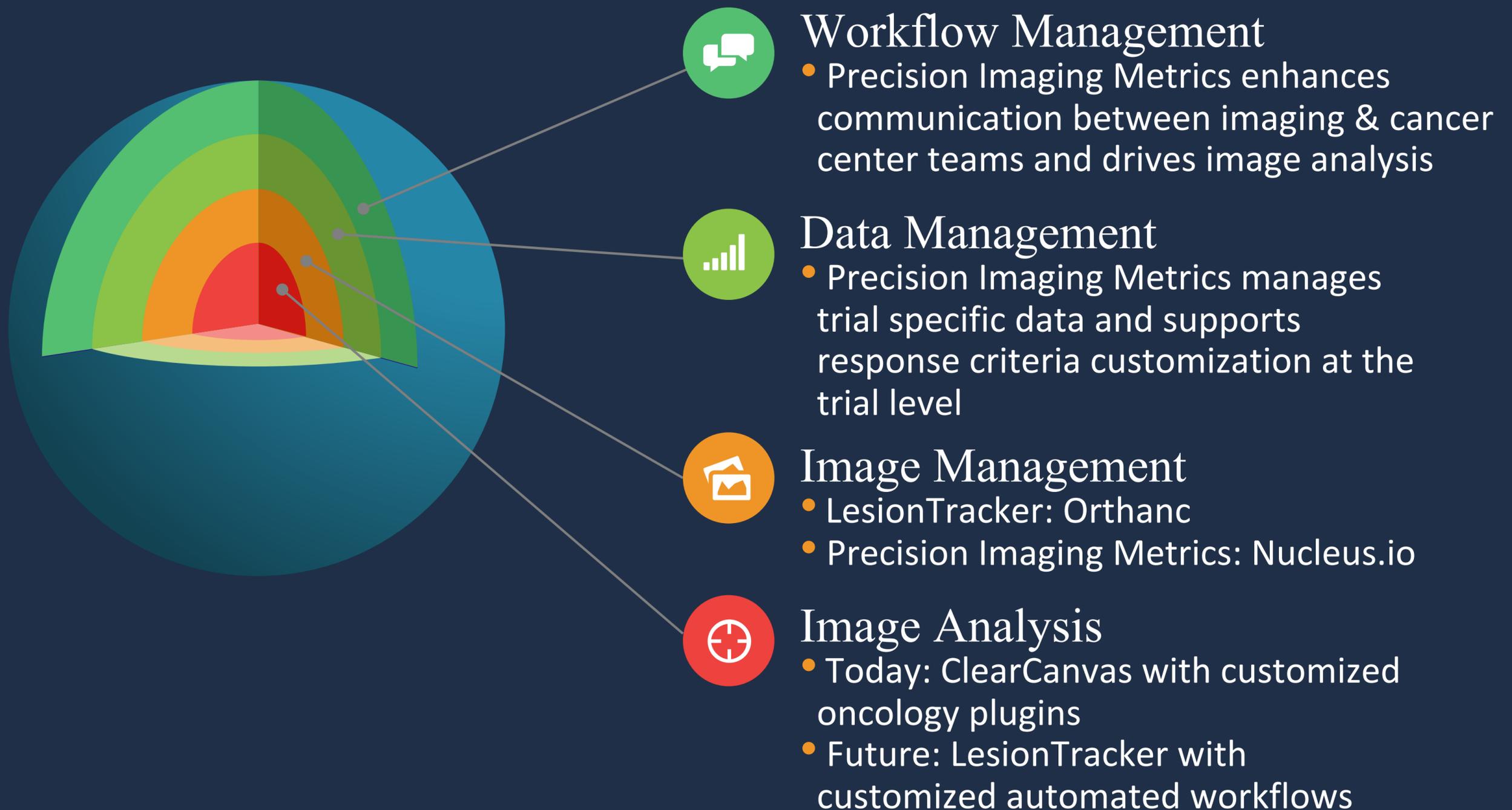
Download the source code at: <http://github.com/OHIF/Viewers> or visit <http://lesiontracker.ohif.org> to test drive the application

LesionTracker

Feature Highlights	
<ul style="list-style-type: none">• Ability to define time points i.e., baseline or follow-up	<ul style="list-style-type: none">• Longitudinal, interactive measurement table
<ul style="list-style-type: none">• User interface (UI) to label lesions consistently across patients, trials, and sites	<ul style="list-style-type: none">• Synchronized scrolling of images from multiple time points
<ul style="list-style-type: none">• Bi-directional measurement tool	<ul style="list-style-type: none">• Audit logs which captures all data changes –who, what, and when
<ul style="list-style-type: none">• Non-target annotation tool with pre-defined response options	<ul style="list-style-type: none">• Results reporting with screen captures of annotated images
<ul style="list-style-type: none">• Built-in response criteria conformance checks for RECIST 1.1 and irRC	<ul style="list-style-type: none">• UI mechanisms to simplify and accelerate switching between imaging studies

[Click to view LesionTracker highlights video on YouTube](#)

LesionTracker & Precision Imaging Metrics (PIM)





In 2004, Dana-Farber/Harvard Cancer Center investigators were struggling to get reliable, timely, compliant assessments:

- Deviations from trial protocol parameters
- Delays in results to oncologists (or investigators)
- Inefficient workflows
- Lack of QA and QC
- Poor fiscal management
- Difficulty in audit preparation

Tumor Imaging Metrics Core (TIMC), co-Directed by Drs. Harris and Van den Abbeele, was formed to address these issues



Adequate imaging assessment / reporting tools were only available to Clinical Research Organizations (CROs), not meeting needs of cancer center site reads

PIM system was developed by TIMC to manage:

- Results reporting and protocol compliance
- Demanding requirements for turnaround time
- Communication between radiology and oncology

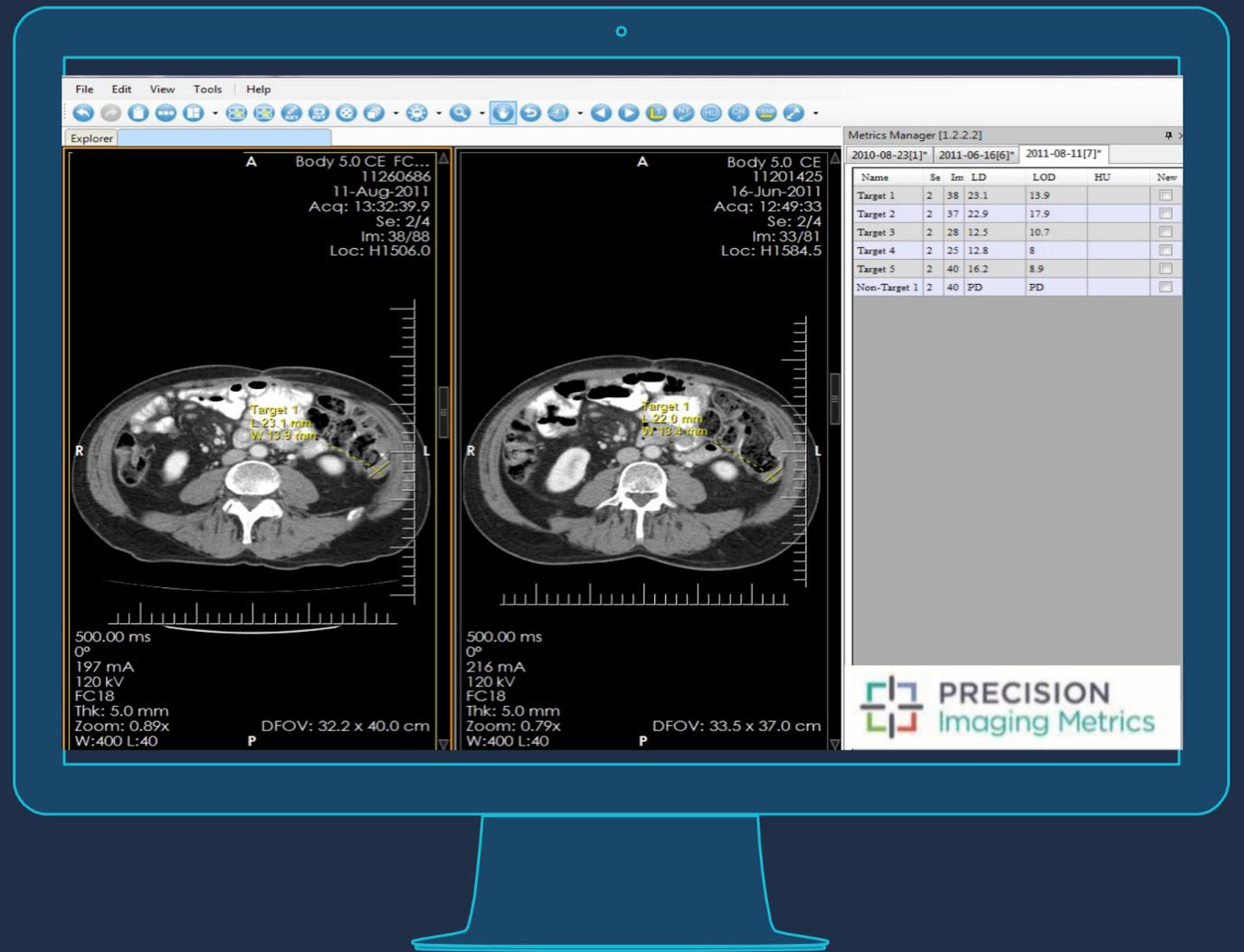
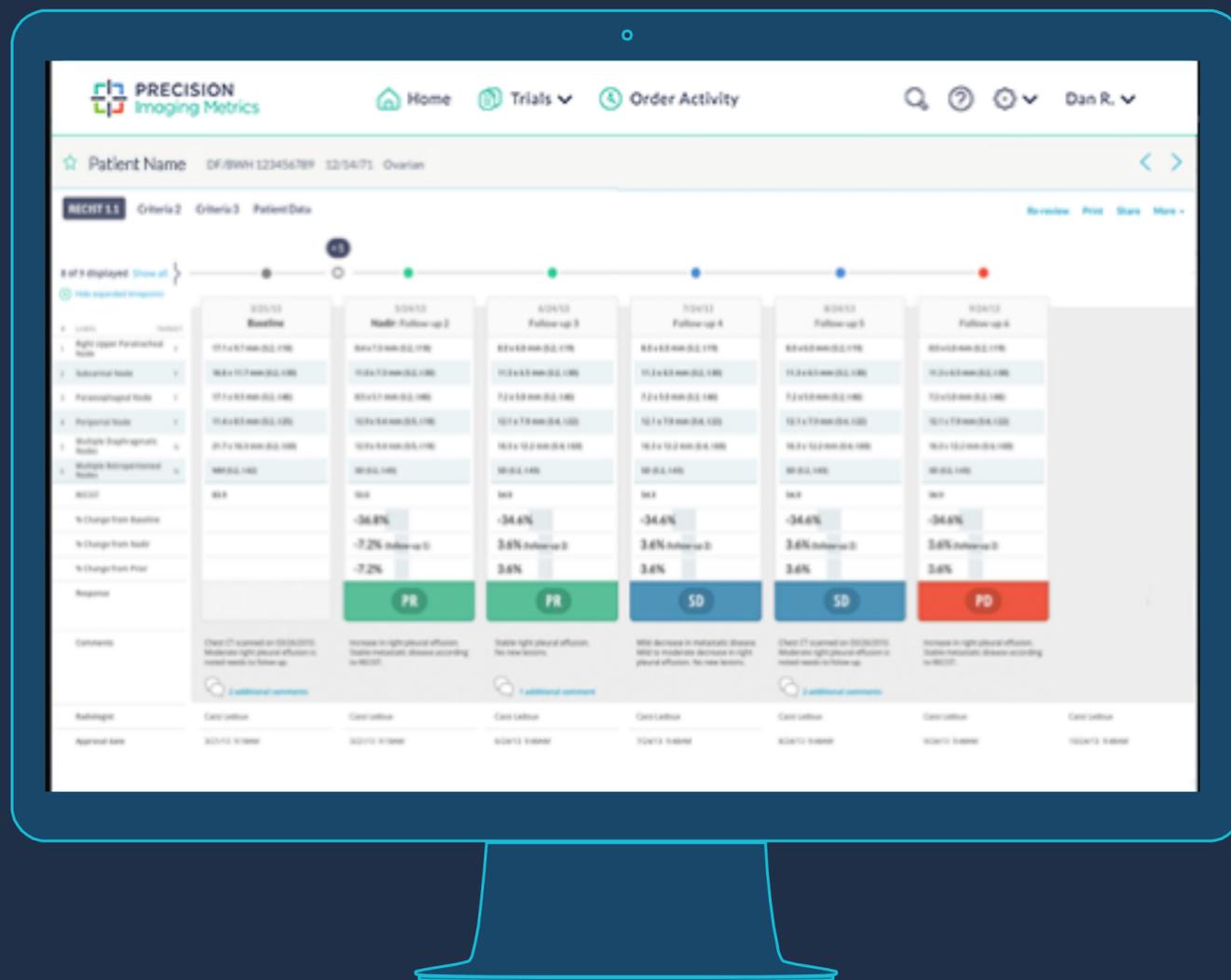
Visit <http://www.precisionmetrics.org> for more information

PIM Solution

Consists of two integrated applications:

1) Workflow & data management system

2) Image analysis platform (Current)

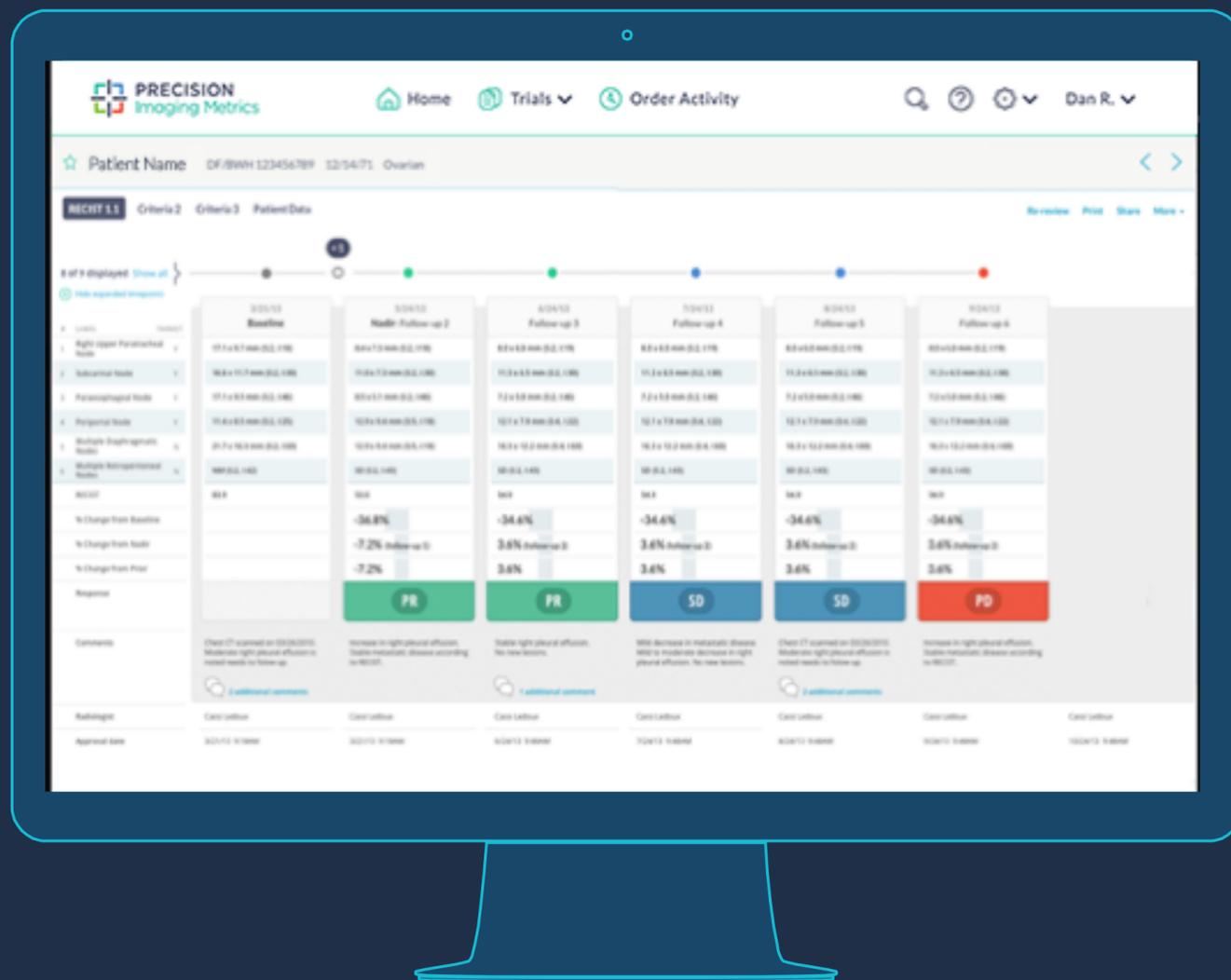


PIM Solution

Consists of two integrated applications:

1) Workflow & data management system

2) Image analysis platform (Future)



PIM: Trial Staff View



[Home](#)
[Trials](#)
[Order Activity](#)

Site Investigator

Activity in the last 14 days

Add Patient
Add Order

All Orders
My Orders
Starred Patients

408 Upcoming

[VIEW ALL](#)

1a2b3c4d	White, Snowyyy	In process	19-Aug-2014
1a2b3c4d	White, Snowyyy	In process	19-Aug-2014
IE11 test	Obama, Barack	In process	29-Aug-2014
IE11 test	Washington, George	In process	04-Sep-2014
IE11 test	Baggins, Bilbo	Inquiry	24-Sep-2014
IE11 test	Baggins, Bilbo	In process	24-Sep-2014
IE11 test	Baggins, Bilbo	Inquiry	24-Sep-2014

128 Completed

[VIEW ALL](#)

PD	00-0011	Kerouac, Jack	04-Feb-2015
SD	00-0011	Dog, Clifford	04-Feb-2015
SD	00-0011	Dog, Clifford	04-Feb-2015
BL	00-0011	Dog, Clifford	04-Feb-2015
BL	00-010	Austen, Jane	03-Feb-2015
PD	1a2b3c4d	White, Snowyyy	03-Feb-2015
PD	1a2b3c4d	White, Snowyyy	03-Feb-2015

 Starred Trials

Trial Name / Number	Status	Phase	Criteria	PI / Sponsor	Sub-Group	Patients
 RECIST 1.1 for RSNA 2014 00-000	Active	II	RECIST 1.1	Lewis, Rob Trinity LTD	Early Therapeutics, Gastrointestinal (GI), Genitourinary (GU), TIMC	9 Data

PIM: Longitudinal Metrics

PRECISION Imaging Metrics Home Trials Order Activity Image Analyst

← 00-000: RECIST 1.1 for RSNA 2014

☆ Dorian Gray MGH0183951 12/02/1916 Bladder

RECIST 1.1 Re-Review Print More

5 of 5 displayed Show summary

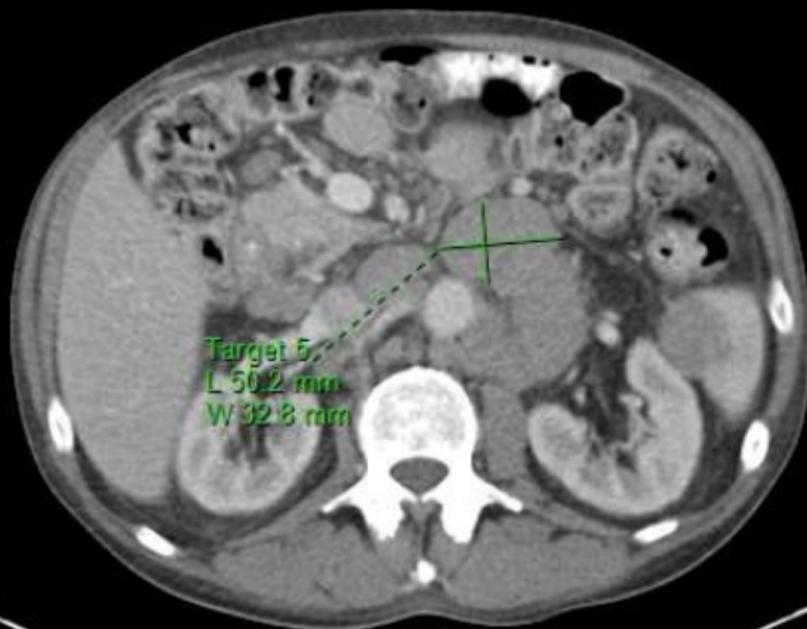
	03-Nov-2014 Baseline	10-Nov-2014 Follow Up 1	17-Nov-2014 Follow Up 2	24-Nov-2014 Nadir: Follow Up 3	29-Nov-2014 Latest: Follow Up 4
Clone Measurements	21 x 19 mm (S:4, I:23)	18 x 16 mm (S:4, I:23)	15 x 12 mm (S:4, I:23)	8 x 6 mm (S:4, I:21)	CR (S:4, I:21)
1 Abd/Pelvis - Pelvis - Right	18 x 23 mm (S:4, I:25)	13 x 21 mm (S:4, I:25)	12 x 15 mm (S:4, I:25)	10 x 12 mm (S:4, I:24)	9 x 11 mm (S:4, I:24)
2 Abd/Pelvis - Lymph Node - Pel...	NM (S:4, I:29)	SD (S:4, I:27)	SD (S:4, I:26)	SD (S:4, I:25)	CR (S:4, I:25)
3 Abd/Pelvis - Lymph Node - Pel...	39.0	31.0	27.0	18.0	9.0
RECIST 1.1					
% Change from Baseline		-20.51%	-30.77%	-53.85%	-76.92%
% Change from Nadir		-20.51% (Baseline)	-12.9% (Follow Up 1)	-33.33% (Follow Up 2)	-50% (Follow Up 3)
% Change from Prior		-20.51%	-12.9%	-33.33%	-50%
Acceptable image quality	Yes	Yes	Yes	Yes	Yes
Presence of contrast	Yes	Yes	Yes	Yes	Yes
Adequate anatomical coverage	Yes	Yes	Yes	Yes	Yes
Response	BL	SD	PR	PR	CR
Radiologist		Radiologist Reviewer	Radiologist Reviewer	Radiologist Reviewer	Radiologist Reviewer
Approval date		30-Nov-2014 10:34AM	30-Nov-2014 10:34AM	30-Nov-2014 10:35AM	30-Nov-2014 10:35AM

PIM: Annotated Images

< Lesion: Lymph Node Mesenteric >

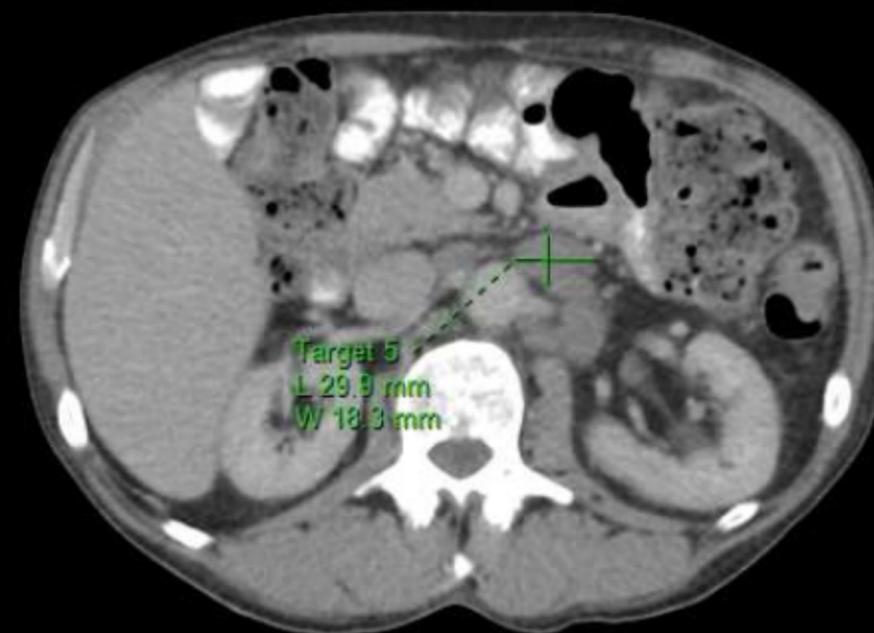
Baseline >

31-Oct-2014
50.2 x 32.8 (S:8, I:44) >

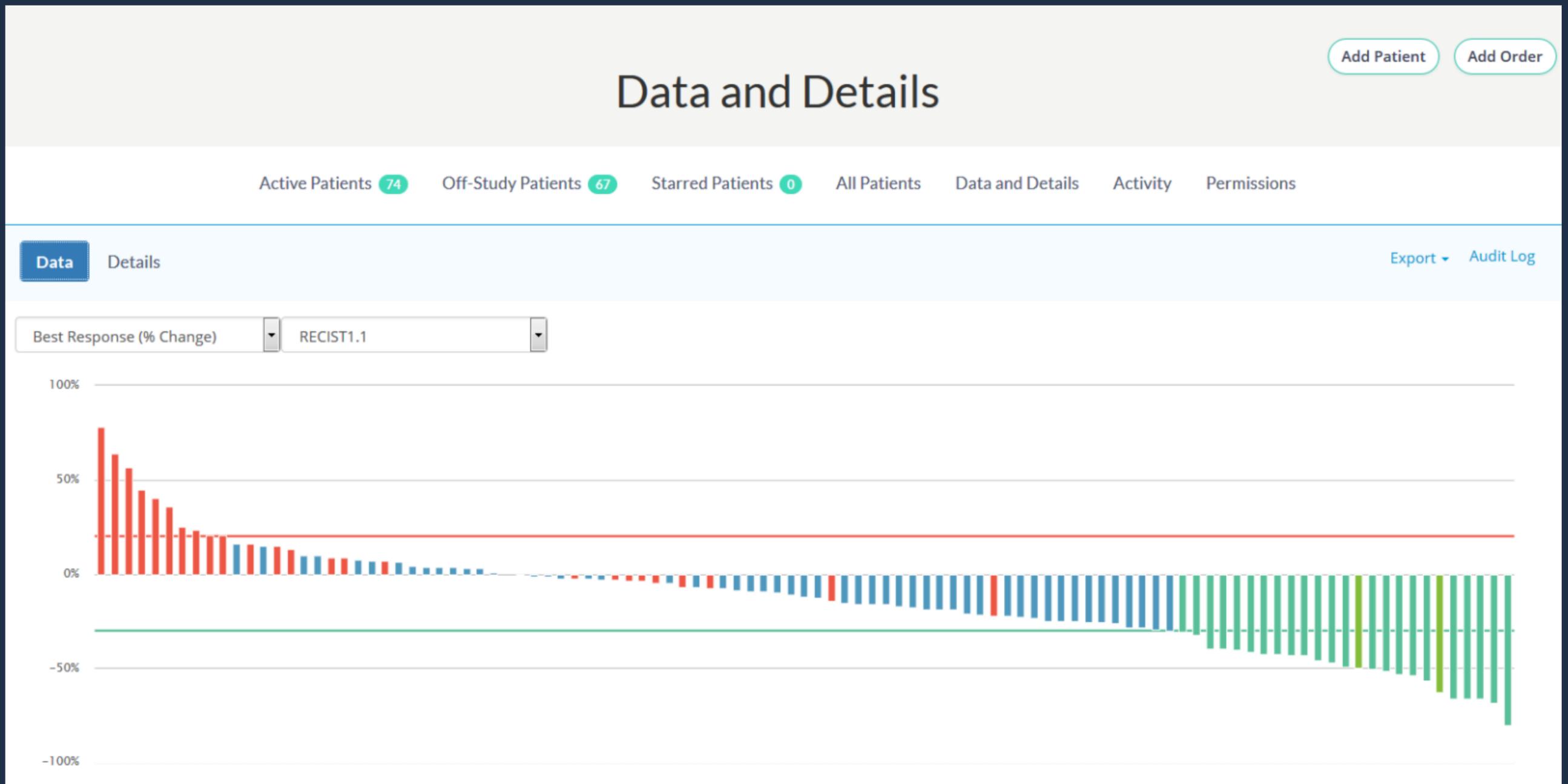


< Follow Up 1 >

24-Dec-2014
29.9 x 18.3 (S:4, I:34) >



PIM: Analytical Tools



PIM: Training and Certification

RECIST Tutorial

RECIST (00:50 / 02:45) | ATTACHMENTS

TUMOR IMAGING METRICS CORE

Outline Thumbnails Notes Search

1. RECIST
2. Response Evaluation Criteria in Solid Tumors
3. Baseline Assessment
4. Target Lesion Documentation
5. Non-Target Lesion Documentation
6. Use of Cytology
7. Baseline Assessment: Measurable Lesions
8. Baseline Assessment: Measurable Lesions
9. Baseline Assessment: Non-Measurable Lesions
10. Baseline Assessment: Lymph Nodes
11. Baseline Assessment: Lymph Nodes
12. Baseline Assessment: Lymph Nodes
13. Baseline Assessment: Lymph Nodes
14. Bone Lesions
15. Cystic Lesions
16. Previously Treated Lesions
17. Definition of CR
18. Definition of PR
19. Definition of SD
20. Definition of PD
21. Possible PD by FDG-PET
22. Clarification of Target PD
23. Clarification of Non-target PD
24. New Lesions

Baseline Assessment: Lymph Nodes

RECIST_{1.0}:

- Long axis is included in measurement total

RECIST_{1.1}:

- Short axis is included in measurement total
- Normal: short axis <10 mm
- Measurable: short axis ≥15 mm
- Non-measurable: short axis ≥10 mm and <15 mm

Meets target criteria by RECIST_{1.0} and RECIST_{1.1}

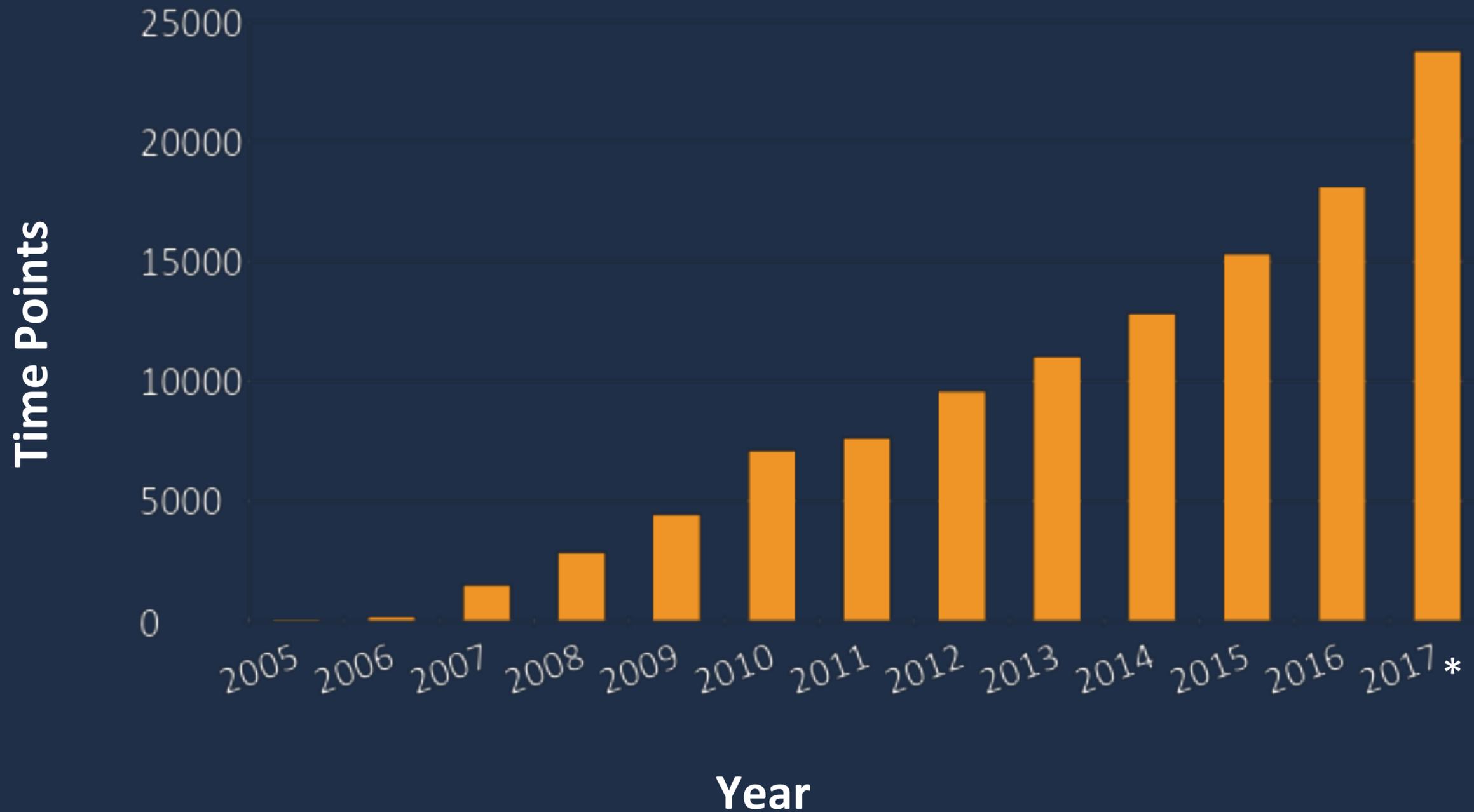
Does not meet target or non-target criteria by RECIST_{1.1}

New to RECIST_{1.1}:
Short axis of lymph node is the critical measurement

Current PIM Usage

Cancer Center	Location	Activation Date	Trials	Time Points
Dana-Farber / Harvard Cancer Center	Boston, MA	August 2004	1,468	74,949
Yale Cancer Center	New Haven, CT	September 2013	358	12,612
Fred Hutchinson Cancer Research Center	Seattle, WA	September 2014	455	13,876
Huntsman Cancer Institute	Salt Lake City, UT	June 2015	72	1,568
Massey Cancer Center	Richmond, VA	September 2015	54	463
Winship Cancer Institute	Atlanta, GA	February 2017	127	409
Medical College of Wisconsin	Milwaukee, WI	Summer 2017	TBD	TBD

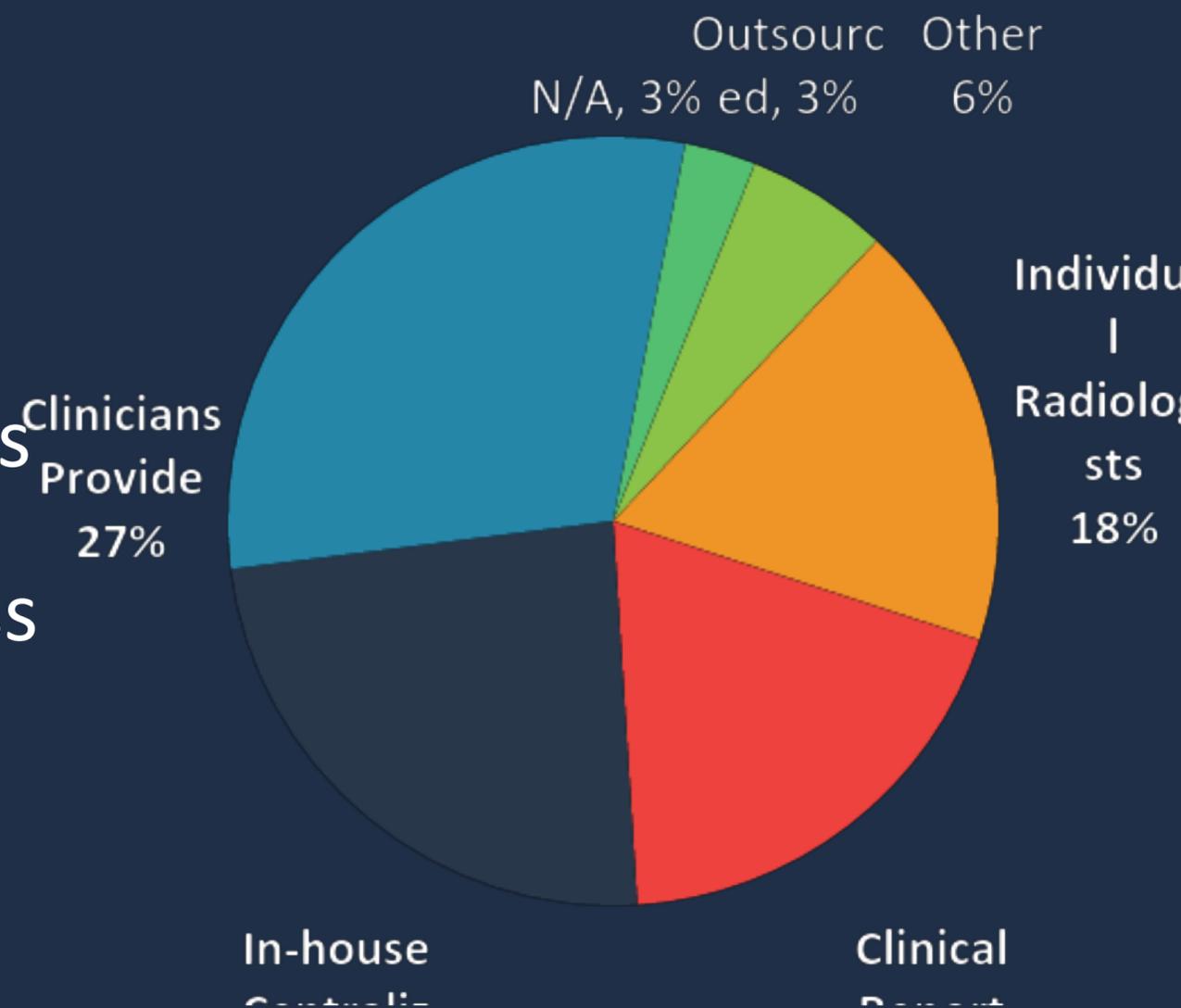
Current PIM Usage



* Projected

Summary

- Most cancer centers struggle to obtain reliable, timely, protocol compliant tumor metrics
- There is a need for advanced cancer imaging informatics tools
- Implementation may vary across cancer centers
 - LesionTracker
 - Precision Imaging Metrics



LesionTracker Development Team



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Chris Hafey
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Development Consultant

Please reach out to us if you have any follow-up questions:
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