Shared Investment to Build a Strong, Streamlined, and Accessible RECIST Foundation in Clinical Research

Carbone Cancer Center
UNIVERSITY OF WISCONSIN
SCHOOL OF MEDICINE AND PUBLIC HEALTH

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Mission

The Clinical Research Imaging Core (CRIC) is dedicated to serving as the University of Wisconsin Carbone Cancer Center's (UWCCC) nexus to the UW Department of Radiology Medical Imaging Research Support (MIRS) to support the effective and efficient use of imaging-based outcomes in cancer research and tumor response assessments.

Personnel

Faculty Lead: Steve Cho, MD

- Associate Professor of Radiology
- Director of the UWCCC Clinical Research Imaging Core
- Co-Director, UW Radiology MIRS

Core Manager: Alex Arbuckle, BS

- BS, Neuroscience with training in brain imaging
- Manages and coordinates UWCCC Research Imaging Services

Service Implementation

Previous tumor response assessment services at UWCCC were hampered by a disjointed user experience. The service was inflexible, cumbersome, did not align with research aspirations, and was cost prohibitive. Previous iterations did not successfully marry the expertise within both UWCCC and UW Department of Radiology MIRS. This resulted in oncologists performing the assessments themselves, detracting their focus from other areas of study.

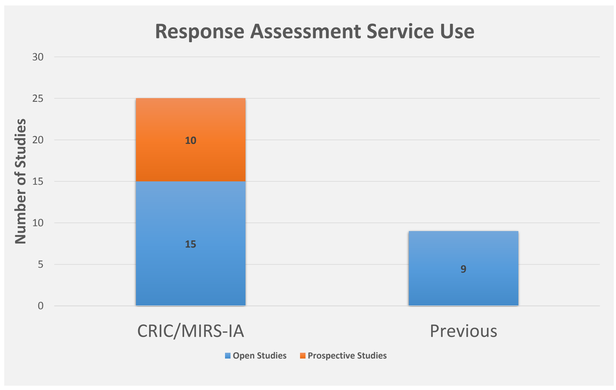
To offer local investigators an effective response evaluation tool the response evaluation tool needed a lower entry cost, improved flexibility for starting and stopping Investigator Initiated Trials (IITs) based on PI needs, faster assessment completion, and improved reporting system. A successful system would be marked by the following: Increased number of assessments, a wider and more varied investigator user base across the UWCCC Disease Oriented Teams (DOTs), and faster assessment completion.

Given the needs of the UWCCC and the expertise of UW Department of Radiology MIRS-Image Analysis (MIRS-IA) there was a joint review of different assessment systems and infrastructure. Ultimately, the Dana-Farber Model was decided upon because of its reputation and efficacy.

The UWCCC and UW Department of Radiology MIRS-IA invested in a centralized tumor response assessment system, Mint Lesion by Mint Medical, in November 2017. UWCCC and UW Department of Radiology chose Mint Lesion over other programs because of its polish, performance, and ease of integration with the Dana-Farber assessment model. In addition to the investment in this system, the UWCCC and the UW Department of Radiology MIRS subsidized the service cost for IITs.

With the system investment and implementation, radiologists and imaging technicians can now do all assessments in the Mint Lesion suite, and are able to support multiple response criteria, including RECIST 1.1 and its variants. Radiologists are able to pull images into the suite from clinical Picture Archiving and Communications System (PACS) for assessment and respective report completion.

To date, the implementation of the centralized assessment system and reliance of local imaging expertise has improved cost effectiveness, continually improved assessment time to completion, and has allowed for quick start-up and navigation of IITs.



Tumor Response Assessment Service

Protocol Review

- The CRIC is made aware of prospective studies via the UWCC Collaborator Sign-off
- At the time of request for Collaborator Sign-off, the CRIC reviews the protocol for the following: study calendar, applicable imaging, assessment criteria specifications, and desired service use
- Protocol assessment criteria are reviewed for any deviations from RECIST1.1, irRECIST, irRC, etc. It is common that protocols will have variations on established criteria that need to be reflected in assessments

Study Start-up & Activation

- After service use is verified, the study team, CRIC, and MIRS-IA develops the budget for study assessments, including possible subsidization of cost
- CRIC provides the protocol and assessment criteria specifications to MIRS-IA technicians
- To match protocol specifications, the study's assessment criteria are then entered into Mint Lesion assessment suite by Image Analysis technicians
- The standard operating procedure for response assessments is provided to UWCCC study team by the CRIC

Tumor Response Assessment

- Study coordinators notify CRIC and MIRS-IA of assessment need via an intake request form
- Assessment request, intake form, clinical report and protocol will be triaged to the radiologist assigned for that day
- Once triaged, technicians pull the images into the Mint Lesion Suite from clinical PACS
- Response Assessment is performed in Mint and the report is generated, reviewed, and sent to the study team with an explanation of next steps needed

Sample Tumor Assessment Report

Time Point Summary Table

made with mint Lesion

		Lesion name	Baseline	Follow-up 1	Follow-up 2	Follow-up 3
Target lesions						
	1	**T01 Lung lower lobe right** Lung lower lobe right	LA: 11.0 mm (CT: SE 4; IN 258; TP -142.875)	LA: 0.0 mm (CT: SE 5; IN 255; TP -129.875) **State**: Disappeared	**State**: Disappeared	**State**: Disappeared
	2	**T02 Lymph node supraclavicular left** Lymph node supraclavicular left	SA: 17.2 mm (CT: SE 2; IN 4; TP 7.25)	SA: 15.2 mm (CT: SE 2; IN 5; TP 15)	SA: 11.4 mm (CT: SE 2; IN 8; TP 26.25)	SA: 14.9 mm (CT: SE 2; IN 1; TP 43.75)
	3	**T03 Lymph node para-aortic left** Lymph node para-aortic left	SA: 25.3 mm (CT: SE 5; IN 50; TP -301.5)	SA: 15.4 mm (CT: SE 2; IN 150; TP -284.5)	SA: 16.9 mm (CT: SE 5; IN 44; TP -267)	SA: 19.4 mm (CT: SE 5; IN 48; TP -249.5)
Non-target lesions						
	1	**NT01 Lung** Lung	LA: -- mm (CT: SE 4; IN 221; TP -119.75) **State**: Present *Multiple Bilateral Lesions*	**State**: Not evaluable *all nodules decreased in size*	**State**: Disappeared	LA: -- mm (CT: SE 4; IN 225; TP -94.375) **State**: Present
	2	**NT02 Lymph node** Lymph node	SA: -- mm (CT: SE 5; IN 32; TP -247.5) **State**: Present *Right Retrocrual*	SA: -- mm (CT: SE 5; IN 125; TP -209.5) **State**: Present	SA: -- mm (CT: SE 5; IN 21; TP -198) **State**: Present	SA: -- mm (CT: SE 5; IN 25; TP -180.5) **State**: Present
New lesions						
	1	**NL01 Mesentery** Mesentery			LA: 21.8 mm (CT: SE 5; IN 50; TP -285) **State**: Present *soft tissue/lymphnode Left Paraaortic/mesentary*	LA: 55.0 mm (CT: SE 5; IN 53; TP -264.5) **State**: Present
	2	**NL02 Liver** Liver				LA: -- mm (CT: SE 5; IN 27; TP -186.5) **State**: Present
	3	**NL03 Liver** Liver				LA: -- mm (CT: SE 5; IN 29; TP -192.5) **State**: Present
Evaluation		**Target sum**	**53.6 mm**	**30.7 mm** *-42.8% ΔB / -42.8% ΔN / -42.8% ΔP*	**28.3 mm** *-47.1% ΔB / -7.7% ΔN / -7.7% ΔP*	**34.2 mm** *-36.1% ΔB / +20.9% ΔN / +20.9% ΔP*
		Target response		**Partial Response**	**Partial Response**	**Progressive Disease**
		Non-target response		**Not Evaluable**	**Non-CR/Non-PD**	**Non-CR/Non-PD**
		New lesions present		**No**	**Yes**	**Yes**
		Timepoint response		**Partial Response**	**Progressive Disease**	**Progressive Disease**
		Approval	Approved by Jessica Robbins	Approved by Jessica Robbins	Approved by Jessica Robbins	Approved by Jessica Robbins
		Revisions	Revision #0	Revision #0	Revision #1	Revision #0

Change is relative to baseline (ΔB), nadir (ΔN) and previous assessment (ΔP)

The timepoint response is an empirical measure to evaluate therapy success according to the response criteria in use. It may differ from the overall radiological assessment and must not be used as a surrogate.

This report has been electronically signed by Jessica Robbins on 01/16/2018 at 08:28 a.m..

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Lesion Overview and Target Sum Charts

made with mint Lesion

Lesion overview chart

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Target sum chart

Dotted line equals measurement value that would constitute PD / PR

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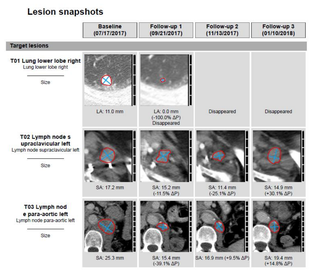
Lesion Tracking

made with mint Lesion

Lesion snapshots



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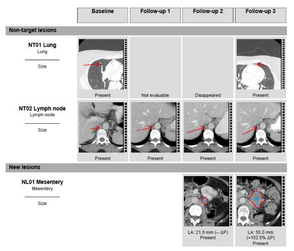

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All progress values are relative to their previous value (ΔP)

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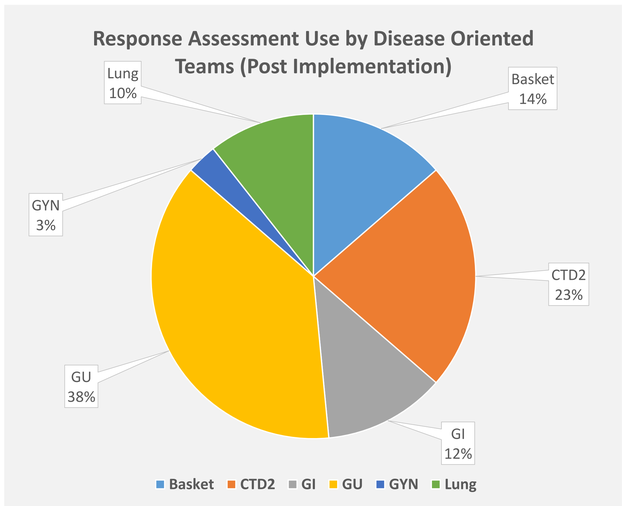
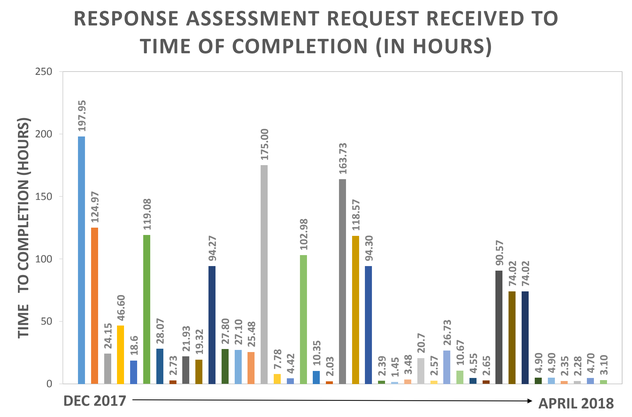
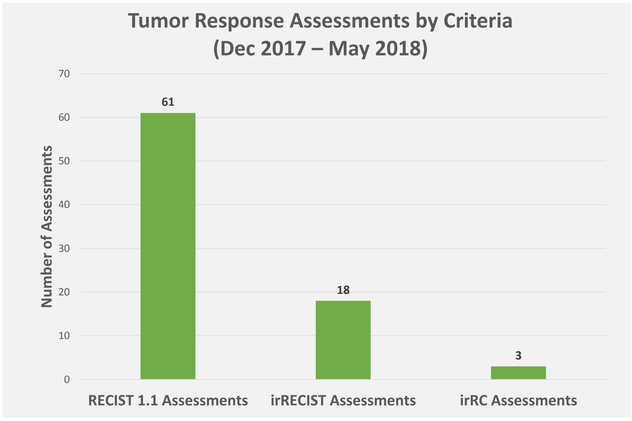
Metrics

Results

- Service expanded from 5 unique users in 2 programs to 12 unique users across 6 programs in the first 9 months of the CRIC and MIRS-IA service
- The new service has improved on time to assessment completion, with the current average being 1 business day from time of the request received to assessment and report completion, halving the previous 2 business day average
- 82 tumor response assessments have been completed and reported since service inception in December 2017 through May 2018, including the newly offered irRECIST criteria







Work In Progress

Tumor Response Assessment

- Expand radiologist assessment reading pool in July 2018 by including trained UW Department of Radiology Abdominal Fellows
- Implement Lugano and Cheson criteria for lymphoma studies
- Include trained Nuclear Medicine physicians in the assessment reading pool
- Integration of tumor assessment requests into hospital Electronic Medical Record (EMR) ordering system to streamline study team access
- Increase the number of licenses for Mint Lesion access