



**CENTER FOR CLINICAL AND
TRANSLATIONAL SCIENCE**

Clinical Research Update

RAU – June 2019

Primary Goals of the CCTS

- Accelerate the translation of basic discoveries into practical, cost effective solutions that improve human health
- Develop and support the next generation of leaders in clinical and translational research

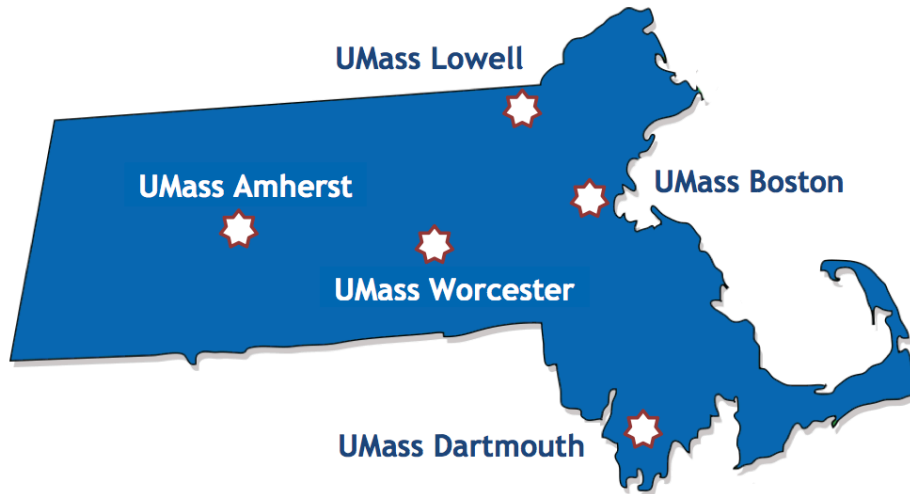


**CENTER FOR CLINICAL AND
TRANSLATIONAL SCIENCE**



**CENTER FOR CLINICAL AND
TRANSLATIONAL SCIENCE**

Create an Ecosystem that drives Innovation in Translational Research



- Capitalizes on 5 campus + clinical system strengths
- Catalyzes trans-disciplinary collaborations across the translational spectrum
- Creates product pipelines; supports their development with cores, services, funding
- Creates new/enhances existing training opportunities



CENTER FOR CLINICAL AND TRANSLATIONAL SCIENCE



Office of Clinical Research



Bioinformatics



Institutional Review Board



Small Molecule Screening



Community Engagement



Clinical Research Center (CRC)



Biorepository & Tissue
Bank



Investigational Drug Services (IDS)



Clinical Research Informatics



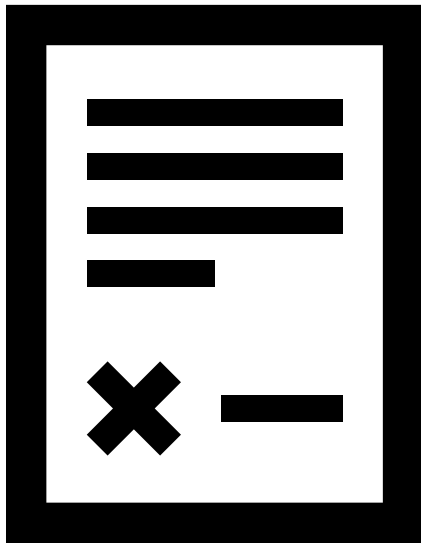
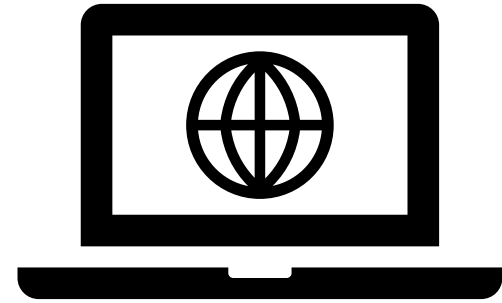
Institutional Centers (M2D2, Mass
Biologics, Commonwealth Medicine,
Meyers Primary Care)



Biostatistics, Epidemiology,
Research Design (BERD)



Science Participation Research
Center (SPRC)



Focus:

Office of Clinical Research (OCR)
& Clinical Research Informatics
Core



Office of Clinical Research (OCR)

- Located: 7th Floor of Ambulatory Care Center (ACC) Building
- Phone: (508) 856-5200
- Email: clinicalresearch@umassmed.edu
- Website: <https://www.umassmed.edu/ocr/>

Office of Clinical Research

The Office of Clinical Research (OCR) works with investigators and their study team members to promote and support clinical research at the University of Massachusetts Medical School.

OCR is responsible for clinical research education & training, budget development, contract negotiation, and a variety of other services intended to support the management and conduct of clinical research.

Who We Are

- **Danielle Howard**
Director, Clinical Research Operations
- **Richard Stevens**
Associate Director, Compliance & Contracting
- **Elena Del Prete**
Contract Administrator III (Pre-Award)
- **Michelle Maynard**
Contract Administrator II (Pre-Award)
- **Kathryn Beauregard**
Contract Administrator III (Pre-Award)
- **Krystal Reno**
Contract Administrator II (Post-Award)
- **Melida Graham**
Clinical Research Coverage Analyst
- **Meg Johnson**
HRPP Compliance Administrator
- **Anne Roussel**
Clinical Research Associate III (Education/Training)
- **Ann Han**
Clinical Research Navigator



What we Do

Contracting & Budgeting

Clinical Trial Management System (OnCore) Content

EPIC Medical Record Research Access

Clinical Research Billing Support

Clinical Research Navigation Support

Clinical Research Recruitment Support

Education & Training

Quality Assurance/Monitoring

Reporting Tools

OCR Intake Portal

<https://arcsapps.umassmed.edu/redcap/surveys/?s=CM-MTRTXTDA>

The UMass CCTS Office of Clinical Research provides a variety of resources and services to support clinical research. To better serve you, please complete the following form.

Date of Request

* must provide value

 Today M-D-Y

Your Name

* must provide value

Last, First

Please choose the role that best describes you

* must provide value


Your e-mail

* must provide value

Please select your Department or Organization. If not listed choose "other/organization"

* must provide value

If applicable, what is the deadline for this request?

 Today D-M-Y

Which of the following services/resources are you requesting?

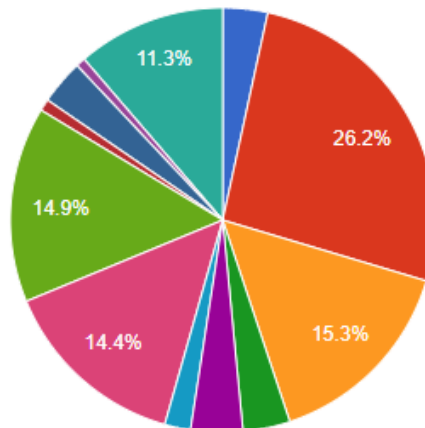
- ☐ I have/want a new Data Use Agreement (DUA)
- ☐ I have/want a new Confidentiality Disclosure Agreement (CDA) or Non-Disclosure Agreement (NDA)
- ☐ I have/want a new Clinical Trial Agreement (CTA)
- ☐ I have a newly awarded clinical research grant
- ☐ I have/want a new federally-funded cooperative group trial
- ☐ I have a new internally-funded clinical research trial
- ☐ I have a protocol or contract amendment
- ☐ I need to revise/correct OnCore information
- ☐ I would like to obtain a Certificate of Confidentiality
- ☐ I want to submit a clinical research account closure request
- ☐ I need help with the Conquering Diseases clinical trial opportunities portal
- ☐ I don't know/ I want to ask a question

OCR Intake Portal – Data

FY2019

Total Count (N)	Missing	Unique
557	<u>2 (0.4%)</u>	12

Counts/frequency: I have/want a new Data Use Agreement (DUA) (19, 3.4%), I have/want a new Confidentiality Disclosure Agreement (CDA) or Non-Disclosure Agreement (NDA) (146, 26.2%), I have/want a new Clinical Trial Agreement (CTA) (85, 15.3%), I have a newly awarded clinical research grant (20, 3.6%), I have/want a new federally-funded cooperative group trial (22, 3.9%), I have a new internally-funded clinical research trial (11, 2.0%), I have a protocol or contract amendment (80, 14.4%), I need to revise/correct OnCore information (83, 14.9%), I would like to obtain a Certificate of Confidentiality (5, 0.9%), I want to submit a clinical research account closure request (19, 3.4%), I need help with the Conquering Diseases clinical study opportunities portal (4, 0.7%), I don't know/ I want to ask a question (63, 11.3%)



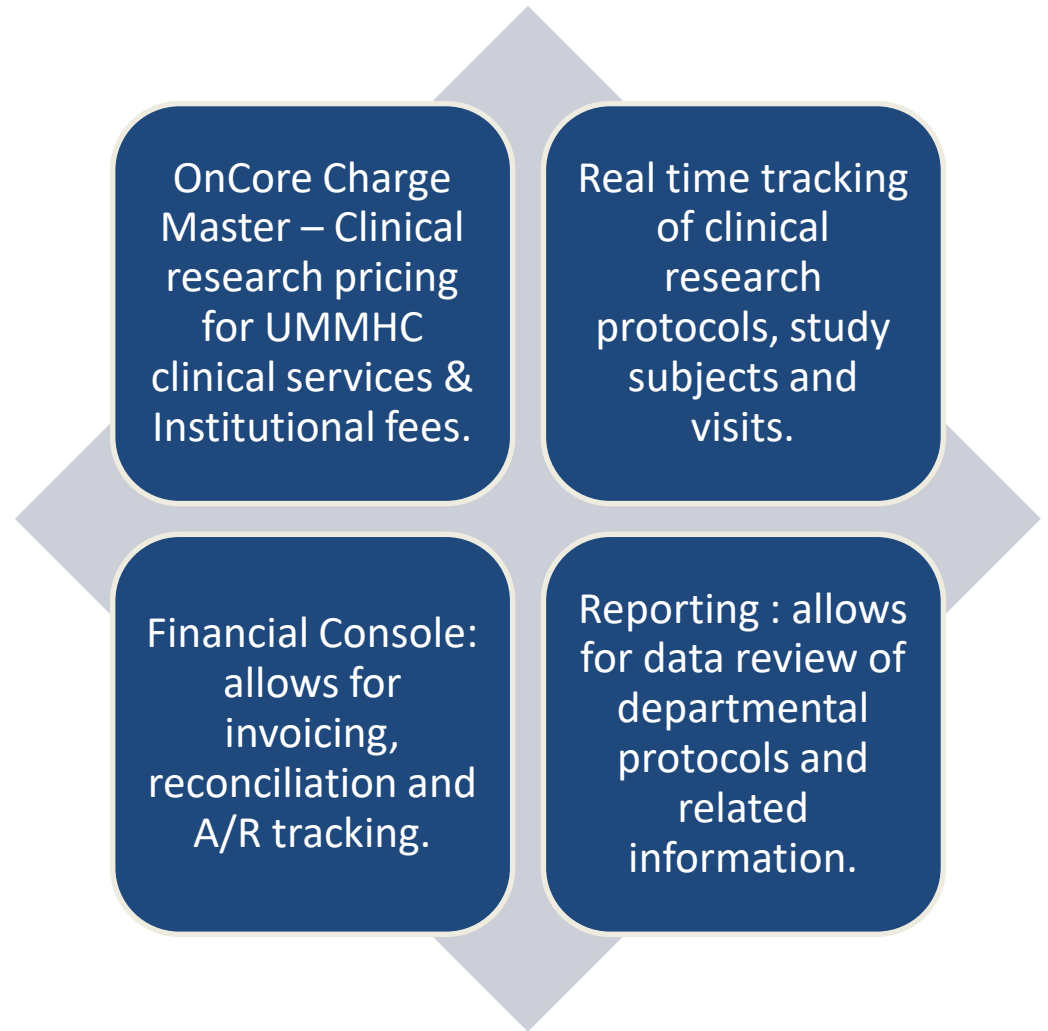
OnCore

Clinical Trial Management System

All clinical research that meets **any** of the following criteria must be entered into OnCore:

- Has an external fund source.
- Uses or purchases a service from UMass Memorial Health Care or any of its affiliates, including UMass Memorial Medical Group.
- Has or requires registration on ClinicalTrials.gov (has a NCT number).
- Uses the UMass Center for Clinical and Translational Science Clinical Research Center.
- Uses the services of the UMass IRB or Investigational Drug Services.
- Flags patients in Epic or uses Epic for recruitment.
- Requires access to <https://www.conqueringdiseases.org/> recruitment tools.

OnCore Tools for Administrators



OCR – OnCore Responsibilities



Creation of all new protocols, based on information received through portal.



Calendar, budget, coverage analysis & billing grid creation.



Financial console data creation and documents



Reconciliation of financial information with agreed upon contract, grant or fund source documentation



Reporting, maintenance & upkeep of data fields

Department - OnCore Responsibilities



Submit all required materials to OCR for protocol build.



Review and complete department specific data entry per OnCore Data Entry Manual .



Review and validate protocol calendar upon receipt.



Review completed coverage analysis and initial draft budget with OCR staff.



Maintain regulatory, study subject and visit information.

EPIC

Electronic Health
Record

- Request research access through OCR.
- Information that is currently shared between the Epic & OnCore includes:
 - Demographic information
 - Clinical research protocol information
 - Patient enrollment
 - Clinical research billing information
 - Regulatory information
 - Financial management information



SERVICES

TRAINING

ABOUT US

CONTACT US



Clinical Research Informatics Core

- Email: researchinformatics@umassmed.edu
- Website: <https://umassmed.edu/informatics>

Informatic Tools



Welcome to the UMCCTS

Our goals: (1) Accelerate the translation of basic discoveries; (2) Develop the next generation of clinical & translational research leaders

READ MORE

New CCTS WebPages



- Updated Spring 2019
- <https://www.umassmed.edu/ccts/>
- Includes links to all information, including a new “request services” page with access to all CCTS related services
- Also includes a “Need Help” button on many pages.



**CENTER FOR CLINICAL AND
TRANSLATIONAL SCIENCE**

What is current state?



288

Active
Protocols



91

Pending
Protocols



76%

Therapeutic
Trials



5,377

Subject
Accrual



141

Principal
Investigators

**LAUNCHED Oct, 2016 * COMPLETED ONBOARDING July, 2017 * EPIC INTEGRATION Oct, 2017
* eIRB INTEGRATION Aug, 2018 * UPGRADE APRIL, 2019**

Charge Master

Protocol Related

Subject Related

Labs

Panels

Procedures

Budget
Procedures

Additional Details »

[Search Events](#)

Procedures

Page Size 500 ▼

Page 1 of 1

Event Search

Order

Event/Item Code

Event/Item Description

Type here to search ▼

Search Clear Close

Search Results

Event Code: 99239

Event Type	Event Code	Event Description	Item Code	Item Description	Comments
Procedure	99239	Hospital discharge day	99239	Facility Fee	Event new in 3 (05/15/2019) Item added in 3 (05/15/2019)
Procedure	99239	Hospital discharge day	99239	Pro Fee	Event new in 3 (05/15/2019) Item added in 3 (05/15/2019)

62323		Injection Interlaminar Epi Lumbar/Sacral W /img Guide	1,434.20	832.31	1,103.23	832.31	05/21/2019
61864		Implant neuroelectrde addl	1,141.03	626.94	877.72	626.94	05/21/2019
61863		Implant neuroelectrode	6,021.66	3,308.60	4,632.04	3,308.60	05/21/2019
76377		Ct Limited Or Local Follow Up	139.29	75.94	107.14	75.94	05/21/2019

Last Updated
06/20/2019
06/20/2019
06/14/2019
06/14/2019
06/14/2019
06/06/2019
05/24/2019
05/24/2019
05/23/2019
05/22/2019

Charge Master

- Defines events that may be associated with a budget for a study.
- Stores both ***protocol-related events*** and ***subject-related events***.
- 3 Rate Base Rate structure for the protocol to determine pricing
 - ❖ Industry
 - ❖ Federal
 - ❖ Other-Non Profit

CHARGE MASTER

Event Details

Event Items Event Groups

Search Events Edit Event Echocardiogram Doppler

Order Event Code Additional ID Event Description **Charge Master Version** Retail FED IND ONP TBD Cost? Indirect?

Procedure Version: 3 (05/15/2019)

Order	Event Code	Additional ID	Event Description	Charge Retail	FED	IND	ONP	TBD Cost?	Indirect?	Delete?		
	93320		Echocardiogram Doppler	102.07	57.42	78.52	57.42	N	N	<input type="checkbox"/>	Edit	Usage

Close

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- ✓ Multiple Versions
- ✓ Not all applicable items for a procedure may be included in a single event

Items Update

Event Items Event Groups

Search Events Add Item Echocardiogram Doppler

Item Code Additional ID Item Description Budget Only? Auto-add? Indirect? Charge Retail FED IND ONP

Event Items Version: 3 (05/15/2019)

Item Code	Additional ID	Item Description	Budget Only?	Auto-add?	Indirect?	Charge Retail	FED	IND	ONP	Delete?		
93320		Facility Fee	N	Y	N	64.34	38.07	49.49	38.07	<input type="checkbox"/>	Edit	Usage
93320		Pro Fee	N	Y	N	37.73	19.35	29.03	19.35	<input type="checkbox"/>	Edit	Usage

Submit Clear Close

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Only a subset of UMMHC clinical services are reflected in the OnCore Charge Master

LET'S EXPLORE TOGETHER

Search



View Trials for Healthy Volunteers →

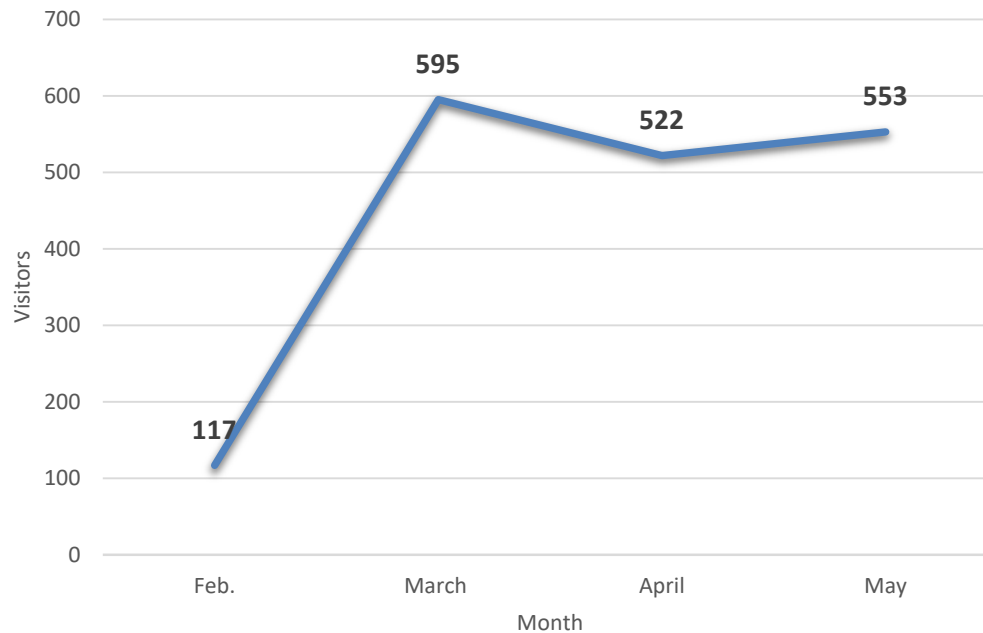
Enroll in our Volunteer Registry

New Tool Patient Research Portal

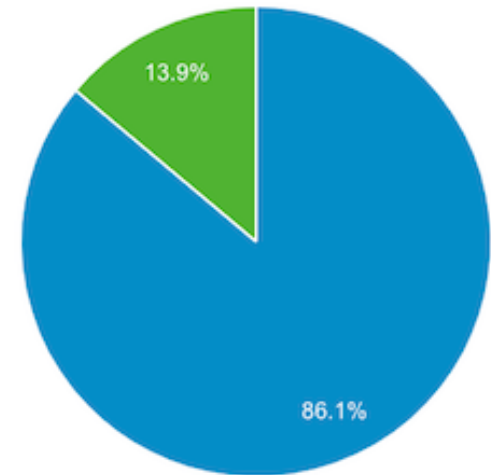
*Making Trials Accessible to our
Patients and Providers*

- **Simplified** Information for Patients & Providers
- Research **patient centric platform** for study search
- Full **integration with OnCore (CTMS)** for study information
- Visitors **express interest** on studies
- Study team **notification** via email on interested patients
- www.conqueringdiseases.org
- Phase II – user profiles & notifications; Summer 2019

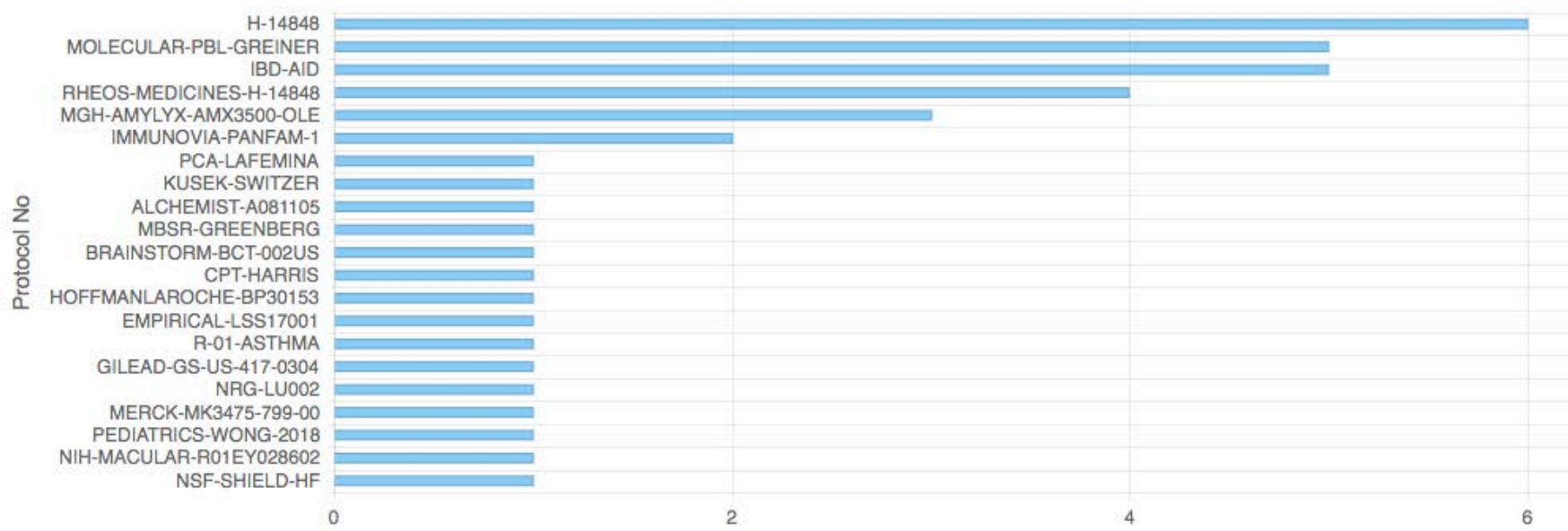
Number of Visitors by Month



■ New Visitor ■ Returning Visitor



Visitor Study Requests Metrics



40 Visitor Requests



21 Studies

Conquering Diseases – Study Requests

Visitors indicating interest in a study by submitting form with contact details



Need patient data for research?

REQUEST CONSULTATION

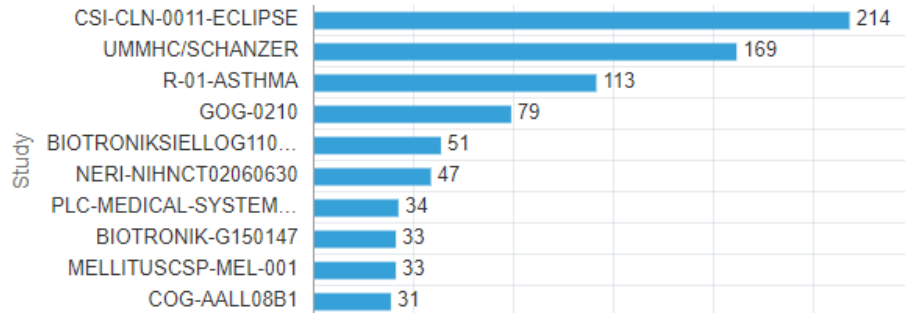
New Tool **Data Sciences** **Core**

- Launched Fall 2018
- <https://www.umassmed.edu/informatics/>
- Goal is to develop and disseminate tools, provide data and analytic approaches to accelerate research, develop effective learning healthcare models, enable cost-effective care, and train the next generation workforce.

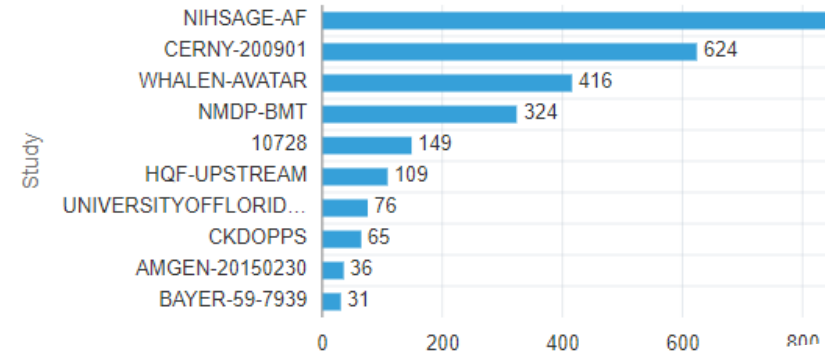
OnCore

This is a snapshot of Current state.

Top 10 Therapeutic Accruing Trial



Top 10 Non-Therapeutic Accruing Trial



New Tool CTMS Dashboard

- Reporting tool developed based on data being captured in OnCore
- CCTS/IT access Summer 2019
- Demo of Dashboard

Coming Soon...

- ConqueringDiseases.org – Phases II +
- OnCore Dashboard – Phase II
- Assistance with PeopleSoft Study Close Out/Final Invoicing
- New CRC Career Ladder
- Debit Card Program for research stipends/payments

