UMASS

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**

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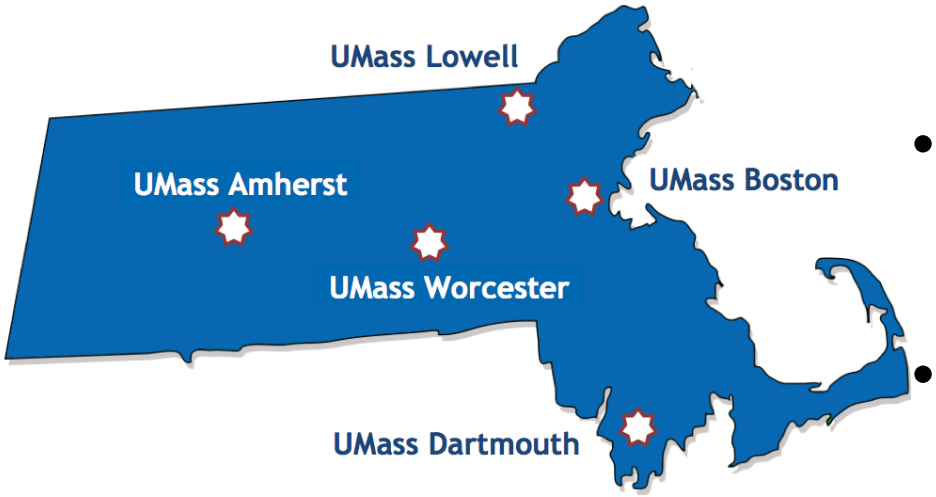
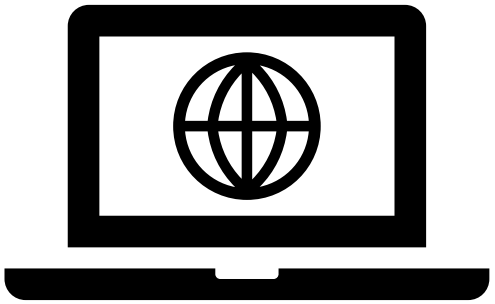
Create an Ecosystem that drives Innovation in Translational Research

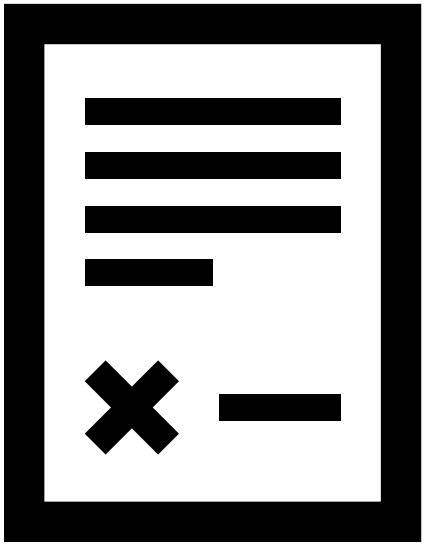


- Capitalizes on 5 campus + clinical system strengths
- Catalyzes trans-disciplinary collaborations across the translational spectrum
- Creates product pipelines; supports their development with cores, services, funding
- Creates new/enhances existing training opportunities

CENTER FOR CLINICAL AND TRANSLATIONAL SCIENCE

- Office of Clinical Research
- Institutional Review Board
- Community Engagement
- Biorepository & Tissue Bank
- Clinical Research Informatics
- Biostatistics, Epidemiology, Research Design (BERD)
- Bioinformatics
- Small Molecule Screening
- Clinical Research Center (CRC)
- Investigational Drug Services (IDS)
- Institutional Centers (M2D2, Mass Biologics, Commonwealth Medicine, Meyers Primary Care)
- 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

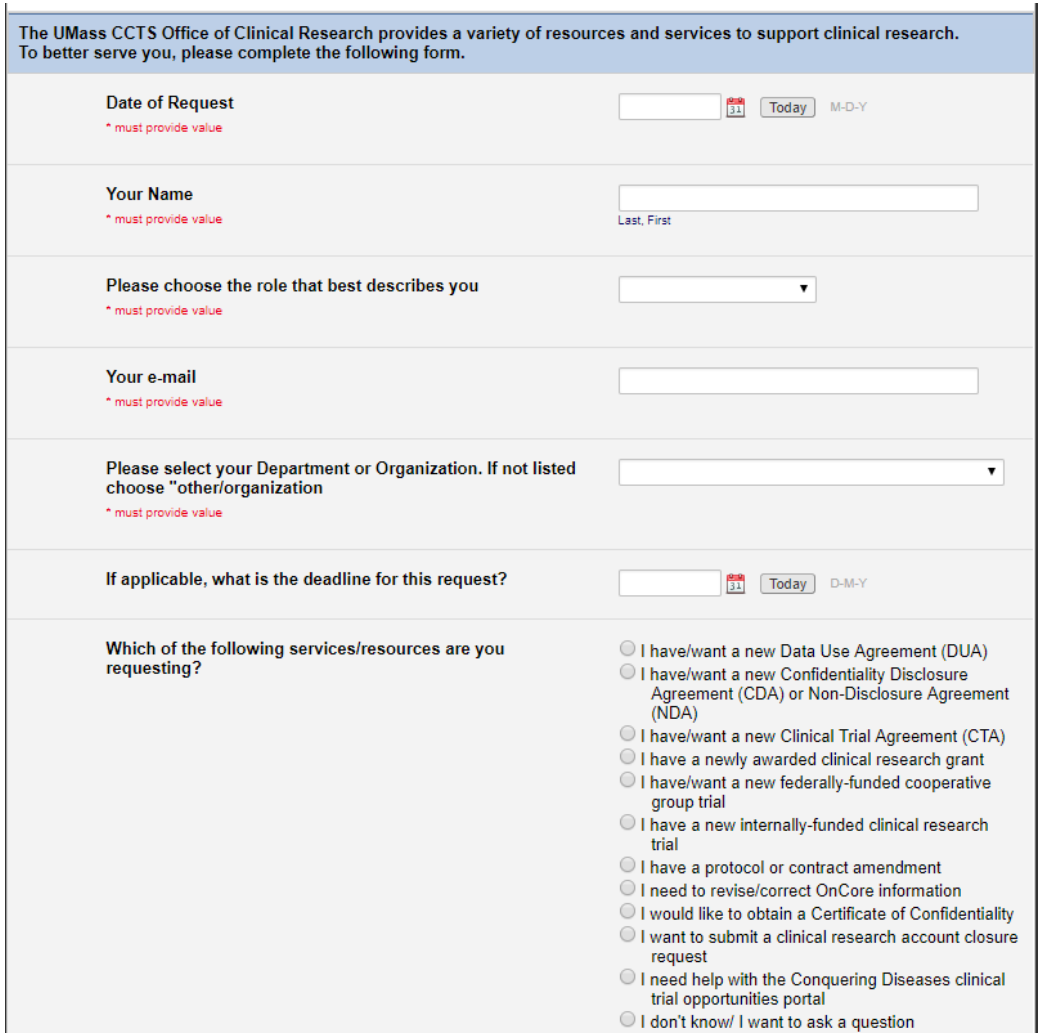
- **Danielle Howard**
  Director, Clinical Research Operations
- **Richard Stevens**
  Associate Director, Compliance & Contracting
- **Elena Del Prete**
  Contract Administrator III (Pre-Award)
- **Michelle Maynard**
  Contract Administrator II (Pre-Award)
- **Kathryn Beauregard**
  Contract Administrator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



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?

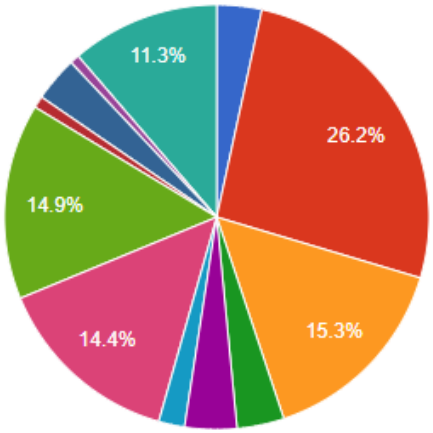
- I have/want a new Data Use Agreement (DUA)
- I have/want a new Confidentiality Disclosure Agreement (CDA) or Non-Disclosure Agreement (NDA)
- I have/want a new Clinical Trial Agreement (CTA)
- I have a newly awarded clinical research grant
- I have/want a new federally-funded cooperative group trial
- 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	2 (0.4%)	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%)



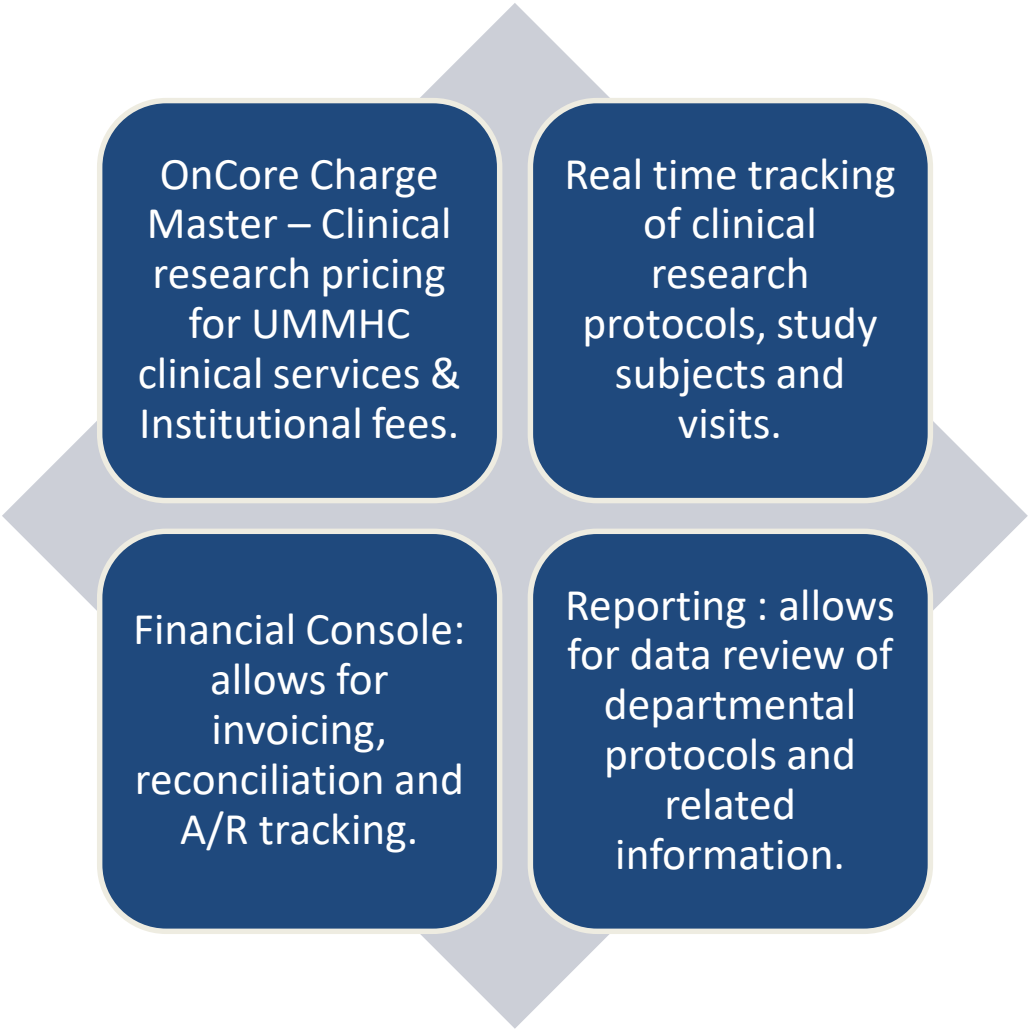
OnCore

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/ recruit ment 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

Clinical Research Informatics Core

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

Informatic Tools

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.

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What is current state?

288
Active Protocols

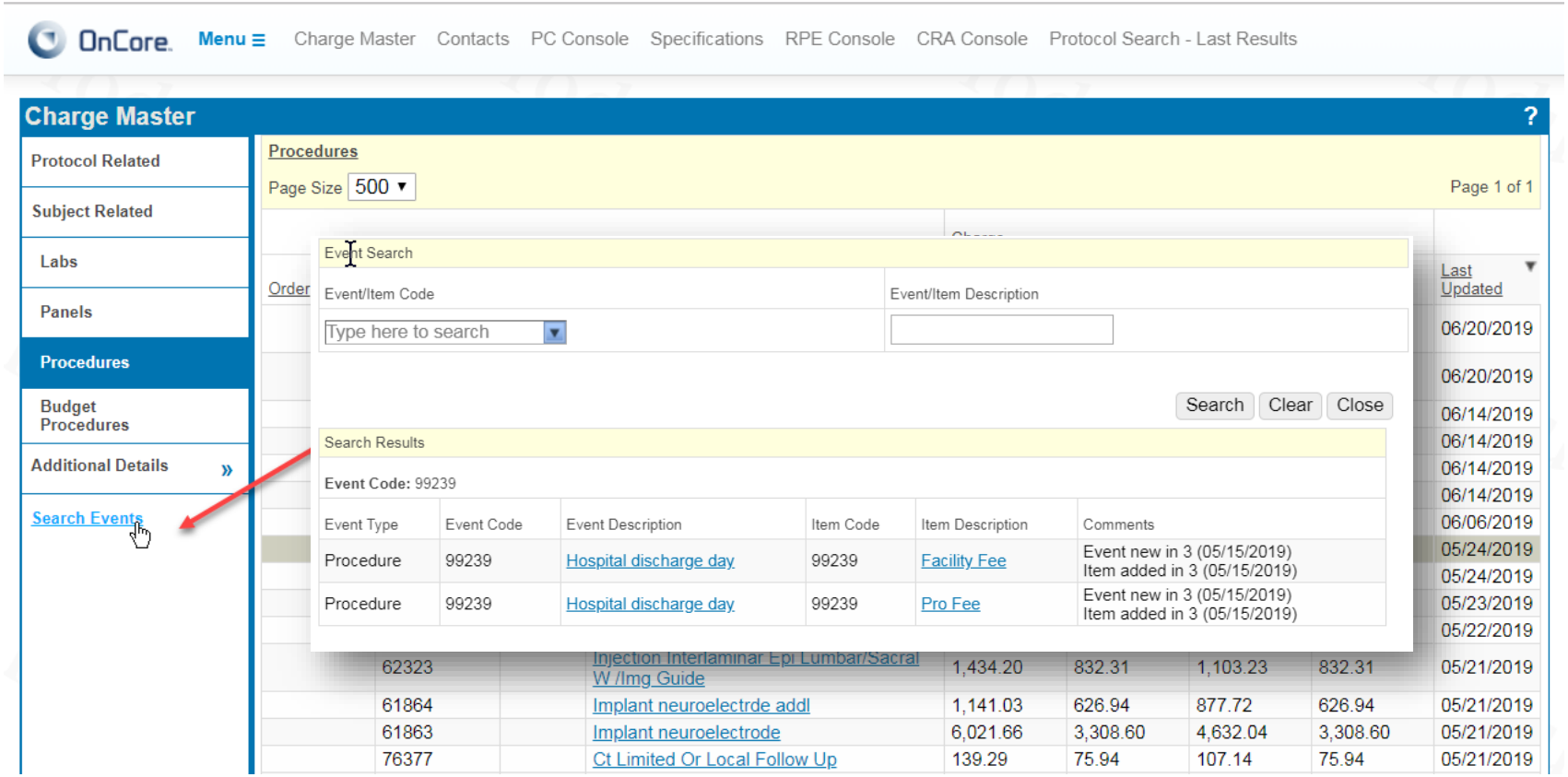
91
Pending Protocols

76%
Therapeutic Trials

5,377
Subject Accrual

141
Principal Investigators

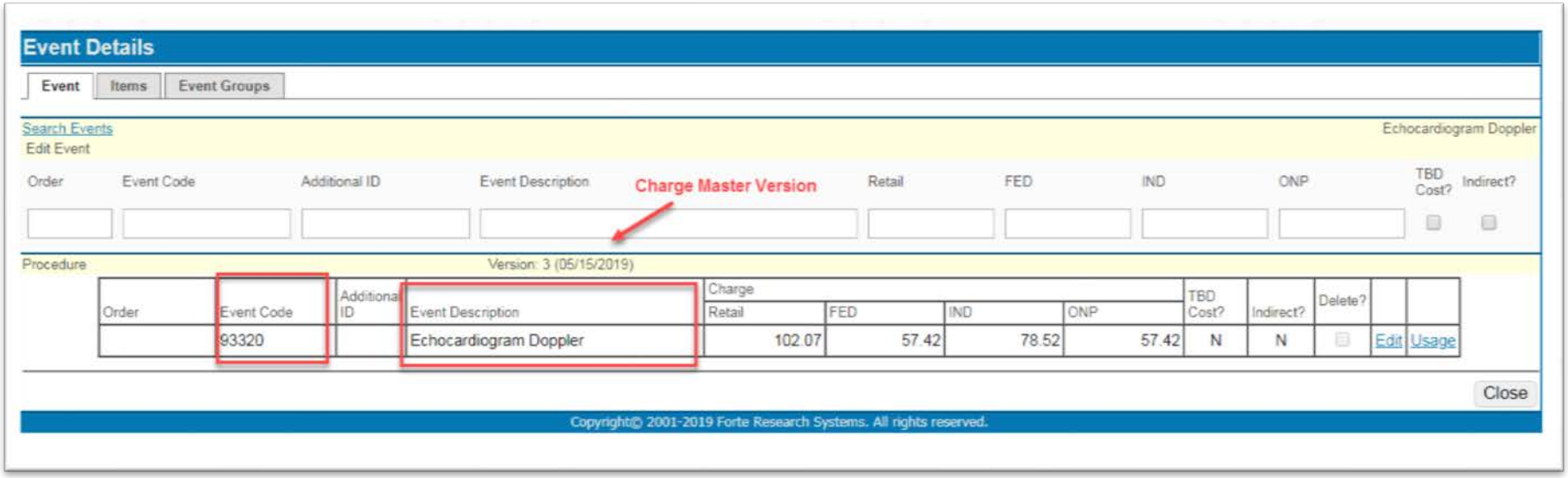
LAUNCHED Oct, 2016 * COMPLETED ONBOARDING July, 2017 * EPIC INTEGRATION Oct, 2017 * eIRB INTEGRATION Aug, 2018 * UPGRADE APRIL, 2019



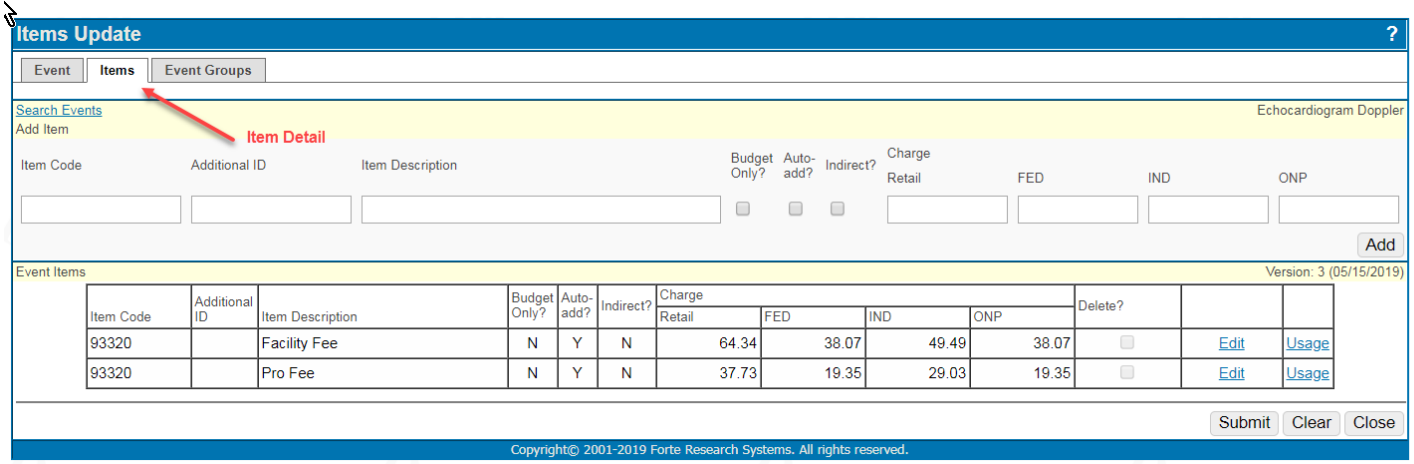
Charge Master

- 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

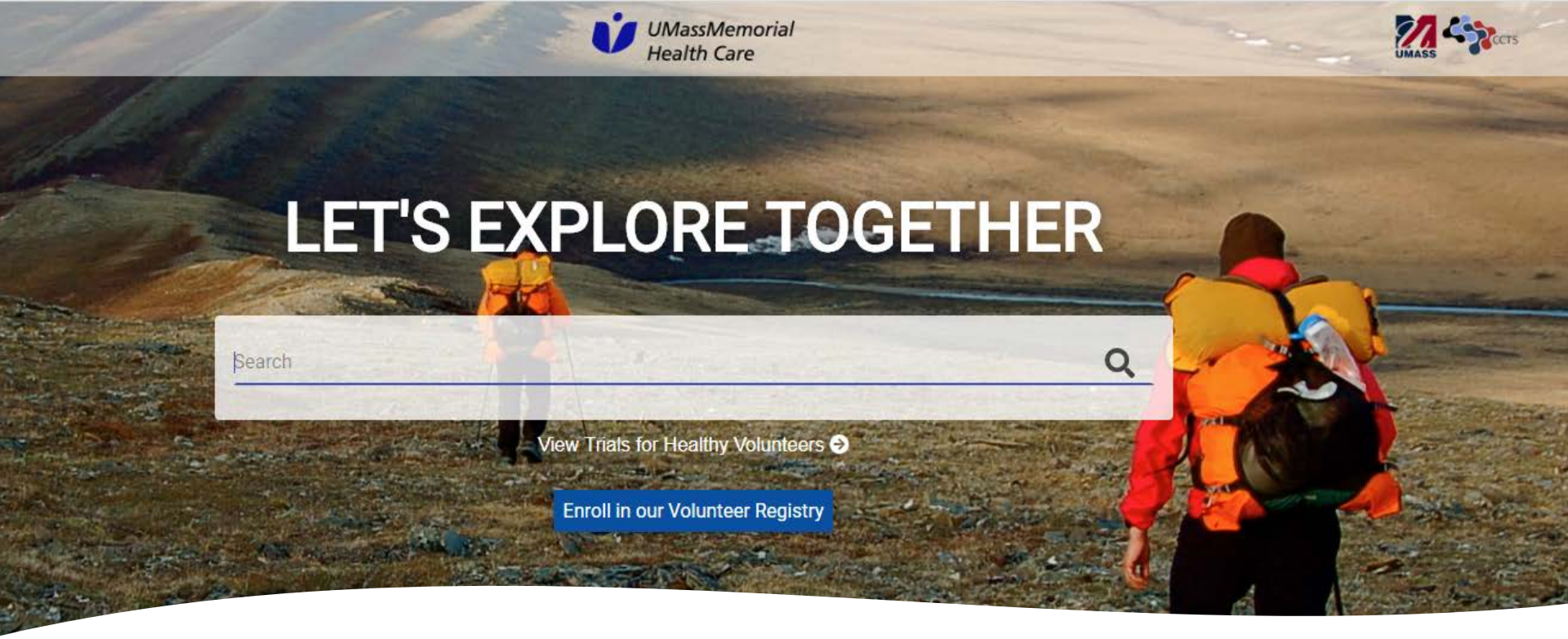
CHARGE MASTER



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



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

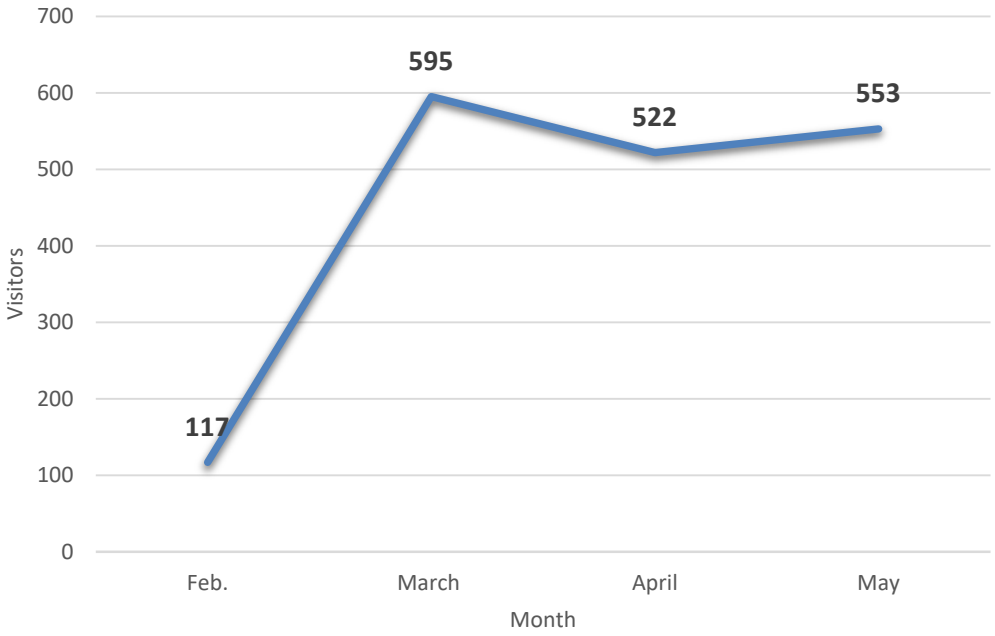


New Tool
Patient Research Portal

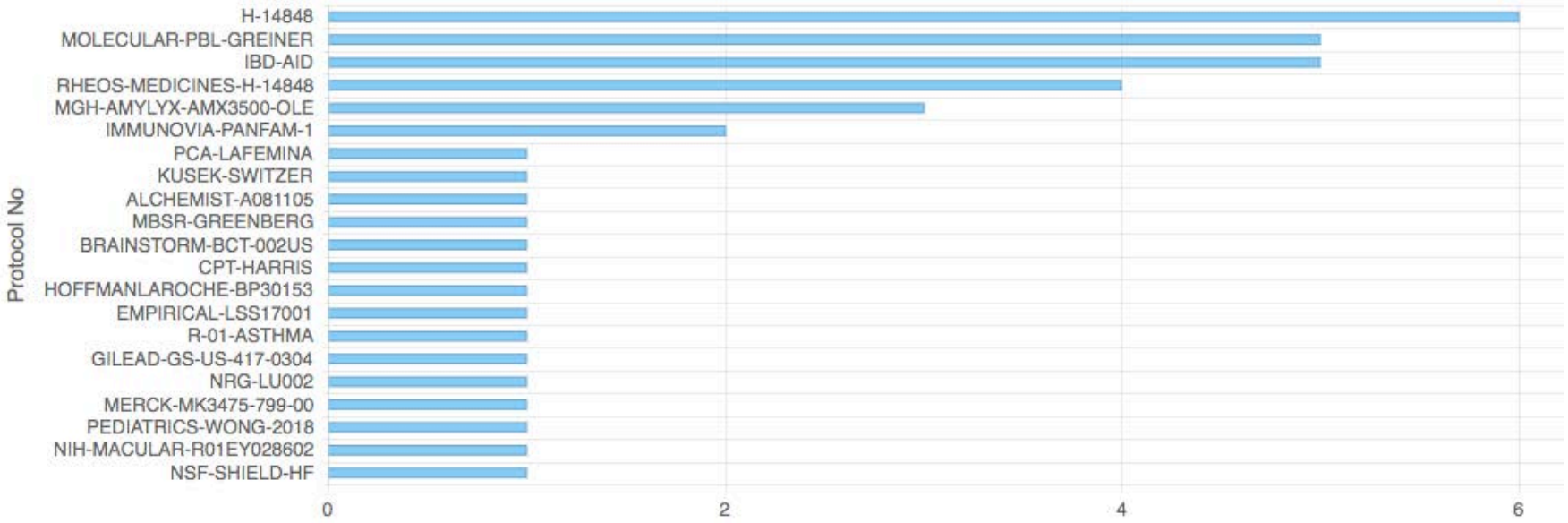
Making Trials Accessible to our Patients and Providers

- 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



Visitor Study Requests Metrics



40 Visitor Requests

21 Studies

Conquering Diseases – Study Requests

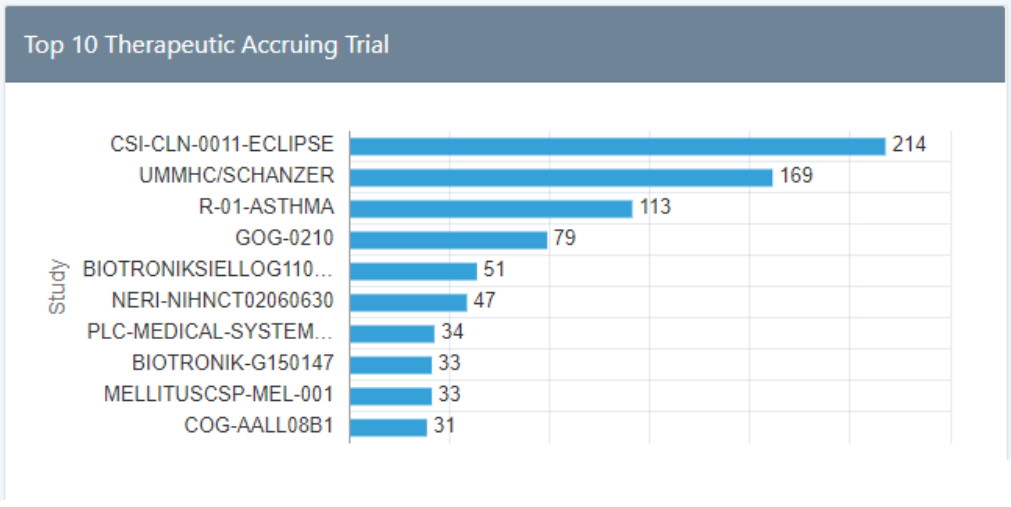
Visitors indicating interest in a study by submitting form with contact details

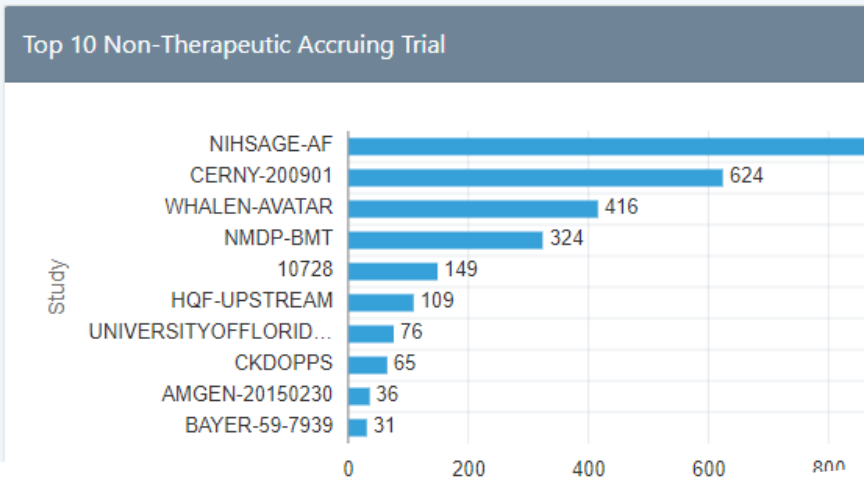
New Tool
Data Sciences Core

- 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.





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