

# DATA MANAGEMENT CENTER NEWSLINE

## Regional Data Management Introductory Workshop Scheduled

The Data Management Center for ACTG and IMPAACT will conduct a Regional Introductory Training Workshop on August 5th—7th, 2019, hosted by Kilimanjaro Christian Medical Center in Moshi, Tanzania. This training is a 2.5 day, interactive workshop for coordinators, data managers, or clinical staff involved with data management. Advanced registration is required and seating will be limited.

The workshop will cover the following topics:

- *Introduction to Frontier Science*
- *Data Management Center Portal Website Highlights*
- *Subject Enrollment System*
- *General Forms Overview*
- *Specifying Diagnoses, Signs, and Symptoms,*
- *Daily Quality Assurance Reports*
- *Monthly Quality Assurance Reports*
- *Medidata Rave Overview and Daily QA in Rave*
- *Case Report Forms and Grading Laboratory Toxicities*
- *Rave Reports*
- *Rave Exercise*

The Registration link containing the proposed agenda and further information is available at the top/center of the Frontier Science Portal project pages for ACTG & IMPAACT. Registration will be limited to two registrants per site until July 1st, 2019. After that date, additional staff registrations will be accepted from your site, pending space availability. Pre-registration of additional attendees will not be permitted.

The training will be conducted in English. Training materials will be provided via a USB flash drive and posted on the Frontier Science Portal. Printed materials will not be provided.

For additional information, please contact Mary Wojcik-Cross ([wojcik@fstrf.org](mailto:wojcik@fstrf.org)).

## INSIDE THIS ISSUE

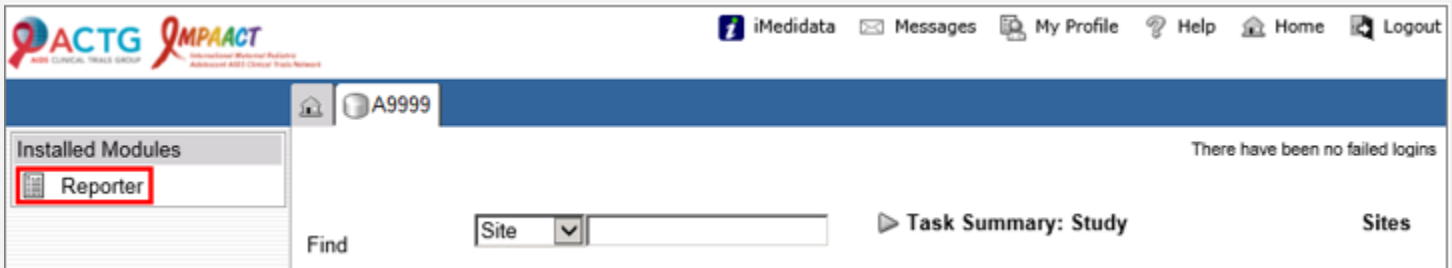
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## SUBMIT AN ARTICLE TO THE DMC NEWSLINE

The DMC Newsline encourages readers to submit articles, news releases, and event listings. Materials submitted are subject to editorial review. Please email information in Microsoft® Office Word format to the Editor, Mary Wojcik-Cross, at [wojcik@fstrf.org](mailto:wojcik@fstrf.org).

# Rave Reports for Quality Assurance

The *Reporter* module in *Rave* provides several reports that site staff can use for quality assurance and internal performance review. The *Rave Reports* reference guide that is available on the Frontier Science Portal under *Site Support > Medidata Rave Resources* compliments the *Rave Reporter* eLearning available from iMedidata *and* outlines many helpful components of using the module. Please note that you may complete eLearning in iMedidata, even if it has not been formally assigned.



The following reports may be helpful in managing your Rave information:

### ***Page Status Report***

Provides the same basic information available through the Rave interface and the Task Summary, with counts. Allows user to drill down from site to subject, folder, and form. Lists basic counts and status (number overdue, number of queries) at each level.

### ***Query Aging Report***

Provides an overview of how long it takes for queries (both automatic and manual) to reach a status of “*Answered*” or “*Closed*.” Does not use open queries for these calculations. Includes a drill down feature.

### ***Query Details Report***

Retrieves all queries that a site has received, including the full text of the query, the query status, the status date, the query response (if any), and the marking group (query sender). Also includes participant identifier, folder, and eCRF.

### ***Query Summary Report***

Provides the number of queries with the “Open”, “Answered”, “Closed”, or “Cancelled” status that a site has received, as well as the total number. Totals are broken down by marking group (query sender).

### ***360 Query Management Report***

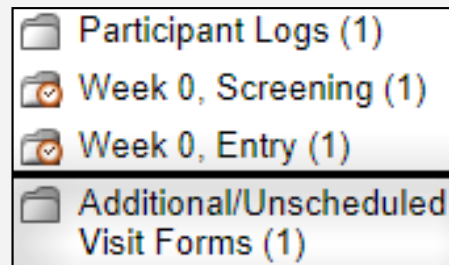
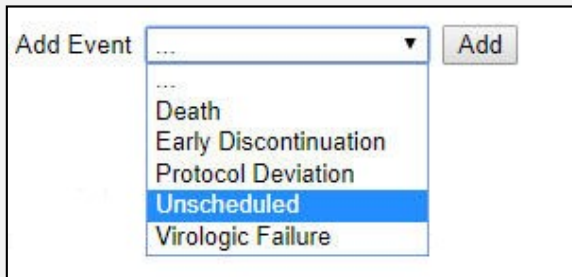
Combines other query-focused reports and offers visualization tools.

Visit the *Training Pages > Presentations* on the Portal for additional training resources, including *Rave Reports* and other *Rave* topics. A *Rave Reports* webinar will be conducted on April 11th as part of the *DMC Webinar Series*. For additional information, contact Mary Wojcik-Cross (wojcik@fstrf.org).

# Reporting Unscheduled Visits in Rave

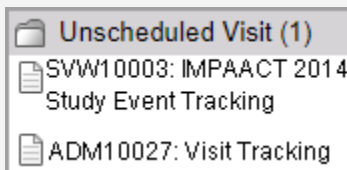
The *Unscheduled Visit* folder should be used to report repeat laboratory tests, repeat vital signs, additional specimen collections, and any other interim visits conducted for clinical management. The reporting of unscheduled and additional visits in *Rave* is handled differently than in our legacy systems. To report an unscheduled visit, the *Unscheduled Visit* folder must be added for the participant before any forms can be completed. The *Add Event* menu at the bottom of the participant's homepage is utilized to add the *Unscheduled Visit* folder:

1. Select **Unscheduled** from dropdown listing.
2. Click **Add**.



The *Unscheduled Visit* folder will appear in the visit folder panel for the participant, with one of two form configurations automatically placed in the *Unscheduled Visit* folder.

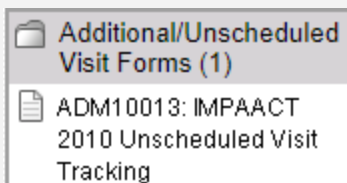
## Configuration 1: Visit Tracking form and Study Event Tracking form



Completion of the Visit Tracking form and Study Event Tracking form will add any other forms needed for the unscheduled visit. If all forms needed for the unscheduled visit cannot be added by completion of the Study Event Tracking form, please contact the protocol data manager for further assistance.

**Note:** This configuration option is widely used in most ACTG and IMPAACT studies.

## Configuration 2: Study-specific Unscheduled Visit Tracking form



In this configuration, the forms needed for the unscheduled visit are selected by checking the box next to the form.

**Note:** This configuration is utilized by ACTG A5300B, ACTG A5321, IMPAACT 2010, and IMPAACT 2008 for unscheduled visits.

Please consult with the protocol data manager if you have questions about any protocol-specific reporting requirements, which forms must be completed, or if you experience any issues when selecting the *Unscheduled Visit* folder.

# Employee Spotlight: Rachel Issa

**What is your name and job title?**

Rachel Issa — ACTG Protocol Data Manager

**Where are you from?**

I'm a born and raised Buffalonian!

**What is your education?**

I'm a Registered Respiratory Therapist, with an AAS in Respiratory Therapy, a BS from University at Buffalo in Speech and Hearing Sciences with a minor in Education, and will complete my MS in Respiratory Therapy from Canisius College this summer.

**How long have you worked at Frontier Science?**

I started at Frontier Science in August 2018.

**What does a typical day for you at Frontier Science look like?**

Every day is a little different, and I'm always learning something new! Being a recent hire, I've spent a lot of time on open studies with my mentor, Kathleen Donahue. I perform QA/QC of data, toxicity review, troubleshooting, and respond to sites' questions for all studies assigned. For new studies in development, we also aid in protocol development and review, forms creation and selection, study build testing, and randomization.

**What is your favorite part about working at Frontier Science?**

My favorite part about working at Frontier Science is the balance between independently driven work, and a collaborative support system. It's been a very conducive environment to learning data management, and I feel I've built a great foundation through interacting with all of the various departments here. From a clinical standpoint, I find the work here meaningful, and look forward to all that I can learn and contribute to in my future here.

**What was your greatest work-related accomplishment since joining Frontier Science?**

Seeing the progress that I've made since starting at Frontier Science is something that I'm certainly proud of. Building good rapport with my sites, teams, and statisticians, as well as utilizing my clinical knowledge/experience (specifically on my tuberculosis studies), I feel that I uniquely contribute to the overall quality of my trials.

**What are your passions/interests outside of the workplace?**

With my father being an immigrant from Lebanon and the remainder of his side of the family still living there, I've traveled internationally quite a bit from a young age. Through that, exploring different states/countries, and being immersed in different cultures has been something that I've loved seeking out when I can! I feel I've learned and come to appreciate so much about how others live, the world, and the versatility that exists within it. I'm certainly a more well-rounded person because of my travels, and therefore will continue to try and do so whenever I have the opportunity.

**It's the weekend. Where can we find you?**

When I'm not busy with school work, my typical weekend consists of playing in my recreational volleyball league, spending time with friends/family, or checking out local events around Buffalo!



## 2019

## JANUARY

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## DECEMBER

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## MARK YOUR CALENDARS

## Data Management Introductory Workshops

May 16 -17, 2019

October 23 -25, 2019

## Regional Data Management Introductory Workshop (Moshi, Tanzania)

August 5-7, 2019

## Webinar Series

See DMC Portal Training Pages for schedule

## CONTACT

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## ACTG and IMPAACT

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