



## Supporting Pediatric Clinical Research with a Clinical Trials Management System in the Children's Hospital Setting

The last year has been a busy one for Cincinnati Children's Hospital Medical Center (CCHMC). They kicked-off their implementation of the OnCore Clinical Research Management system in the fall of 2008, went live with the new software for the Oncology Division in March of 2009, and then brought on the Hematology and Blood and Marrow Transplant Divisions a few months later.

Cincinnati Children's is the first stand-alone pediatric hospital to use the system to implement their portfolio of clinical trials.

"Pediatrics is unique," said Tamara Nordheim, RN, BSN, OCN, Hematology Clinical Research Manager at CCHMC.

Compared to the majority of clinical trials at an adult cancer center, for example, pediatric trials have some key differences. These include different diagnoses, studies being open longer, lower accrual, increased complexity, and additional requirements for handling patient safety and consent.

One of the first enhancements made to OnCore in support of pediatric clinical trials was the ability to track and prompt for "reconsent." This addresses the requirement, when a pediatric subject reaches the age of majority, for the investigator to circle back with them in order to renew consent from the patient who can now make this important decision for themselves.

"Even the definition of 'care' is different," said Rebecca Turner, Oncology Clinical Research Manager at CCHMC. "Sometimes you are providing care to the whole family because the family situation affects the child's ability to participate in a trial." Plus, she added, family members may also be enrolled on a trial when the investigation of family genetics is one of the goals of the study.

It's partly this complexity which led to Cincinnati Children's to search for a new clinical trials management system.

"We had a small homegrown system that served our purposes pretty well but we were interested in looking around at other products before we expanded further. We wanted to incorporate functionality our system didn't do at the time, like financials and electronic data capture," said Rebecca.

"Having a trial management system that walks you through all those specific steps and allows you to pull data to create reports has been beneficial," said Tamara. "Some of the new features in OnCore, like reconsenting at the age of majority are essential."

Other enhancements made to OnCore include the ability to completely customize the fields related to diagnosis and the ability to handle both a primary diagnosis and a secondary diagnosis, if needed.

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Co-hosted by UNC Lineberger Comprehensive Cancer Center Rizzo Center, Chapel Hill, NC, February 10<sup>th</sup> - 12<sup>th</sup>

## Get the full story at Onsemble.net

Want to learn more about something you read here? For full details and additional information, visit [Onsemble.net](http://Onsemble.net), your complete resource for the OnCore community.



## The meeting place of the OnCore Community.

### General Session Expanded on First Day of Spring Conference Popular Workshop is Now the Opening Session

In order to allow more people to participate in presentations and discussion on topics related to measuring and improving clinical research operations, the general session at the 2010 Spring Conference will start earlier. What had been a pre-conference workshop at the last five events will now be the leading session of the upcoming conference in February.

“We had been offering concurrent workshops oriented toward a variety of interests,” said Program Committee member Henry Durivage, PharmD, Associate Director of the Yale Center for Clinical Investigation at the Yale University School of Medicine. “Because there was significant interest in this topic we decided to make the workshop a part of the general meeting.”

The newly expanded session will build on the themes of the previous workshops. As before, presentations will provide updates on and new data from work taking place in the Onsemble Metrics Collaborative Initiative.

“To kick-off the session, we’ve invited Suanna Bruinooge, Director of the Research Policy Division from ASCO to talk about several initiatives including measuring the impact of regulatory complexity and

clinical trial accrual strategies,” said Kerry Bridges, MBA, RN, CCRC, of the Indiana University Simon Cancer Center.

Next, an update will be given by the Resourcing Initiative Working Group. This group has made a lot of progress in the last six months on a project in which participants piloted a new Effort Tracking system to gather detailed, objective clinical trial resourcing data across centers.

“Given today’s environment of constrained resources, this tool gives us important data that we can use to analyze how staff are spending their time. With this knowledge, we can evaluate barriers and ultimately reengineer steps in trial conduct to improve efficiency,” said Charleen Pagel Jue, Associate Program Director at the UMN Masonic Cancer Center who worked to spearhead the project.

Wrapping up the session, Ellen Graves Wojcik, MBA, CCRP, Business Analyst at Winship Cancer Institute at Emory University will discuss strategies for reducing the burden of low accruing trials and present the findings from a community-wide survey on this topic.

**Effort Tracking - Track Time**

[Return to Protocol list](#) [Logoff](#)

Protocol: CDUS-CDS      Trial Type: Therapeutic      First Subject Enrolled: 06/06/2004      Number of  
Phase: Phase II      Last Treatment Visit: none      Number of Sub

Comments are really nice.  
You should have one every day.

User	Stage	Activity	Week Beginning	Time Worked (Hours)	For the v
All	Select Stage	Select Activity	01/11/2010		can mea
beau	Start Up	Clinical Activities	08/17/2009	14.75	the activi
beau	Start Up	Clinical Activities	08/17/2009	0.25	Start

*The Resourcing Initiative Working Group is piloting a system on the Crescendo website (CrescendoEx.com) for tracking effort on key activities for particular protocols.*

## Dr. Jeffrey W. Clark to Deliver Keynote Address

### Director of Clinical Trials Support at Dana-Farber/Harvard Cancer Center will Focus on Process Improvement

Kicking off the afternoon session at the Onsemble 2010 Spring Conference, Jeffrey W. Clark, MD, Medical Director, Clinical Trials Operations at Dana-Farber/Harvard Cancer Center, will deliver the keynote presentation. The topic will focus on process improvement for clinical trials operations with an emphasis on trial startup.

An expert on this topic, Dr. Clark devotes much of his clinical efforts to evaluating and improving the performance of clinical trials in oncology. He is able to put this into practice in his role as medical director and as a member of the Institutional Review Board. His work in this area includes not only continuous reassessment of systems issues in the performance of trials, but also evaluation of the informed consent process and ways in which this might be improved for patients.

Dr. Clark's clinical work centers on using combined modality approaches, including surgery, radiation therapy, and chemotherapy, to treat gastrointestinal malignancies. He is specifically interested in the development of approaches targeting proteins

mutated or over expressed in malignant cells. His work includes early evaluation of novel agents in phase I studies as well as the integration of these agents with standard chemotherapeutic regimens.

The training of Hematology/Oncology fellows is the focus of Dr. Clark's teaching efforts. In this, he addresses the diagnosis and care of patients with gastrointestinal malignancies as well as issues related to the enrollment of patients on clinical trials. In the latter regard, he lectures in the "Design and Conduct of Clinical Trials" course for fellows and junior faculty and is also involved in the development of the curriculum for the ongoing education of fellows and faculty in issues related to the performance of clinical trials.

## Welcome Reception will Feature Local Jazz Musician

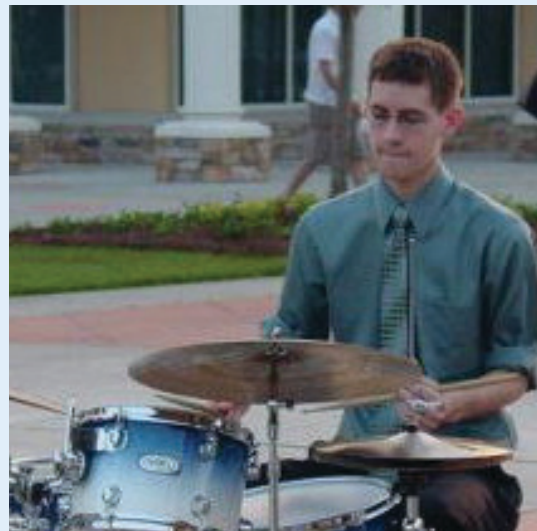
### William Flowers will head Quartet During Event at the DuBose House

From first being captivated by music at age 12, William Flowers wanted to play drums.

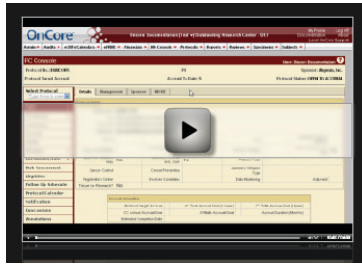
"When I asked my parents for drum lessons, my mom first made me take piano lessons for a year, which now I'm glad I did," said William. But, it was during his ninth grade year at Durham magnet school, the Durham School of the Arts, when William became interested in jazz. "There was a teacher who came there who was an excellent jazz drummer and I was able to study with him for two years."

In high school, William began performing at restaurants and local venues with ensembles made up of classmates. He continues to perform and looks forward to graduate school and eventually pursuing a career in music education or music ministry after completing his degree in Music Education in the jazz program at North Carolina Central University in Durham.

William is the son of Onsemble member, Dale Flowers, a clinical research coordinator at UNC Lineberger Comprehensive Cancer Center. Samples of William's music are available for download on the Onsemble.net website.



*William Flowers will bring his jazz rhythms to the Welcome reception at the Onsemble 2010 Spring Conference on Wednesday, February 10th.*



## The meeting place of the OnCore Community.

### OnCore Learning Portal Launched

Resources are Now Available, Organized by Product through the New Web Portal via Onsemble.net

At the Onsemble 2009 Fall Conference, it was announced that PercipEnz would soon be making a portal available that would provide a one-stop place for product training, documentation and release-related materials for the OnCore family of software products. In December, it was announced that the OnCore Learning Portal is now available.

Phase one of the OnCore Learning Portal brings together several resources that were previously found in various places throughout Onsemble.net:


- Training Videos
- Product Documentation
- Release Notes
- Webinar Schedules and Materials

Materials found via the portal support not only the Clinical Research Management product (OnCore-CRM) but also the Biospecimen Management

product (OnCore-BSM). As promised, 10 new training videos specifically for Biospecimen Management have been created. These cover such topics as Banking Protocol Setup, Analysis Protocol Setup for Correlative Studies, and Custom Reporting.

For easy access, all of the materials are organized by product on the OnCore Learning Portal which is accessed via the Onsemble.net website. Simply log-in to Onsemble.net and select the OnCore Learning Portal link from the side menu.

Continuing the concept of easy access, starting with OnCore Version 10.0 (targeted to be available at the end of March), the OnCore Learning Portal will be accessible directly from within the CTMS.



Clinical Research Management
Biospecimen Management
Unified Registries Management
Onsemble
Crescendo

*Clinical Research Management*

**Webinars**

Each OnCore Webinar addresses an aspect of OnCore-CRM functionality, with the topic determined by Onsemble community requests.

Webinars are delivered via the GoToMeeting Web conferencing tool and consist of a demonstration followed by a question and answer session. Use the link above to view a schedule of past and future Webinars, as well as download descriptive overviews and presentation materials.

**Documentation**

OnCore's extensive documentation is designed with the end user in mind. It is written in a Tutorial style, which serves the dual purpose of describing the OnCore application while directing the reader through its use.

**Training Videos**

There are over sixty CRM-related training videos, each focused upon a single aspect of OnCore-CRM functionality.

Each video is a brief tutorial, with a narrator discussing and demonstrating how to use OnCore to accomplish a CRM task.

Use the videos to expand (or refresh) your OnCore knowledge!

**Release Notes**

OnCore Release Notes detail the changes, enhancements, corrected defects, and known issues of each OnCore release.

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## Rutgers-Cleveland Clinic Consortium of AFIRM Selects OnCore® to Support its Collaborative Clinical Research on Regenerative Therapies

When evaluating what was needed to support a widely distributed consortium comprised of 15 organizations across the country who are conducting cutting-edge collaborative clinical research, the Rutgers-Cleveland Clinic Consortium (RCCC) selected the OnCore Clinical Research Management system (OnCore-CRM) to administer their studies and coordinate the group's efforts.

The Rutgers-Cleveland Clinic Consortium is part of the Armed Forces Institute of Regenerative Medicine (AFIRM), a multi-institutional, interdisciplinary network working to develop advanced treatment options for the nation's severely wounded servicemen and women.

*Read more on Onsemble.net in the Onsemble News section.*

### Pediatric

*(continued from front page)*

Some of the issues that make administering pediatric trials complex are logistical in nature.

"You have to consider what laboratories you're sending your patients to," said Rebecca. "Do they have pediatric reference ranges? If the patient gets ill, is there a hospital that can care for the type of disease they have? How much blood can you draw?"

The procedures are different, too. Procedures that would be out-patient for an adult become in-patient for a pediatric subject. For example, an MRI, which would be a fairly routine procedure for an adult, may require general anesthesia for a child, significantly increasing risk

"We have barely touched the surface of what OnCore can offer, in my opinion," said Tamara. "The calendars (specifications) are one thing we haven't begun to work with, yet. I think OnCore is going to help with some of the logistical aspects of the trials because we will be able to track them through forms and through the calendars."

Since the beginning of their implementation, Rebecca and Tamara have been participating in activities of the OnCore community and providing input into the evolution of OnCore. Some of their suggestions, which are now part of OnCore Version

9.5, include the ability to track that a patient started treatment before being officially enrolled in the trial, a common exception made for pediatric patients.

"I think it's been helpful to be involved as a new facility coming on board with a system that's new to us, to be able to be involved with some of the Onsemble community teleconferences," said Tamara. "For me, I can not only learn what OnCore has to offer but also be part of the planning and decision making for OnCore's future."

Transitioning to the new software has gone smoothly, according to Rebecca and Tamara. The biggest challenge has been finding time to really learn the system and to take advantage of additional functionality they'd like to start using.

"I really like the look of some of the reports that I'm able to pull out of OnCore, for example the accrual for the sites, and reports related to the management group (i.e. Sickle Cell, BMT, IMM, Hemophilia)," said Tamara. "I like being able to pull a report that suits my needs rather than having someone else make one behind the scenes. In our old system, the data was in there but I had to go to someone else to pull that information."

Age Reconsent Details		
Status	Subject requires age reconsent.	
Subject Age of Majority	18.0	Reconsented at Legal Age

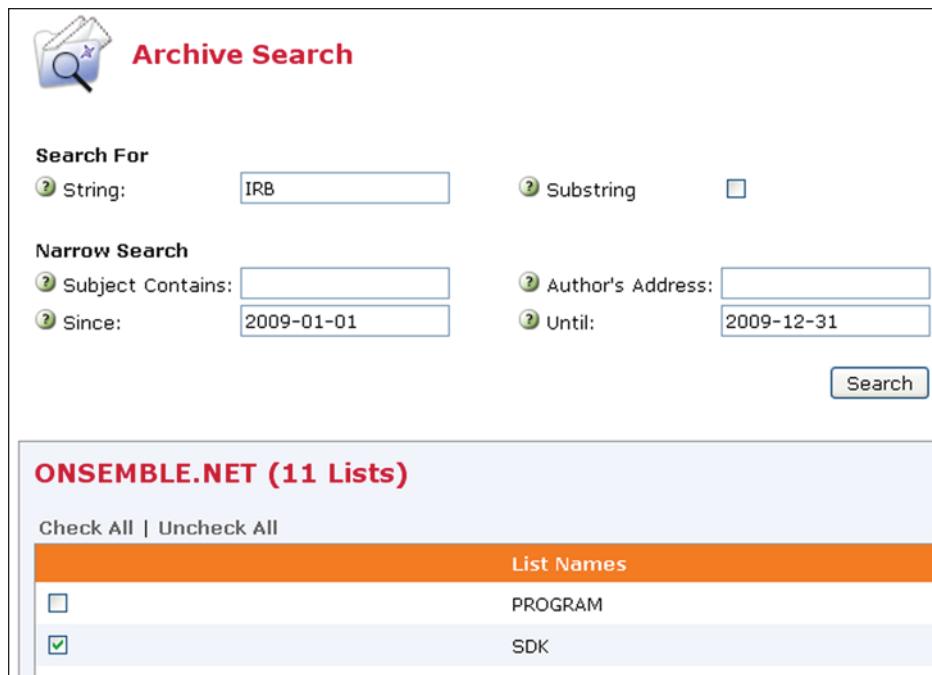
## Finding Information in the ListServ Archives

### How to Search for Answers in the Growing Knowledgebase

Which centers have experience using an external IRB? Would they recommend it? How about procedures for opening a cooperative group protocol for rare diseases when patients present with them? These are some examples of the questions that are routinely asked via the Onsemble Listservs. And, since February 2008, the accumulation of helpful answers has been growing. Today, there are over 2100 posts in the 18 list archives which can be used as an invaluable source of information.

#### To Search the Archives:

1. Go to <http://onsemble.net/cgi-bin/wa?HOME>.
2. If you have not logged-in previously, click the “get a new LISTSERV password” link and follow the instructions to set-up your login.
3. Click the [Email Lists] menu item at the top of the screen. All the lists to which you are subscribed are displayed.
4. Next to **Options:**, click on **Search Archives** to bring up the Archive Search form.
5. Below the form is a list of all of the Listservs to which you are subscribed. Check the list(s) you’d like to search, complete the form with the keywords you are looking for, and click the [Search] button. Matching posts will be displayed.



**Archive Search**

**Search For**

String:  Substring:

**Narrow Search**

Subject Contains:  Author's Address:

Since:  Until:

**ONSEMBLE.NET (11 Lists)**

Check All | Uncheck All

	List Names
<input type="checkbox"/>	PROGRAM
<input checked="" type="checkbox"/>	SDK

#### To Change Your Preferences:

1. Go to <http://onsemble.net/cgi-bin/wa?HOME>, log-in and click the [Subscriber's Corner] menu item at the top of the screen. All the lists to which you are subscribed are displayed.
2. Next to a particular list, click on the [Settings] link. Several options are displayed.
3. Make changes as desired and click the [Update Options] button to save your selections.



We return to the Rizzo Center for the Onsemble 2010 Spring Conference.

## Onsemble 2010 Spring Conference

**Registration  
Now Open!**

Rizzo Center  
Chapel Hill, NC  
February 10<sup>th</sup> - 12<sup>th</sup>

Co-hosted by  
UNC Lineberger  
Comprehensive Cancer Center

The Onsemble Notes newsletter is provided by PercipEnz Technologies, Inc. as a service to the OnCore community. Submissions, corrections, and comments are always welcome. Subscriptions may be requested.

**PercipEnz** Technologies, Inc.  
708 Heartland Trail, Suite 1800  
Madison, WI 53717  
608 826 6000 | [info@PercipEnz.com](mailto:info@PercipEnz.com)  
[PercipEnz.com](http://PercipEnz.com)  
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