



Bari and Penny

NEWS FROM THE CASG

As most of you know, **Bari Cotton** retired the end of December. As you can imagine, we miss her terribly. Bari has been with us for nearly 10 years, first serving as a coordinator and then moving to manager of the pediatric trials. Her grace, amazing sense of humor and genuine caring and love for the people around her, assures our friendships will continue. Bari will continue working with us part-time as a valuable resource for the staff, and a backup for her replacement, Jill Griffin.

You may also know that **Penny Jester** retired in January after more than 20 years at UAB. She will be missed all across UAB's campus! As all of you who have worked with Penny know, she has a wealth of experience and knowledge in clinical research and regulatory issues that is hard to find in one person. She served as Program Director for the CASG since 2003, and based on this experience with multi-site trials, she was asked to establish and direct the Clinical Research Support Program that serves all UAB investigators across the medical center. She also helped create campus-wide Research Coordinator and Investigator research training programs that are provided over 5-6 sessions twice a year. Although she has moved "home" to Cincinnati to be near family and is enjoying time with her first grandchild, we expect to keep her cell phone and email inbox full with requests for advice and assistance.

We are delighted to welcome back **Jill Griffin**, RN, MSN, a former CASG staff member! Jill has returned as the Pediatric Clinical Trials Administrator as of February 12, 2018. She is taking over for Bari Cotton who retired in December. Please welcome Jill back, and begin sending your study related questions to her at JGriffin@peds.uab.edu or (205)996-7698.

Help completing your 1572s



For clinical investigations being conducted under an IND, the Form FDA 1572 is required for each Investigator at each site. “The 1572 has two purposes: 1) to provide the sponsor with information about the investigator’s qualifications and the clinical site that will enable the sponsor to establish and document that the investigator is qualified and the site is an appropriate location at which to conduct the clinical investigation, and 2) to inform the investigator of his/her obligations and obtain the investigator’s commitment to follow pertinent FDA regulations. It is important to remember that if the study drug for your site is to be delivered to a location *other than* the site where the clinical investigation will be held, then you should mark “**Continuation Page for Item 3**” under Item #3 and indicate that the investigation drug should be shipped to the other address. **The pharmaceutical company will only ship the study product to the address listed on your 1572. Use the continuation page to identify a different address!**

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
STATEMENT OF INVESTIGATOR (TITLE 21, CODE OF FEDERAL REGULATIONS (CFR) PART 312) (See instructions on reverse side.)			
1. NAME AND ADDRESS OF INVESTIGATOR		Form Approved: OMB No. 0910-0014 Expiration Date: April 30, 2015 See OMB Statement on Reverse.	
Name of Principal Investigator		NOTE: No investigator may participate in an investigation until he/she provides the sponsor with a completed, signed Statement of Investigator, Form FDA 1572 (21 CFR 312.53(c)).	
Address 1			
City			
2. EDUCATION, TRAINING, AND EXPERIENCE THAT QUALIFY THE INVESTIGATOR AS AN EXPERT IN THE CLINICAL INVESTIGATION OF		State/Province/Region	Address 2
		Country	
		ZIP or Postal Code	



How to Navigate the eDES (Electronic Data Entry System) and Certify on your First Try

If you are enrolling study patients in the current group of CASG DMID protocols, you know that patient data is now entered into a database using a website, and has become electronic. In order to use the electronic data entry system, you need to be certified in how to use the database before you can enroll a patient. If you are certified, and then do not enter patient data over a period of six months, then you have to re-certify, to keep your skill set fresh. The FDA requires that re-training be provided to each person using electronic data entry systems if a person does not enroll a study subject within a six month window of time. A person also has to be re-certified if a pre-determined period of time has elapsed between the **enrollment of a study patient(s) and the current date**.

The eDES training will help you remember how to properly enter data in the different areas of the website, and it is important for adherence to the current GCP principles for a conducting a research study. Beginning on March 1, 2018, if your period of certification on the eDES website expires and you are not able to renew your certification at that time, your access to the eDES will automatically be placed in **CERTIFICATION**. No data entry will be allowed in the production system until the users complete the certification process. When the user has successfully completed the re-certification process, your record will be restored to **PRODUCTION**. When you are entering study participant's data in the eDES make sure that you are in the **PRODUCTION** system and not certification. Otherwise, your data will not be entered into the database for this study and you will be required to re-enter the data once certification has been completed. It is very important that sites maintain their certification on the eDES to ensure that your site is ready when and if a subject shall arise for study participation.

The subcontract budgets for each study each contain a small amount of salary support, currently 5%, to cover the cost of your time that you spend on this training, so the NIH recognizes the importance of the training component.

Using the eDES system can be hard at first, and lots of people have questions about how to enter data. The group at the CASG have all received training in data entry, and we would like to offer a few suggestions to make the process of Certification a bit less painful.

- 1) Please have the eDES User Manual open on your computer or a written copy somewhere to refer to if you have a question or get stuck. It contains a lot of good screen shots and troubleshooting tips for your reference.
- 2) Pay close attention to the "colors". Each protocol has its own unique color page. Valgan Toddler is orange, Neonatal HSV is green and Gan Premie is blue. This may help you to make sure that you are doing your training in the proper place. Please also make sure that the word CERTIFICATION appears on the top of the page, so you are not entering data in the PRODUCTION area of the website, where live patient data is entered.

- 3) Speaking of colors, when you click on the link to the Data Entry Form menu, where all the padlocks reside, the padlocks all have their own unique colors, depending on the status of the form that the padlock contains. You want to see those blue padlocks open up for you, right? A blue padlock means that you can click on the lock and open up the form. When you put all the data in the form and lock the form, then the icon will turn gray. In certification training, keep looking for those blue padlocks.
- 4) Not all the forms are located on the Data Entry Form menu. There are forms that are kept in other areas of the website. To find those forms, it is important to use the “ribbon” near the top of the page. It is a bit darker than the background color of the page. Look for the word “FORMS”, click on the link, and you will find other menus that contain the forms that you need.

Remember the general, primary categories of forms:

- Data entry forms are for “per subject” inclusion/exclusion information, labs, other tests, etc. by treatment period.
- Unscheduled forms are for “per subject” unplanned events that may occur at any time during the study, e.g. serious adverse events, protocol deviations. **IMPORTANT NOTE:** Always follow the instructions that are provided on your packet checklist. It is possible that a form that is available to you on the unscheduled menu might also be shown as a padlock on the main data entry form menu. Yes, a form may appear in more than one location on the site, depending on the study or the circumstances that pertain to a particular study subject.
- Sitewide forms are for activities that may include multiple subjects (e.g. shipping logs) or relate to non-subject, site factors such as the freezer temperature deviations.
- Subsequent forms are Forms 48 (SAE), A,B,and C, to enter data if there are SAE Lab test results (A), Diagnostic Test Results (B), or Concomitant Medications (C).

The main lesson to be learned during the certification process is how to navigate around the website, so the people who created the training packets placed the forms that you use for data entry in an order that makes you go from menu to menu so you know how to get around the site. Watch your pop-up windows for handy hints, and please don't worry if you get a WARNING message or other strongly-worded advisory. Just proceed and follow the advice of the pop-ups and don't be afraid to move from one menu to the next.

We are here to help you with any questions that you have, so please don't hesitate to pick up the phone and call us, or send us an e-mail message and we pledge to reply as quickly as possible. Thank you for your support of the CASG DMID studies.

Study Status!

Update on 11-0071 BK Viremia Adult Study

Recruitment ended for this study on December 15, 2017. 340 subjects were consented. All subjects consented prior to December 15, 2017 are being followed to protocol completion requirements. There were 53 BK Viremia subjects, who were identified by a PCR viral load with >10,000 copies/ml. We appreciate the time and effort all investigators and team members have devoted to this research project.

Update on 11-0070 GeneXpert Group 1 and Group 2

This research protocol completed enrollment on October 31, 2017 with 12,500 subjects for Group 2. We appreciate the dedication and action of the investigators and their study teams in the recruitment and follow-up of subjects consented for Group 2. Group 2 data clean-up and site closure is in its final stages. Recruitment for subjects in Group 1 of the study continues at UAB satellite clinics. There are 31 subjects enrolled in Group 1 with an expected target of 300 subjects.

Staff Travel to Peru for New Studies

In January, two CASG staff members got a first-hand look at infectious diseases research in South America during a trip to Peru as part of two NIH funded studies: Zika in Pregnancy (ZIP) and Incidence of Neonatal HSV. They met a group of hard working investigators at Universidad Peruana Cayetano Heredia (UPCH) who are very dedicated to improving the health and welfare of infants and mothers in their country. PI David Kimberlin provided guidance and information on latest findings for both HSV research and clinical practice, and heard about the difficulties of conducting studies with limited resources.



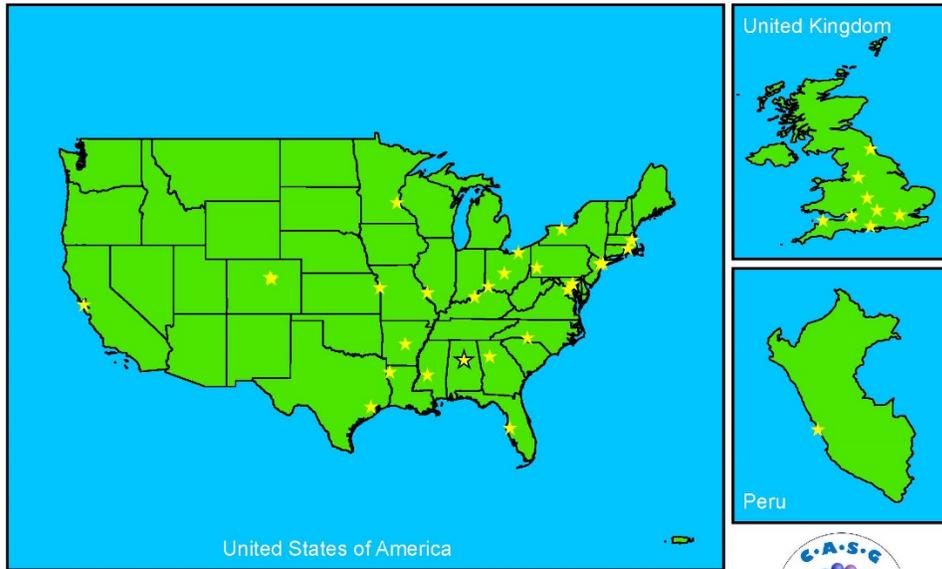
PI David Kimberlin and Mary Wyatt Bowers from the CASG (both in center) take supplies for the ZIP study in Iquitos on the Amazon. Cesar Ugarte (left) and Theresa Ochoa (right) are the investigators for the study.



Dr. Kimberlin tours the NICU at one of the study sites.

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