Data Management Updates

Jenny Darcy
Statistic and Data Center

Alliance Fall Meeting, November 3, 2016

Presentation Objectives

- Provide a high level overview of the Alliance Data Management team initiatives and tips.
  - Introduce each attending Data Manager
  - Provide RAVE Tips

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Alliance Data Management Team

- Jenny Darcy--Director
- Marcia Wilson--Associate Director
- Tiffany Schafer--Supervisor
- Kayla Dietzenbach--DM
- Ryan Potaracke--DM
- Carla Hilton--DM
- Misty Bova-Solem--DM
- Amy Hrtanek--DM

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Why do I have to log my samples in both Rave and BioMS?

- Answer: Currently there is no mechanism to create an overdue material report from BioMS directly. Thus we are asking sites to enter minimal information in Rave about sample submission so we can utilize the role specific task summary (within Rave) and overdue material reporting (on the Alliance Web Site) to remind sites if required samples have not been submitted.

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Future

- Alliance is working on sending BioMS key clinical data to allow for adjustment of sample expectations which will allow for the creation of an overdue sample report from BioMS.
- Once this work is complete, Alliance will no longer require sample submission data to be entered within Rave.

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What is source?

- A ***source document*** is a ***document*** in which data collected for a clinical trial is first recorded. This data is usually later entered in the case report form. The ICH-GCP guidelines ***define source documents*** as "original ***documents***, data, and records".

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What is the difference between clinical survival and overall survival?

- Clinical Follow Up – the patient is still on study, no longer receiving any study treatment, but still being followed via the test schedule at the consenting site.
- Overall and Disease Status – the patient has reached a study endpoint and is off treatment and being followed for survival.

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Patient Status Form

- Documents key data at the **end of each treatment** visit regarding survival status, disease status, protocol treatment, etc.
- Data collected will determine subsequent folder/form roll out in Rave
- **Date of most recent contact** will typically correspond with the **reporting period end date** from the Adverse Event form

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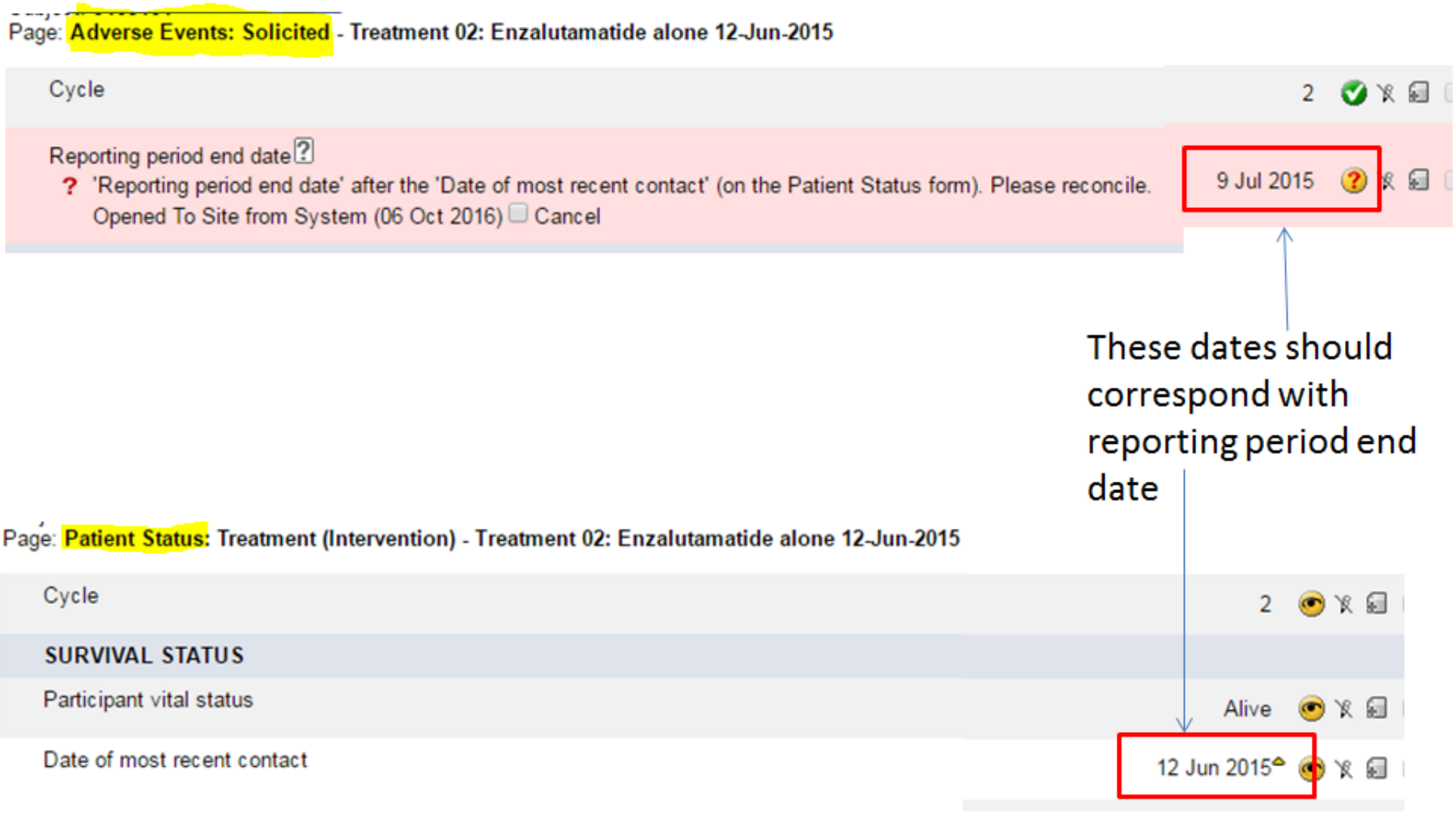
Treatment Cycle: 6/12/15 – 7/9/15



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Forms Consistency Task Force

Forms Consistency (Convene in August)		
MEMBER LIST | CONTACT INFORMATION	Name	Email
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Frequently Asked Questions

- New PP located on the Alliance Web site.
- Log into Member Login
- On the right side of the page you will see several Quick Links, click on CRP Resources
- Resources at your finger tips!!

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Refresh--RAVE On Line Training

- If you want to refresh your RAVE training an e-learning training module is available to you in iMedidata. It is located in the right margin Task Column at the end of the protocol invites.

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Future Task Force Initiative

- DSS Template
- Instructional Text Enhancements

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Other Data Management Initiatives

- Conversion of Teleform trials to RAVE
  - Full Build
  - FU Only Build
  - Terminated Trials

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First Reaction to 2017 Deadline

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Conclusion

- Questions from Audience

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