**ECP Registry Observational Arm Tests with ctt\_test\_db (11/13/2014)**

1. Test for fewer than 5 FEV1s collected in the last six months. (Participant 100100)
   1. Dates: May 3, 10, 17, 24, 31 input into Check Enrollment/Arm Eligibility Form.
   2. FEV1s of all 2s.
   3. Enrollment date of 11/13/2014.
   4. Submit Confirmation of Elig Form.
   5. Open Observation Pulmonary Eval Log
   6. Select the Check ECP Treatment Elig button.
   7. Three dates appear in the crossoverEligibilityForm.xhtml
   8. Select the Determine Study Arm Eligibility button.
   9. The crossoverResultsForm.xhtml button has the following message: **Outcome: The crossover calculator can only be run within 7 days of a pulmonary function evaluation. The last evaluation was done on 2014-05-22.**
   10. Select the Return to Registry button.
   11. Add another date within the last 7 days such as 11/13/2014 with a FEV1 value of 2.0
   12. Select the Check ECP Treatment Elig button.
   13. Four dates appear in the crossoverEligibilityForm.xhtml
   14. Select the Determine Study Arm Eligibility button.
   15. The crossoverResultsForm.xhtml button has the following message: **Outcome: Fewer than 5 FEV1 values were recorded in the last 6 months.**
   16. Select the Return to Registry button.
2. Test for 5 FEV1s collected in the last six months with the wrong slope and significance. (Participant 100100)
   1. Add another two dates such as 7/1/2014 with a value of 1.9 and one within the last 7 days such as 11/5/2014 with a FEV1 value of 1.9.
   2. Do not select the save button.
   3. Select the Check ECP Treatment Elig button.
   4. Five dates appear in the crossoverEligibilityForm.xhtml
   5. Select the Determine Study Arm Eligibility button.
   6. The crossoverResultsForm.xhtml button has the following message: **Outcome: The participant is not eligible to cross over into the treatment arm. Collect up to 4 pulmonary evaluations from either the enrollment date or the end of the 2 month hold period date: 11-05-2014.**

**Eligibility failed on the following criterion: The slope is NOT OK and/or the significance is NOT OK with fewer than 4 FEV1s collected since enrollment date or the end of the 2 month hold period.**

**Rate of lung function decline (Slope) = -18.403885 ml / month**

**Statistically significant rate of decline (P-Value less than 0.05) = 0.0037809287**

**The minimum FEV1 value = 1900.0 ml**

1. Test for 5 FEV1s collected in the last six months with the correct slope and significance. (Participant 100100)
   1. Add the following three dates such as 7/1/2014 and 10/1/2014 with values of 1.9 and one within the last 7 days such as and 11/5/2014 with a FEV1 value of 1.5.
   2. Select the Check ECP Treatment Elig button.
   3. Five dates appear in the crossoverEligibilityForm.xhtml
   4. Select the Determine Study Arm Eligibility button.
   5. The crossoverResultsForm.xhtml button has the following message: **Outcome: The participant is eligible to cross over into the ECP treatment arm.**

**Eligibility failed on the following criterion: The slope is OK and significant.**

**Rate of lung function decline (Slope) = -66.9058 ml / month**

**Statistically significant rate of decline (P-Value less than 0.05) = 0.01789**

**The minimum FEV1 value = 1500.0 ml**

* 1. Select the Transfer Participant to ECP Treatment Arm button.
  2. The Crossover Safety Check CRF appears. I answered the question and submitted it successfully.

1. Test end of first hold period and going into second hold period (Participant 100101)
   1. Original Dates: June 1, 8, 15, 22, 29 input into Check Enrollment/Arm Eligibility Form.
   2. FEV1s of all 2s.
   3. Enrollment date, Informed Consent, and Version dates of 7/1/2014.
   4. Select the Determine Enrollment and Study Arm Eligibility button. Select the Go to COE Form to Print button.
   5. View the Confirmation of Eligibility CRF. Change the date in 4A to 7/1/2014.
   6. Submit Confirmation of Elig Form.
   7. Go into the Postgresql database and change all of the today’s dates to the 7/1/2014 date.
   8. Open Observation Pulmonary Eval Log
   9. Add 4 new dates within the last 7 days such as July 6, 13, 20 and 27 2014 with FEV1 values of 1.5, 2.5, 1.5, and 1.9.
   10. Select the save button.
   11. Add another date like today with an FEV1 value of 1.5.
   12. Select the Check ECP Treatment Elig button.
   13. Ten dates appear in the crossoverEligibilityForm.xhtml
   14. Select the Determine Study Arm Eligibility button.
   15. **Participant ID: 101001**

**Outcome: Participant is in the two-month hold period. The period will end on 09-30-2014.**

Eligibility either failed or passed based on the following criterion: Participant is in hold period.

* 1. The holdstatus attribute in the participant table is still listed as ‘t’ or true even though today’s date is beyond the hold date of 9-30-2014. The holdstatus needs to be changed to false somehow.
  2. You will need to enter 4 more dates into the Observation Pulm Eval Log such as Oct 1, 8, 15 and Nov 13 with values of 1.5, 2.5, 1.5, and 1.9.
  3. Select the Check ECP Treatment Elig button.
  4. 13 dates appear in the crossoverEligibilityForm.xhtml
  5. Select the Determine Study Arm Eligibility button.

1. Test initial crossover override with the addition of 4 additional FEV1s to the originally input 5 FEV1s. (Participant 100102 and 100103)
   1. Original Dates: Sept 1, 8, 15, 22, 29 input into Check Enrollment/Arm Eligibility Form.
   2. FEV1s of all 2s.
   3. Enrollment date, Informed Consent, and Version dates of 10/1/2014.
   4. Select the Determine Enrollment and Study Arm Eligibility button. Select the Go to COE Form to Print button.
   5. View the Confirmation of Eligibility CRF. Change the date in 4A to 10/1/2014.
   6. Submit Confirmation of Elig Form.
   7. Open Observation Pulmonary Eval Log
   8. Add 4 new dates within the last 7 days such as Oct 6, 13, 20 and 31 2014 with FEV1 values of 1.5, 2.5, 1.5, and 1.9.
   9. Select the save button.
   10. Go into the Postgresql database and change all of the today’s dates to the 10/1/2014 date.
   11. Add today’s date with an FEV1 value of 1.5.
   12. Select the Check ECP Treatment Elig button.
   13. Ten dates appear in the crossoverEligibilityForm.xhtml
   14. Select the Determine Study Arm Eligibility button.
   15. The crossoverResultsForm.xhtml button has the following message: **Outcome: The participant does not meet all of the criteria for inclusion in the ECP treatment arm. Do you wish to override this and move the participant anyway?**

**Keeping the participant in the observational arm starts a two month long holding period during which the participant will not be eligible to crossover into the treatment arm. The participant can next be evaluated for crossover on 01-05-2015**

**Eligibility either failed or passed based on the following criterion: 4 or more FEV1 values in the last 4 weeks and not (slope is OK and significant).**

**Rate of lung function decline (Slope) = -93.7631 ml / month**

**Statistically significant rate of decline (P-Value less than 0.05) = 0.29594**

**The minimum FEV1 value = 1500.0 ml.**

* 1. Select the Keep Participant in Observation Arm button.
  2. The participant table was set to a hold date of 11/6/14 since today was 11/5/14. With a hold status of true.
  3. I tried to run the calculator again, but received the message that the participant was on hold.
  4. I deleted the hold date and hold status from the participant table.
  5. I then selected the Override and Transfer Participant to the Treatment Arm.
  6. The participant was enrolled in the Treatment Arm with all of the CRFs added.