

## 4. Ready to Randomize

### 4.1 Eligibility for Randomization: Daily Study



**Frequent Hemodialysis Network (FHN) Clinical Trial**  
**Eligibility Report for the Daily Study**

07/30/2008 11:12 AM

Page 1 of 3

PID: 900XXX      Alpha Code: ML      Screening Date: XX-JUN-2008      Last Day: XX-SEP-2008

Is this patient eligible to be randomized to the Daily Study?

1 Is this patient eligible?

**Form 110: Daily Trial Eligibility Confirmation Form available and supports eligibility?**

1 100% of items have valid answers (refused is a valid answer for Race/Ethnicity)

2 Patient is eligible based on the data on this form?

**Form 104: Comorbidity Assessment Form Available?**

1 100% of items have valid answers?

**Form 105: Basic Demographic Form Available?**

1 100% of items have valid answers?

**Form 111: Documentation of Six Consecutive Days Form Available?**

1 100% of items have valid answers?

**Form 202: Amputation Form Available?**

1 100% of items have valid answers?

**Form 203: IV Iron Therapy Form Available?**

1 100% of items have valid answers?

**Form 204: Injectable Medications Form Available?**

1 100% of items have valid answers?

**Form 205: Medications and Supplements Form Available?**

1 100% of items have valid answers?

**Form 206: Residual Renal Function Acceptable?**

1 Form 206 entered into the database?

2 Has the residual renal function been calculated?

3 Residual renal urea clearance less than or equal to 3 ml/min/35 L?

**Form 207: Local Laboratory Test Results Form Available?**

1 All items except sodium (optional) have been answered and are within a valid range?

**Form 220: SF-36 Form Available?**

1 100% of items have valid answers?

2 SF-36 date within 15 weeks?

**Form 221: Beck Depression Inventory Form Available or Not Applicable?**

1 At least 75% of questions completed?

2 All completed items have valid answers?



Frequent Hemodialysis Network (FHN) Clinical Trial  
Eligibility Report for the Daily Study

07/30/2008 11:12 AM  
Page 2 of 3

PID: 900XXX      Alpha Code: R9      Screening Date: XX- JUN-2008      Last Day: XX- SEP-2008

**Form 223: Health Utilities Index 3 Available?**

- 1 Enough of the items are completed such that the index can be calculated.  
Note that responses of don't know or refused can't be used in calculations  
- they are missing data?

**Form 230: Feeling Thermometer Results Form Available?**

- 1 100% of items have valid answers?

**Form 231: Mini Mental Status Available?**

- 1 100% of items have valid answers?

**Form 232: Trailmaking B Score Sheet Available?**

- 1 Form available?
- 2 100% of items have valid answers?

**Form 233: Clinical Center Miscellaneous Questions Form Available?**

- 1 100% of items have valid answers?

**Form 234: FHN Combination Physical Function Tests Form Available or N/A?**

- 1 100% of items have valid answers?

**Form 250: Dialysis Session prior to MRI Available?**

- 1 100% of items have valid answers?

**Form 251: MRI Mailing Form Available?**

- 1 100% of items have valid answers?
- 2 MRI date within 15 weeks?

**Form 252: Central MRI Results Form Available?**

- 1 100% of items have valid answers?

**Form 271: Details on Patient's Access at Start of Trial Form Available?**

- 1 Q4: Non-tunneled catheter?
- 2 100% of items have valid answers?

**Kinetic Modeling Criteria:**

- 1 At least two valid KM sessions with corresponding forms 273 and 274?
- 2 Baseline  $eKt/V$  of  $\geq 1.0$ ?
- 3 Kinetic volumes of two baseline KM sessions have a CV no more than 20%?
- 4 No more than six KM sessions have been performed?

**Form 406: Consent for Repositories Form Available?**

- 1 100% of items have valid answers?

**Form 113: Ready For Randomization Confirmation Form Available?**

- 1 100% of items have valid answers?
- 2 Form confirms ready to randomize?
- 3 Form completed within 2 weeks?



Frequent Hemodialysis Network (FHN) Clinical Trial  
Eligibility Report for the Daily Study

07/30/2008 11:12 AM

Page 3 of 3

PID: 900XXX

Alpha Code: R9

Screening Date: XX-JUN-2008

Last Day: XX-SEP-2008

Within 15 weeks of patient's screening date?

1 Within 15 weeks of the screening date on Form 110?

The last day to randomize this patient is 18/SEP/2008

Sample

## 4.2 Eligibility for Randomization: Nocturnal Study



### Frequent Hemodialysis Network (FHN) Clinical Trial Eligibility Report for the Nocturnal Study

07/30/2008 11:22 AM

Page 1 of 3

Pid: 900XXX      Alpha Code: 7S      Screening Date: XX-MAY-2008      Last Day: XX-SEP-2008

**Is this patient eligible to be randomized to the Nocturnal Study?**

1 Is this patient eligible?

**Form 100: Nocturnal Trial Eligibility Confirmation Form available and supports eligibility?**

- 1 100% of items have valid answers (refused is a valid answer for Race/Ethnicity)
- 2 Patient is eligible based on the data on this form?

**Form 101: Nocturnal Trial Evaluation of Home Environment Form Available?**

- 1 Q14a Are there plans to make the recommended modifications?
- 2 100% of items have valid answers?

**Form 102: Nocturnal Trial Evaluation of Patient and Caregiver Form Available?**

- 1 Q12 - Is this patient capable of performing the necessary procedures to conduct his/her dialysis at home if randomized to the nocturnal arm?
- 2 Q13 - Will this patient have remote monitoring and/or a partner living in the home that is willing to help the patient?
- 3 100% of items have valid answers?

**Form 104: Comorbidity Assessment Form Available?**

- 1 100% of items have valid answers?

**Form 105: Basic Demographic Form Available?**

- 1 100% of items have valid answers?

**Form 202: Amputation Form Available?**

- 1 100% of items have valid answers?

**Form 203: IV Iron Therapy Form Available?**

- 1 100% of items have valid answers?

**Form 204: Injectable Medications Form Available?**

- 1 100% of items have valid answers?

**Form 205: Medications and Supplements Form Available?**

- 1 100% of items have valid answers?

**Form 206: Residual Renal Function Acceptable?**

- 1 Form 206 entered into the database?
- 1 Has the residual renal function been calculated?
- 2 Baseline GFR less than or equal to 10 ml/min/1.73m<sup>2</sup>?

**Form 207: Local Laboratory Test Results Form Available?**

- 1 All items except sodium (optional) have been answered and are within a valid range?





Pid: 900XXX      Alpha Code: 7S      Screening Date: XX-MAY-2008      Last Day: XX-SEP-2008

**Form 211: Nocturnal Study v3.0 Results Of Baseline Home Training Form Available?**

- 1 100% of items have valid answers?
- 2 Successfully able to complete Phase I of home training?

**One Form 215 for MID WEEK: Nocturnal Study 2-Day Home Blood Pressure Form Available?**

- 1 100% of items have valid answers?

**One Form 215 for Weekend: Nocturnal Study 2-Day Home Blood Pressure Form?**

- 1 100% of items have valid answers?

**Form 220: SF-36 Form Available?**

- 1 100% of items have valid answers?
- 2 SF-36 date within 18 weeks?

**Form 221: Beck Depression Inventory Form Available?**

- 1 At least 75% of questions completed?
- 2 All completed items have valid answers?

**Form 223: Health Utilities Index 3 Available?**

- 1 Enough of the items are completed such that the index can be calculated.  
Note that responses of don't know or refused can't be used in calculations  
- they are missing data?

**Form 230: Feeling Thermometer Results Form Available?**

- 1 100% of items have valid answers?

**Form 231: Mini Mental Status Available?**

- 1 100% of items have valid answers?

**Form 232: Trailmaking B Score Sheet Available?**

- 1 Form available?
- 2 100% of items have valid answers?

**Form 233: Clinical Center Miscellaneous Questions Form Available?**

- 1 100% of items have valid answers?

**Form 234: FHN Combination Physical Function Tests Form Available or N/A?**

- 1 100% of items have valid answers?

**Form 250: Dialysis Session prior to MRI Available?**

- 1 100% of items have valid answers?

**Form 251: MRI Mailing Form Available?**

- 1 100% of items have valid answers?
- 2 MRI date within 18 weeks?

**Form 252: Central MRI Results Form Available?**

- 1 100% of items have valid answers?



Pid: 900XXX      Alpha Code: 7S      Screening Date: XX-MAY-2008      Last Day: XX-SEP-2008

**Form 271: Details on Patient's Access at Start of Trial Form Available?**

- 1 Q4: confirm that they don't have Non-tunneled catheter?
- 2 100% of items have valid answers?

**Kinetic Modeling Criteria:**

- 1 At least two valid KM sessions with corresponding forms 273 and 274?
- 2 Baseline eKt/V of  $\geq 1.0$ ?
- 3 No more than six KM sessions have been performed?

**Form 406: Consent for Repositories Form Available?**

- 1 100% of items have valid answers?

**Within 18 weeks of patient's screening date?**

- 1 Within 18 weeks of the screening date on Form 100?  
The last day to randomize this patient is 17/SEP/2008

Sample