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Nothing herein is to be disclosed without the expressed written consent of Outset Medical.

Study # 2019-03

Study Title: A Post-Market, Single Blind, Randomized Clinical Prospective Study on Intradialytic Symptoms in Subjects treated with Qd 500vs Qd 300

Study Dates:	**September 2019 to December 2019**
Principal Investigator:	**Dr. George Coritsidis, MD**
Sponsor Contact Information:	**Michael Aragon, MD, CMO,** **Outset Medical** **San Jose, CA 95112, USA**
GCP Compliance:	**Investigators agreed to conduct the investigation in accordance with applicable FDA regulations, ISO 14155:2011, ICH-GCP Guidelines, and in accordance with the ethical principles originating in the Declaration of Helsinki (64th WMA General Assembly, Forteleza, Brazil October 2013) and any conditions imposed by the reviewing Institutional Review Board (IRB). Investigators agreed to ensure appropriate informed consent was obtained from all subjects prior to inclusion.** **The study is conducted in accordance with the study protocol, relevant Good Clinical Practice (GCP), and International Conference on Harmonization (ICH) guidelines, as well as in conjunction with 21 CFR Part 812, 50, 54, 56 and other applicable government regulations.**

Table of Contents

1 PROTOCOL SYNOPSIS

Title	A Post-Market, Single Blind, Randomized Clinical Prospective Study on Intradialytic Symptoms in Subjects treated with Qd 500 vs Qd 300
Study Goal	To determine the impact of dialysate flow rate (Qd) on Subject reported dialysis related symptoms and on time to recovery post dialysis.
Study Background	Subjects undergoing conventional intermittent thrice weekly hemodialysis using a Qd of 500ml/min or higher report many inter and intra dialytic symptoms. Common symptoms include fatigue, cramping, and insomnia. Subjects treated on the Tablo hemodialysis system report 'feeling better'. Tablo has a dialysate flow rate of 300 ml/min.
Study Objective	The objective of this study is to determine if Subjects who report dialysis symptoms while meeting adequacy (as determined by Kt/V of 1.2 or greater) on thrice weekly dialysis or who have a recovery time of at least 4 hours when treated on a conventional, i.e. non Tablo, hemodialysis device feel better with a reduced dialysate flow rate of 300ml/min based on an assessment of time to recovery post dialysis and Subject reported symptoms via a modified weekly ESAS survey.
Study Length	The study will last approximately 8 weeks consisting of chart review, Subject selection, medical record review, data collection and data analysis.
Inclusion Criteria	1. Subject has provided informed consent and has signed a Health Insurance Portability and Accountability Act of 1996 (HIPAA) compliant authorization statement. 2. Subject is at least 18 of age. 3. Subject has end stage renal disease (ESRD) adequately treated with thrice weekly dialysis. 4. Subject is currently stable on dialysis for at least 3 months on a conventional dialysis machine and Qd of 500ml/min or higher with no change in the following dialysis prescription parameters over that time: Qb, Qd, Dialyzer, Time. 5. Subject has a baseline Kt/V of greater than 1.2. 6. Subject has a stable vascular access. 7. Subject reports time to recovery of more than 4 hours or a modified ESAS with at least 5 symptoms of which at least 2 are rated as moderate (rating of 4-6) or severe (rating of 7-10).
Exclusion Criteria	1. Subject is unable to complete the questionnaires. 2. Subject is pregnant or planning to become pregnant. 3. Subject is scheduled for a change in modality or expected kidney transplant in the next 3 months. 4. Any other documented condition that the Investigator feels would prevent the Subject from successful inclusion in the study.
Primary Endpoint	Change in time to recovery and self-reported symptoms.
Secondary Endpoint	Caregiver assessment of changes in Subject's health, missed or reduced treatments, number of intradialytic interventions (saline, prn medications, early discontinuation, UF change related to sxs) and the reason for intervention.

2 ABBREVIATIONS

BUN	Blood Urea Nitrogen
CBC	Complete Blood Count
CFR	Code of Federal Regulations
CO2	Carbon Dioxide
QD	Dialysate Flow Rate
QB	Blood Flow Rate
ESRD	End Stage Renal Disease
ESAS	Modified Edmonton Symptoms Assessment System
FDA	Food and Drug Administration
GCP	Good Clinical Practice
HRQoL	Health Related Quality of Life
ICH	International Conference on Harmonization
KDQoL	Kidney Disease Quality of Life Survey
PHOS	Phosphorus
IRB	Institutional Review Board
K	Potassium
Na	Sodium
PI	Principle Investigator
TTR	Time to Recovery
UF	Ultrafiltration, volume of fluid removed

3 BACKGROUND

Subjects experience various symptoms during hemodialysis. Prior studies have shown that fatigue, muscle cramps, insomnia and pruritis are most commonly reported as symptoms associated with dialysis[(5)]. The frequency and severity of intradialytic symptoms are associated with missed treatments, shortened treatment time and delayed time to recovery after dialysis [(3,7,8)]. Longer time to recovery has also been shown to be a simple, reproducible, tool associated with poorer HRQoL, hospitalization and mortality [(3,4)]. Subjects treating on the Tablo system have previously reported feeling better when dialyzing thrice weekly with this device. The Tablo system utilizes a dialysate flow rate of 300ml/min to achieve the standard adequacy target as defined as a Kt/V of 1.2 or greater [(1,9)]. To better understand the feeling better effect on Tablo, this study was designed to determine if a decrease in dialysate flow rate on a conventional dialysis device produces a similar effect on Subject reported symptoms. This study assesses time to recovery as well as prevalence and severity of Subject reported symptoms via a weekly modified Edmonton Symptom Assessment System when dialysate flow rate is decreased from 500ml/min or higher

to 300ml/min on standard thrice weekly dialysis. In addition, the Subject's primary caregiver will be given a KDQoL SF-36 to complete as to their perception of the Subject's quality of life at baseline as well as after each 4-week interval. These assessment tools have been shown to be reliable, simple methods for symptom assessment [2,4,8,10,11,12].

4 STUDY OBJECTIVE

The objective of this study is to determine if Subjects who report dialysis symptoms while meeting adequacy (as determined by Kt/V of 1.2 or greater) on chronic thrice weekly dialysis or who have a recovery time of more than 4 hours when treated on a conventional, i.e. non Tablo, hemodialysis device feel better with a reduced dialysate flow rate of 300ml/min based on an assessment of time to recovery post dialysis, weekly modified ESAS, and Subject's caregiver assessment of the Subject's symptoms.

5 STATEMENT OF COMPLIANCE

This study will be conducted according to the protocol, good clinical practice (GCP) and all applicable regulatory requirements (21CFR).

6 STUDY DESIGN

This is a single center, post market, prospective, single blind, randomized, cross-over study involving approximately 50 subjects currently dialyzing on a conventional dialysis machinevat a dialysate flow rate of 500ml/min or higher thrice weekly. The study may collect retrospective and prospective medical records and other treatment data. Enrolled subjects will answer the question, "How long does it take you to recover from a dialysis session?" (TTR) along with a modified ESAS at baseline and weekly. Subjects will be screened prior to entry into the study and enrolled if time to recovery at baseline of > 4 hours or the results of their modified ESAS demonstrate at least 5 dialysis related symptoms with at least 2 being described as moderate (rating of 4-6) or severe (rating of 7-10). Caregivers of screened Subjects meeting the study criteria will be given a baseline KDQoL SF-36 to determine their perception if the Subject's current state of health. Subjects enrolled will be randomized to two groups. Group 1 will dialyze for the first 4 weeks of the study at a Qd of 300ml/min, then for the last 4 weeks at a Qd of 500ml/min. Group 2 will dialyze for the first 4 weeks of the study at a Qd of 500ml/min, then for the last 4 weeks at a Qd of 300ml/min. At the end of each week, the Subject will respond to the TTR question as well as the modified ESAS survey. Subject caregivers will complete the KDQoL at the end of each 4-week interval. The study will assess the Subject and Subject caregiver responses to the survey tools as well as other outcome measures which may include but are not limited to, kinetics, laboratory values, blood pressure measurement, intradialytic interventions, missed or shortened treatments, and/or changes to treatment parameters. The study will collect subject demographics and dialysis related medications. The goal is to enroll at least 15 Subjects who report intradialytic symptoms as the ITT group for study analysis.

6.1 Effort to Minimize Bias

All eligible Subjects that, in the treating physician's best medical judgement, meet the selection criteria will be asked to participate in this study. Subjects will not be excluded based on gender, race, ethnicity or sexual orientation.

6.2 Evaluation of Safety

Treatment with a Qd of 300ml/min has been shown to be safe and effective in the treatment of ESRD subjects. It has also been demonstrated that dialysis at a Qd of 300ml/min can achieve the prescribed adequacy target of a Kt/v of 1.2 or greater. Standard safety precautions as per clinic protocol will be continued. No portion of this study will be beyond the standard of care.

6.3 Blinding and Randomization

This study is a single center, post market, prospective, single blind, randomized, cross-over study comparing symptoms with a conventional dialysis device at a Qd of 500 ml/min and a Qd of 300 ml/min. Only Subjects will be blinded to the dialysis device Qd.

Subjects will be randomized to either arm at a 1:1 ratio using excel's RANDBETWEEN function. Subjects will be randomly assigned a 0 or a 1. Subjects that are assigned '0' will go to Group 1, and subjects that are assigned '1' will go to Group 2.

7 SUBJECT SELECTION

7.1 Study Population

Subjects with a diagnosis of end stage renal disease (ESRD) who meet the inclusion and exclusion criteria will be eligible for participation in this study. Subjects with all vascular access types are eligible for the study and may include catheters, grafts, and fistulas. Potential study candidates should be screened for eligibility according to the study inclusion and exclusion criteria.

7.2 Informed Consent

IMPORTANT: The Code of Federal Regulations requires that the consent form signed by the Subject must be dated at the time consent is given. Also, medical records must contain documentation that informed consent was obtained prior to participation in a study. (21 CFR Parts 50 and 812)

The Investigator may determine whether potential Subjects are interested in participating in an investigation, but shall not request the written informed consent of any Subject to participate, and shall not allow any Subject to participate before obtaining Institutional Review Board (IRB) and FDA approval. The consent process shall begin before care is altered beyond the scope of a routine comprehensive examination for the purpose of participating in this study.

All Subjects in this research study should be completely informed about the purpose, duration, and pertinent details of the study. The informed consent process must be documented using a written form that has been approved by the IRB and includes all *Basic Elements of Informed Consent* and pertinent *Additional Elements* (21 CFR Part 50.25).

The Investigator must keep the original signed copies of all consent forms in the Subject's medical records and provide a copy to each Subject.

Appendix A outlines the screening and enrollment process and illustrates the point where informed consent should be obtained.

7.3 Subject Privacy

In accordance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA), all Subjects should be informed of potential uses and disclosures of their medical information for research purposes, and their rights to access information about them by covered entities. Each Investigator will follow the procedures for securing HIPAA compliance as directed by their respective IRB or Privacy Board, and to obtain written authorization to use and disclose Subject information for all clinical research and research involving questioning of the Subject's or

Subjects' physician(s). Per individual site procedures, this authorization may be included as part of the Subject informed consent form.

7.4 Inclusion Criteria

Subjects must meet **ALL** of the inclusion criteria to be enrolled in the study.

1. Subject has provided informed consent and has signed a Health Insurance Portability and Accountability Act of 1996 (HIPAA) compliant authorization statement.
2. Subject is at least 18 of age.
3. Subject has end stage renal disease (ESRD) adequately treated with thrice weekly dialysis.
4. Subject is currently stable on dialysis for at least 3months on an FMC 2008K machine and Qd of 500ml/min or higher with no change in the following dialysis prescription parameters over that time: Qb, Qd, Dialyzer, Time.
5. Subject has a baseline Kt/V of greater than 1.2.
6. Subject has a stable vascular access.
7. Subject reports time to recovery of more than 4 hours or a modified ESAS with at least 5 symptoms of which at least 2 are rated as moderate (rating of 4-6) or severe (rating of 7-10).

7.5 Exclusion Criteria

If **ANY** of the exclusion criteria are met, the Subject is excluded from the study.

1. Subject is unable to complete the questionnaires.
2. Subject is pregnant or planning to become pregnant
3. Subject is scheduled for a change in modality or expected kidney transplant in the next 3 months.
4. Any other documented condition that the Investigator feels would prevent the Subject from successful inclusion in the study.

7.6 Subject Discontinuation and Replacement

Every Subject should remain in the study until completion of the required follow-up period. Subjects may voluntarily withdraw from the study at any time with or without reason and it will not have any negative impact on subsequent treatment. Conceivable reasons for Subject discontinuation may include, but are not limited to, the following:

- **Subject Withdrawal:** Subject participation in this study is voluntary. The Subject may choose to discontinue participation at any time without loss of benefits or penalty.
- **Discontinuation:** Subject participation may be discontinued by the Subject or Investigator because of a kidney Transplantation, relocation to another dialysis center, treatment modality change, hospitalization or death.
- **Sponsor/Investigator Termination:** The Sponsor/ Investigator may terminate the Subject's participation without regard to the Subject's consent if the Sponsor/Investigator believes it is necessary.
- **Exclusion Criterion Discovered After Enrollment:** A small number of Subjects may be enrolled despite meeting an exclusion criteria due to timing of study required clinical procedures. This will be documented by the study personnel and will be considered a protocol deviation.

8 STUDY PROCEDURES AND DATA COLLECTION

8.1 Baseline Evaluation

Subjects will be asked for their response to the TTR question and a modified ESAS. Subjects meeting the inclusion and exclusion criteria, will be consented and enrolled into the study. Enrollees will be randomized to treatment Group 1 or 2. Enrollee caregivers will be asked to complete a KDQoL SF-36 regarding their perception of the Subject's overall health. Additionally, historical dialysis treatment information including hemodialysis prescription and any recent changes, baseline laboratory values including kinetics, temperature, height, weight, body mass index, vascular access type, presence or absence of diabetes mellitus, hypotension, ejection fraction, arrhythmia, high blood pressure, and any other co-morbid conditions considered relevant may also be collected where available. Any subjects of child-bearing potential will be given a pregnancy test to confirm negative results. Those subjects will also be utilizing medically acceptable means of contraception during the study period. Demographic information will be collected including age, gender, ethnicity and race. Dialysis related medications, laboratory values, blood pressure readings taken before, during and after dialysis treatments and adverse event data may also be collected if available.

8.2 Group 1

Subjects will undergo staff administered dialysis treatment 3 times/week for 8 weeks In-Center with prescription adjustments as outlined in the Schedule of Events. Subjects will respond to the TTR question and modified ESAS at the completion of every week. Caregivers will be asked to respond to the KDQoL SF-36 during week 4 and week 8. Subjects Serum Potassium, BUN, CO2, Phos, Na, Beta-2-Microglobulin, Vitamin B12and Kt/V labs and treatment flowsheets will also be evaluated. Dialysis prescription changes, dialysis related medications, blood pressure readings taken before, during and after dialysis treatments and adverse event data may also be collected if available. Group 1 will dialyze for the first 4 weeks of the study at a Qd of 300ml/min, then for the last 4 weeks at a Qd of 500ml/min.

8.3 Group 2

Subjects will undergo staff administered dialysis treatment 3 times/week for 8 weeks In-Center with prescription adjustment as outlined in the Schedule of Events. Subjects will respond to the TTR question and modified ESAS at the completion of every week. Caregivers will be asked to respond to the KDQoL SF-36 during week 4 and week 8. Subjects Serum Potassium, BUN, CO2, Phos, Na, Beta-2-Microglobulin, Vitamin B12 and Kt/V labs and treatment flowsheets will also be evaluated. Dialysis prescription changes, dialysis related medications, blood pressure readings taken before, during and after dialysis treatments and adverse event data may also be collected if available. Group 2 will dialyze for the first 4 weeks of the study at a Qd of 500ml/min, then for the last 4 weeks at a Qd of 300ml/min.

9 STUDY LIMITATIONS

Limitation of this include its small size and in a single center. Additionally, every attempt has been made to remove any variables other than change in dialysis treatment device; however, Subjects with ESRD have complex medical histories and the effect of illness unrelated to ESRD (whether worsened or improved) was not taken into consideration. Socioeconomic factors that can affect a Subject's sense of wellbeing or any changes to these factors during the study were also not accounted for.

10 ETHICAL CONSIDERATIONS

Risks: The risks to subjects participating in this study are minimal. Subjects will be informed of the potential risk of an overall decrease in weekly Kt/V due the change in Qd. A possible risk is exposure of protected health information. Every effort will be made to maintain subject privacy.

Benefits: The study will provide information on Subject self-reported symptoms in the real world setting for subjects who dialyze thrice weekly with a dialysate flow rate of 500ml/min who are changed to a dialysate flow

rate of 300ml/min. Pts will be informed of the potential benefits from none to possible reduction in symptoms from the potential intervention. Subjects and their caregivers will be compensated for their time and effort to complete the surveys as requested.

Participation in this study is voluntary. Failure to participate in the study will not impact Subject care.

11 STATISTICAL METHODS

Descriptive statistics will be performed. Data resulting from this study may be compared to prior studies evaluating the frequency of Subject reported symptoms.

12 STUDY RECORD MANAGEMENT

Trained personnel at the site, as directed by the principle investigator (PI), will collect data in accordance with this protocol and ensure that it is appropriately recorded on paper worksheets and case report forms and/or in an electronic data capture system.

The Investigator agrees to maintain all essential study documents and source documentation, in original format, that support the data collected on the study subjects in compliance with the ICH/GCP guidelines (the Investigator's File, including signed informed consent forms (ICF) and subject-related materials) in a location that is secure and to which access can be gained if required.

Documents must be retained for at least two years after (1) study completion, or (2) the study has been terminated by the Sponsor. These documents will be retained for a longer period of time by agreement with the Sponsor or in compliance with other regulatory requirements. When these documents no longer need to be maintained, it is the study Sponsor's responsibility to inform the Investigator. The Investigator will take measures to ensure that these essential documents are not accidentally damaged or destroyed. If, for any reason, the Investigator withdraws responsibility for maintaining these essential documents, custody must be transferred to an individual who will assume responsibility. The Sponsor must receive written notification of this custodial change.

13 TRAINING

Prior to opening the study and enrolling Subjects, the PI and all participating study personnel will be trained on the study requirements. Initial training and any needed follow-up training will be documented in the appropriate regulatory binders.

14 QUALITY CONTROL AND ASSURANCE

14.1 Selection of Sites and Investigators

The Sponsor will select the Investigators who are qualified by training and experience to perform the procedures as required per this protocol and to participate in this investigation. A site selection process will be followed, including a qualification visit to the institution as necessary. In order to participate in the clinical study, the Investigator must be in good standing, provide a current Curriculum Vitae to validate his/her experience and a current copy of his/her medical license.

14.2 Institutional Review Board Protocol and Informed Consent Approvals

A sample Informed Consent form (ICF) will be provided for the study Investigator(s) to prepare for use at his/her site prior to participation in the study. The written Informed Consent documents should be prepared in the language(s) of the potential Subject population. The ICFs that are used should be in accordance with the current guidelines as outlined by the 21CFR Part 50, Good Clinical Practices (GCP) guidelines and the International Conference on Harmonization (ICH).

The study Sponsor and reviewing IRB must first approve the language and the content within the Informed Consent form that is to be used by each study site. A copy of the proposed Informed Consent form, other written Subject information and any proposed advertising material must be submitted to the IRB for written approval. A copy of the written IRB approval of the protocol and Informed Consent form must be received by the study Sponsor before recruitment and enrollment of Subjects into the study. The written approval must identify the study, protocol version, and the date of approval. The Investigational site must submit to and, where necessary, obtain approval from, the IRB for all subsequent protocol amendments and changes to the Informed Consent Form prior to implementation.

The Investigator will be responsible for obtaining annual IRB approval and renewal throughout the duration of the study. The Investigator and site personnel must forward copies to the Sponsor of all required correspondence with the IRB, including the annual and continuing review reports and IRB continuance of approval. Copies of such correspondence should be filed in the Investigational site study files. Additionally, the Investigator will provide an IRB membership list or assurance number to the Sponsor annually.

14.3 Privacy and Confidentiality

In accordance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA), all subjects will be informed of potential uses and disclosures of their medical information for research purposes, and their rights to access information about them by covered entities. Each Investigator will follow the procedures for securing HIPAA compliance as directed by their respective IRB or Privacy Board, and to obtain written authorization to use and disclose subject information for all clinical research and research involving questioning of the subject's or subjects' physician(s). Per individual site procedures, this authorization may be included as part of the ICF.

All information and data sent to Outset, and its authorized representatives, concerning subjects or their participation in this study will be considered confidential. All data used in the analysis and reporting of this evaluation will be used in a manner without identifiable reference to the subject.

The Investigator will ensure that this study is conducted in full conformity with the current revision of the regulations and guidelines of FDA (21 CFR Part, 50, 54 and 56, and the relevant parts of the ICH Guidelines for Good Clinical Practice).

Information from this study may be used in publications, presentations, abstracts, and advertising but will not reveal any personal identifying information for any study subject.

15 REFERENCES

1.Leypoldt, K, Prichard S2, Chertow GM3, Alvarez L4. Differential Molecular Modeling Predictions of Mid and Conventional Dialysate Flows. Blood Purification 2019 Jan 30:1-8.

2.Davison SN, Jhangri GS, Johnson JA. Cross-sectional validity of a modified Edmonton symptoms assessment system in dialysis patients: A simple assessment of symptom burden. Kidney Int. 2006;69,1621-1625

3.Mapes DL, Lopes AA, Satayathum S, et al. Health-related quality of life as a predictor of mortality and hospitalization: The Dialysis Outcomes and Practice Patterns Study (DOPPS) Kidney Int. 2003;64:339–349.

4.Lindsay RM, Heidenheim PA, Nesrallah G, Garg AX, Suri R. Minutes to Recovery after a Hemodialysis Session: A Simple Health-Related Quality of Life Question That Is Reliable, Valid, and Sensitive to change. Clin J Am Soc Nephrol. 2006;1(5):952–959.

5.Flythe, JE, et al. Patient-Reported Outcome Instruments for Physical Symptoms Among Patients Receiving Maintenance Dialysis:A Systematic Review. Am J Kidney Dis. 2015;66(6):1033-1046

6.Flythe JE, Assimon MM, Wenger JB, Wang L: Ultrafiltration Rates and the Quality Incentive Program: Proposed Measure Definitions and Their Potential Dialysis Facility Implications. Clin J Am Soc Nephrol. 2016;11(8):1422-33

7.Dimitri Augustin, MD et al. In-vivo Dialysis Kinetics of 300 ml/min and 500 ml/min Dialysate Flows. In: American Society of Nephrology Kidney Week Oct. 23-28. San Diego California. ASN; 2018.

8.Hugh C. Rayner, Lindsay Zepel, Douglas S. Fuller et al. Recovery Time, Quality of Life, and Mortality in Hemodialysis Patients: The Dialysis Outcomes and Practice Patterns Study (DOPPS) Am J Kidney Dis. 2014;64(1):86-94

9. Luis Alvarez MD, PhD et al. Urea Clearance Results in Patients Dialyzed Thrice Weekly Using a Dialysate Flow Rate of 300ml/min. In: Annual Dialysis Conference March 16-19. Dallas, TX. ADC; 2019.

10.Hays RD, Kallich JD, Mapes DL, Coons SJ, Carter WB. Development of the kidney disease quality of life (KDQOL) instrument. Qual Life Res 3: 329-338, 1994.

11.Aiyegbusi OL, Kyte D, Cockwell P, Marshall T, Gheorghe A,Keeley T, et al. Measurement properties of patient-reported outcome measures (PROMs) used in adult patients with chronic kidney disease: A systematic review. PLoS One 12:e0179733, 2017.

12. Ricardo AC, Hacker E, Lora CM, Ackerson L, DeSalvo KB, Go A, Kusek JW, Nessel L, Ojo A, Townsend RR, Xie D, Ferrans CE, Lash JP; CRIC Investigators. Validation of the Kidney Disease Quality of Life Short Form 36 (KDQOL-36) US Spanish and English versions in a cohort of Hispanics with chronic kidney disease.Ethn Dis. 2013 Spring;23(2):202-9.

APPENDIX A: SCHEDULE OF ASSESSMENTS

Study Schedule	Source	Week -1	Week 0	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8	Week 9-12
Baseline												
Chart Review for Inclusion/Exclusion Criteria	Medical Record	X										
Review of Dialysis Related Medications	Medical Record		X									
Informed Consent	Subject		X									
Enrollment	Subject		X									
Modified ESAS and TTR	Subject	X										
KDQoL SF-36	Caregiver	X										
Kt/V Assessment	Medical Record		X									
Serum Potassium, BUN, CO2, Phos, Na, Beta-2-Microglobulin, Vitamin B12	Medical Record		X									
Trial												
Group 1												
Qd 300				X	X	X	X					
Qd 500								X	X	X	X	
Group 2												
Qd 500				X	X	X	X					
Qd 300								X	X	X	X	
Modified ESAS and TTR	Subject			X	X	X	X	X	X	X	X	
KDQoL SF-36	Caregiver						X				X	
Kt/V Assessment	Medical Record			X				X				
Serum Potassium, BUN, CO2, Phos, Na, Beta-2-Microglobulin, Vitamin B12	Medical Record			X				X				
Trial Conclusion												
Review of Tx Records and Intradialytic interventions	Flow Sheet											X
Review of Missed or shortened treatments	Medical Record/Flow Sheet											X
Analysis of Responses to TTR, ESAS, KDQoL												X
Draft final study report												X