

CLINICAL EVIDENCE COUNCIL 2011 – PERITONEAL DIALYSIS OVERVIEW

Mission

The Clinical Evidence Council (CEC) will:

- Evaluate and facilitate research endeavours aimed at:
- Expanding the clinical evidence supporting peritoneal dialysis (PD) therapy
- Exploring the opportunity to widen the benefit horizons of Baxter PD products
- Fund and support studies that are judged of highest value

The CEC will not:

- Have a supervisory role on research efforts or publications

Process

1. Submission Deadlines:
 - Investigator submits to Baxter MD (**Michelle Duddington**) for review by Regional MD, by **March 4th 2011**
 - Funding Decision by May 6th 2011
 - Funding Disbursements – 2011 Q3 & 4
2. Studies are to be submitted on the Clinical Study Submission Forms
 - Investigator form to be completed by Primary Investigator at the study institution
3. CEC members and (if needed) Expert Panel members will evaluate all submitted studies using the criteria described on the Clinical Study Review and Response Form.
4. The total budget available for 2011 is approximately \$250,000. Funds will be allocated in the following way:
 - \$100,000 will be divided equally between the four regions (\$25,000 per region)
 - \$150,000 will be used to fund applications deemed by the council, to be of the highest quality, regardless of region
 - Maximum funding available per grant is \$50,000 per year for 3 years
5. The Investigator is responsible for the following:
 - Submission of manuscripts/data for courtesy review prior to publication
 - Submission of an annual and/or end-of-study report

CLINICAL EVIDENCE COUNCIL 2011 – HOME

HAEMODIALYSIS

Mission

The Clinical Evidence Council (CEC) will:

- Facilitate and evaluate research endeavours aimed at expanding the clinical evidence supporting Home Haemodialysis (Home HD) therapy and/or Baxter's Home Haemodialysis product offering

The CEC will not:

- Have a supervisory role within research projects or publications arising from CEC grants

Process

1. Submission Deadlines:
 - Investigator submits to Baxter MD (**Michelle Duddington**) for review by Regional MD by **Feb. 18th 2011**
 - Funding Decision by April 29th 2011
 - Funding Disbursements, Q3 2011
2. Studies are to be submitted on the Clinical Study Submission Forms
 - Investigator form to be completed by Primary Investigator at the study institution
3. CEC members and (if needed) Ad Hoc members will evaluate all submitted studies using the criteria described on the Clinical Study Review and Response Form
4. The total budget available for 2011 will be up to \$400,000. Funds will be allocated in the following way:
 - All funding will be used to fund applications deemed by the council, to be of the highest quality, regardless of region; there will be no region specific funding
 - 30% of all funded applications should be for young investigators (within 5 years of an academic or clinical appointment)
 - Maximum funding available is \$100,000 per year for 2 years
5. For funded studies of one year in duration, prior to disbursement of funds it must be ensured that an investigator agreement is signed. Seventy percent of funds will be disbursed upon signing of the investigator agreement and 30% upon submission and approval of a final study report.
6. For funded studies of two years in duration, prior to disbursement of funds it must be ensured that an investigator agreement is signed. Fifty percent of funds will be disbursed upon signing of the investigator agreement, an additional 40% upon submission and approval of an annual report, and the remaining 10% upon submission and approval of a final study report.
7. The Investigator is responsible for the following:
 - Submission of manuscripts/data for courtesy review prior to publication
 - Submission of an annual and/or end-of-study report