

EC Minutes from 5.21.15

Meeting called to order- 3:35pm | Adjourned- 4:30pm

Present: Saul Malozowski, Anastassios Pittas, David Robbins, Clifford Rosen, Patricia Sheehan, Myrlene Staten, James Ware.

Gabapentin stability in dose at inclusion

- Currently the MOP required a participant to be on a stable dose 6 months prior to screening.
- In the previous SC meeting some sites said the Gabapentin requirements were causing several non-eligible individuals.

Action: CC will clarify in MOP 19 FAQs

Low A1C results- follow up discussion

- In EDC the value "0" is considered not measurable and can't be entered that low.
- EC discussed if there is a low A1c enter "3.5" into EDC going forward.

Use of smart phones

- EC discussed how to implement an app on smart phones to use as a D2d recruitment tool.
- Apple has developed ResearchKit which can help collect data through different apps.

Action: EC will look over ResearchKit and about possible apps that D2d could implement for participants.

Reports Reviewed.