



MEMORANDUM

**NIH winners of Advanced AP Trial grants: Cambridge, DREAM, and BU/MGH
- October 26, 2015**

In hallway chatter with NIH's renowned Dr. Guillermo Arreaza-Rubin at DTM this weekend, we learned the winners of the major UC4 grant for Advanced Clinical Trials to test artificial pancreas systems: Cambridge (\$6.4 million), the DREAM consortium (\$2.0 million), and Boston University/MGH (\$1.5 million). More details on the award winners will be in our DTM report - coming tomorrow - but for those who can't wait, the NIH pages listed [here](#) (Cambridge, Dr. Roman Hovorka et al.), [here](#) (DREAM, Drs. Richard Bergenstal, Moshe Phillip), and [here](#) (BU, Dr. Ed Damiano et al.) have the details. What is unclear from these posts is whether the Cambridge and DREAM groups will use these studies to support a regulatory submission of their closed-loop systems. We assume Medtronic will be involved in both studies, as the company [licensed DREAM's MD Logic in April](#), and Cambridge plans to use Medtronic's MiniMed 640G/Enlite 3 in its now-funded study. In speaking to the bionic pancreas team, this funding will go towards a bridging study in 4Q16 of the [dual-chambered iLet device revealed at FFL](#). The team expects to submit another NIH proposal to fund its pivotal study, with potential to begin the trial in early 2017 (slightly behind the [AADE timeline](#) to begin in late 2016). This \$10 million in funding accounts for half of the [original](#) "up to \$20 million," and the [UC4 grant for advanced artificial pancreas studies has notably been reissued here](#) (again it is "up to \$20 million for one to three awards; letter of intent deadline is February 9, 2016, for an earliest start date of December 2016). The Bionic Pancreas team hopes its pivotal will be funded through this mechanism. We'll have more specifics on the proposed studies in our very packed DTM Days 2-3 report, coming tomorrow afternoon on the [Close Concerns Knowledgebase](#) (do you know how to access this? If not [be in touch!](#)) and tomorrow evening in *Closer Look*.

-- by Adam Brown and Kelly Close