DRAFT Tidepool Pre-submission Meeting Notes

Presubmission Q Number: Q160340
Meeting Date: March 4, 2016
Location: FDA White Oak Campus, Silver Spring, MD, Building WO-66
Attendees:

For Tidepool: Howard Look (in person), Brandon Arbiter (via phone), Sheila Ramerman
For FDA (in person): Stayce Beck, Patricia Bernhardt, Andrea Bell-Vlasov, Josh Balsam, Courtney Lias, Naomi Schwartz, Alain Silk, Katie Serrano, James Mullally, Ross Mackey, Jisun Yi

See also: Presentation (PDF)

Meeting Notes

Tidepool Overview (for new attendees)

- Small, open source, non-profit startup
- Engaging early and often with FDA. First meeting March, 2013.
- Giving away everything:
    - Applications are free
    - Source code is freely available
    - All regulatory documents and quality system are freely available and open for inspection (see tidepool.org/documents)
        - Asked by FDA at last meeting to share with other startups. Have been doing that, including collaborating with 23andMe.
        - Good example of a quality system tailored for agile software environments
        - Constantly evolving and improving, a work in progress

Recap of Prior Pre-submission Meetings

- Sept. 2014 (Q141215)
    - Guidance on MDDA, MMA, Class1/Exempt. FDA asked that we choose and document our choice. Done: Chose Class1/Exempt, see regulatory status memo.
- June, 2015 (Q150777)
    - Review of Tidepool's Quality System and architecture
    - Guidance from FDA: Please share with other startups! Done.
    - Brief overview of use of: Trello, GitHub, Google Docs, TravisCI
    - FDA notes that Google Docs access is blocked via FDA network. HL suggests using personal WiFi hotspot to review.

Update on Current Status

- Tidepool and Tidepool apps are now registered and listed. See FDA registration and listing database.
- Tidepool Platform and Tidepool Uploader listed under: Code OUG, Medical Device Data System
- Blip, Blip Notes and Nutshell listed under: Code PHV, Continuous Glucose Monitor Retrospective Data Analysis Software

Brief Live Demonstrations

- Tidepool Uploader
    - Installable from Chrome Web Store
    - Time Zone and UTC aware, handles CGM and pump time change events
    - Review of supported devices (see presentation)
- Blip
    - Consolidated data from multiple devices
    - Overview of Blip data visualizations: Basics view, Daily View, Weekly View
    - FDA question: Attention to accessibility (e.g. glare issues with mobile devices). Tidepool: We've addressed some accessibility issues, e.g. for black & white printers and for color blindness. But more to do. We avoid excessive iconography that adds to cognitive burden.
- Blip Notes
    - Simple mobile app for entering contextual notes that appear in Blip.
    - Available for iOS and Android.
- Nutshell
    - Mobile app for recording meals and correlating them with insulin therapy data from BGM, CGM and insulin pump
    - FDA question: Is insulin bolus information entered manually? Tidepool: No, only meal name is entered. Therapy data is automatically pulled from the Tidepool back-end.
- FDA question: Do you host your own servers?
- Tidepool: No, we use Amazon Web Services, HIPAA-compliant dedicated instances. (For more detail, see architecture overview in presentation from June 2, 2015 pre-sub meeting.)

Tidepool Platform Discussion

- Secure, hosted platform via Amazon Web Services
- Modern APIs for data access

Prototype of Location-Aware CGM Monitoring App

- Review of "Follow Find" application prototype that shows real-time secondary display of CGM data along with location services. See presentation for screen shot.
- Tidepool: Confirming prior pre-submission discussion with Stayce Beck: Class2/Exempt for secondary display of real-time CGM data.
- FDA: Confirmed - Class2/Exempt for secondary display of real-time CGM data.

Prototype of Artificial Pancreas monitoring dashboard

- Early prototype of using Tidepool Platform to provide monitoring, telemetry, data gathering for closed loop systems.
- Tidepool received prior guidance on establishing a master file.
- Tidepool question: Best way to document platform for use by future A/P systems that would enable Tidepool to continue developing and iterating on software.
- FDA question: For both trials and commercialization? Tidepool: both
- FDA: Telemetry system does not needed to be submitted as part of an IDE for studies.
- FDA:
    - For commercialized system, document your **process** in the master file. Process can allow you to keep iterating even after PMA submission.
    - Document the things that are critical to the operation of the AP that would need to be locked down for review, hopefully less than 5% of system.
    - Document a decision tree that makes it clear how you are making a determination about what is critical to the system performance and what is not critical.
    - We will look at HOW you are doing software testing, but not feasible to look at all software tests.
- Tidepool: Examples of how should we define things that are critical to system operation?
- FDA:
    - Delivery of insulin is critical.
    - For an AP device (e.g. Tidepool UI designs for iLet), the user interface IS critical, would need to be documented in PMA.
    - Data upload, location services or secondary display of data is NOT critical, does not need to be in PMA.
    - These items should be identified by a comprehensive hazard analysis. This analysis will feed back into your decision tree (mentioned above)

Review of FDA's Draft Thinking on AP Device Interoperability

The FDA presented early, draft thinking on device interoperability and requested Tidepool's feedback. Tidepool committed to ongoing review and to providing further thoughts.

Miscellaneous Questions and Guidance

HL: As discussed early, real-time secondary display of CGM data is Class2/Exempt. What about putting real-time data into HealthKit?
FDA: No problem putting real-time data into HealthKit. It is considered MMA [Class1/Exempt, Enforcement Discretion] unless it calculates an insulin bolus.
HL: If Tidepool or Dexcom puts real time CGM data into HealthKit, and a third party makes an app that creates insulin boluses, it’s that third party app’s responsibility [to comply with FDA regs]?
FDA: Correct.

HL: Do we make it clear that the data is contra-indicated for real-time use?
FDA: You can just say what it's for [not say contra-indicated].

HL: Taking off Tidepool CEO hat, now wearing Geek Dad hat. Built an OpenAPS system for my daughter. She wears it full time, takes it to school. It's awesome. Built a Class 3 medical device in the privacy of my own home. There are 30-something people currently using OpenAPS.

HL: Now wearing Tidepool CEO hat. People want to use our software [Tidepool Platform and Tidepool apps] to gather and display the data from their homebrew class 3 medical device.

FDA:

- If they use Blip and Blip doesn't distinguish [between real-time and retrospective], you guys don't have to do anything, it's not an FDA concern.
- If you write a new app for this [real time data display], that is an FDA concern. It's not OK to tell them how to do it, and it's not OK to say to use Blip for this specific use [real-time display].

FDA:

- If someone is writing an app that is real time CGM monitoring, it's Class2/Exempt, must follow quality system requirements. If Tidepool is facilitating that [real time display], Tidepool has regulatory responsibility.
- If you were the Tidepool guy talking about doing it, it could be considered promoting.
- If Tidepool is participating in the uploading, then you are involved and there is some regulatory responsibility.

FDA:

- We understand being the concept of a platform that other people will use. We understand that platforms get used in ways that were not imagined.
- As long as you're not saying this is how you should use the platform, it's fine.
- Be careful of being seen to help others to do something that's not compliant.

FDA:

- We understand that you're doing this [building OpenAPS as a Dad] for your child, and we think you are capable. If you help 15 other people get setup or hold workshops, that's a different story.

HL: New topic: "N of 1 Research." A community of people who want to conduct and contribute to research, sometimes based on a DIY project, sometimes based on existing devices. For example, while my daughter has been on OpenAPS, we done a much better job of figuring out her basal rates. I'd like to publish that data. How does the FDA think of N=1 studies?

FDA: Seems like this isn't a clinical study where people are being enrolled. You're just looking into your diabetes.

HL: Correct. Hypothetically, I have invented a protocol for analyzing nighttime basal rates based on analyzing OpenAPS data. People could take my study protocol, run their own study, and publish their data.

FDA:

- If you did this and sent this to a journal and they published it, it has nothing to do with us.
- Write it up as a 'Dad', not as coming from Tidepool, then it will have no effect on Tidepool.

HL: I will write up an example of such an N=1 study and send it to you.