Tidepool FDA Pre-submission Draft Meeting Minutes

October 14, 2014, 2:00pm EDT
Food and Drug Administration, 10903 New Hampshire Ave., WO 66, Silver Spring, MD 20993
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Pre-submission document and presentation

Attendees

Tidepool

- Howard Look - President and CEO
- Kent Quirk - VP Engineering
- Brandon Arbiter - VP Product and Business Development
- (via phone) Sheila Ramerman - SJR Associates, software quality system consultant

FDA

- Courtney Lias
- Stayce Beck
- Joshua Balsam
- Brendan O'Leary
- Beth Stephen

Summary

Tidepool Uploader:

- Tidepool demonstrated Dexcom data being uploaded through the Tidepool Uploader, running on a Mac, uploading data to the Tidepool Platform.
- Tidepool clarifies that there is no data transformation. Data values do not change, they are uploaded exactly as they are retrieved from the device.
- FDA comments that this is pretty clearly MDDS (moving data from point A to point B). FDA will have follow up discussion and clarify/confirm.
- Tidepool acquires data using one of three mechanisms:
    1) using protocol specifications provided by the device company,
    2) using client- or cloud- connectivity (i.e., importing data that has been exported from data management software), or
    3) by inspecting, implementing, and validating the device's data protocol specification.

  FDA will have internal follow up discussion to clarify thoughts about mechanisms 2 and 3.

Blip and Nutshell:

- These fall under either MMA (enforcement discretion) or the new class 1 designation that applies to Dexcom Studio (PHV 862.2120).

- Tidepool should make the decision whether Blip and Nutshell should be considered MMA (enforcement discretion) or new Class 1 (PHV 862.2120) and document the rationale for the decision.

Third party software use of Tidepool Platform:

- Third parties who leverage the data storage and retrieval capabilities of the platform are responsible for how they use it. If they should apply for regulatory approval, burden is on them, not on Tidepool. Tidepool is not responsible for those third parties' use. Tidepool should clearly state the capabilities of the platform APIs.
- Creating a Master File for the platform is an option. It would encourage re-use. The FDA will look at it when a third party refers to it. Tidepool should update it in advance of use/reference by a third party.
- Tidepool could also help the community define standards for data storage. The FDA can then review those standards, and third parties can simply state they're following the approved community standard.

Engaging with volunteers/contributors:

- If testing an app that falls under enforcement discretion, you don't need to do anything. For devices/software with significant risk, see IDE requirements. Tidepools current applications do not have significant risk.
- Tidepool's volunteer/contributors are contributing to or testing development/test software not for patient use. Tidepool is not distributing to them for device or medical decision making.

Detailed Minutes

Courtney – Uploader we haven't seen before. We've seen Nutshell and Blip. Why don't you show us the Uploader?

Howard –

Background about Tidepool: We're a non profit, open data (the patients owns the data) with standards and interoperability, architecture also works well for research and conducting trials. We've also learned the platform can be applied for post-market efficacy studies of closed loop systems. We're open source, which enables us to give what we build to industry for free.

My frustration came from not being able to see my daughter's data from Medtronic and Dexcom in one place at one time. This made it very hard for me as a parent to deliver effective therapy. It turned out clinicians felt this way as well.

Tidepool is working on three apps. They are the Tidepool Uploader, Blip, and Nutshell (which is on the backburner for now).

Tidepool Uploader is our newest product, funded by JDRF. It's a device agnostic way to get data into our platform. [Howard demos getting data from Brandon's Dexcom into Blip via the Tidepool Uploader.]

Brandon - Before the Tidepool Uploader, Mac users couldn't get their Dexcom G4 data onto their computers.

Howard -
Once data is stored in the Tidepool Platform back-end, Blip can display it. Here's Dexcom and Medtronic data in one place.

Courtney - Medtronic is working with you?

Howard – Would like to talk more about that. We're fetching the data out of CareLink [via CSV download] and uploading it back into Tidepool. We've been discussing it with them and they say they're open to it.

Courtney - They're warming.

Howard – We're using AAMI TIR45, which Bakul helped write, as our guide into agile best practices. Sheila is going to help us properly document our quality system.

Stayce – Working with device makers through protocol specifications?

Howard –

Some give them to us, but there are issues. Some device makers don't have specs. Others have inaccuracies in the spec. Let's talk more about this.

MDDS seems to be written about what we're working on. We're using volunteers, we don't want to surprise anyone.

Courtney – let's talk about Blip and Nutshell.

MDDS may not apply, it is not supposed to be doing correlation and analysis, things like that. But we want to make sure pathway for Blip and Nutshell is low burden, not class III, that would make no sense. MMA would make more sense. Also, Dexcom Studio is now Class 1 (GMPs, registration and listing, etc., but no submissions).

It does seem Blip is similar to the Dexcom Studio. Either it's MMA or Class 1. The responsibility is Tidepool's: You should look into your software and tell FDA: is it enforcement discretion/MMA or is it more like Dexcom Studio, which is PHV 862.2120 (Class I/501(k)-exempt, no

submissions required). Then it's Tidepool's job to justify that as we file. Bottom line is that FDA agrees that this software seems useful and don't want to be standing in the way.

Howard – If we decide ourselves, might you disagree?

Courtney –

There's a chance, but that's unlikely. We will always prefer design controls and GMP. But you guys seem to do that anyway, so we have less of a practical concern.

The uploader we didn't understand. It's data transfer, may be MDDS. We may have questions about how you get the data into the product. But that may be MDDS because it just moves data from one end point to another. Do you (FDA colleagues) agree?

Stayce – Yes, I agree.

Courtney – Do you guys change the form of the data?

Beth – By "change the data", we mean, "Do the values change?"

Kent – No. Values are the same from device into our system.

Courtney – Then that's probably MDDS.

On screen -
[Mechanisms for getting data from devices:

1. Using data protocol specifications
2. Reading data from existing client- or cloud-based backends (CareLink, Dexcom Studio export)
3. Inspecting, documenting and implementing existing protocols]

Howard –
The specifications we get have bugs, so we still have to do the work of looking at what's coming out of the device. Sometimes, we end up writing the specification ourselves.

With CareLink, we download the CSV, convert it into our normalized format, and upload it into the Tidepool Platform. We can also read exported data from Dexcom Studio.

Stayce – Other than your partnerships, you're always using data exports from existing software?

Howard – Yes.
[Clarifying in these minutes: We are also seeking to understand the FDA's thoughts on 'reverse engineering' device protocols. As described in the meeting, we do this anyway even when we

have the protocol specification because it helps to improve the specification based on empirical observation of the device. We believe that even without having the specification, the 'reverse engineering' provides an accurate representation of the operation of the device and data protocol.]

Courtney – What about glucose meters? There's a lot of variety. We're interested in pushing this forward. Regardless of device, we believe patients should have access to their data.

Howard – J&J/Lifescan [and others] have published protocols. In other cases it's been a conversation. They're new to open source. There's a fear of how people will use the code, but those conversations generally go well. New, small meter companies want very much to be in our Platform.

Courtney – 75% of the glucose meter submissions are from Asia.

Courtney – Glooko?

Howard – They are a cloud backend [and also make apps and cable], but not a BG meter.

Howard – Sometimes device makers provide protocols, sometimes they don't. What are your thoughts?

Courtney – We look at integrity of transfer. Getting to the goal of having patients have access to the device data is something the FDA believes in.

Brendan – With the Tidepool Uploader, are you looking at data that's been processed or are you reading pre-processed data?

Howard – For example, from the Dexcom we could be looking at raw ISIG values, but we're not. We're not computing estimated blood glucose values. We're reading the estimated blood glucose values calculated by the Dexcom receiver, then putting exactly those numbers into the Tidepool Platform for display. Our platform stores and displays exactly what the device displays.

Courtney – Where the protocol is published or they're giving it to you, that's clear. When you're taking Medtronic's export or inspecting and documenting on your own, we need to talk about that internally.

Stayce – For some companies, they have cyber security claims. They claim they don't release their protocol and that's secure.

Stayce – What about cyber security? We require companies to submit security claims. Some say they don't release their protocols and that makes their devices secure. If you're publishing

code that can be used to communicate to these devices, does that reduce security of the device?

Howard - There is common misconception that “security through obscurity” works. If a malicious intender wants to reverse engineer a protocol, they can and will do it without documentation. We are actively working with device makers to make their devices safer in the long run. Choosing to not publish a protocol does not make a device secure. Security comes from using well understood mechanisms for authentication.

Courtney – You’ve talked about getting the data off the uploader, what about other applications? What do they have to do to ensure the other end. Do they have to work on your platform?

Howard – The model we use is similar to how apps like Strava and FitBit share their data. They have a mechanism for authentication [called Oauth].

Kent - Facebook is similar. Sometimes you’ll download an app (e.g., Twitter), and it will ask if you want to authenticate using your Facebook account. You click “yes”, it takes you to a Facebook page that says “Twitter wants to access these data points in Facebook. Do you agree.” You click yes. This is called Open Authentication [Oauth] and is how Tidepool’s Platform will work with third party apps as well.

Courtney – So Tidepool Platform is the data warehouse.

Howard – Yes, Tidepool Platform is a cloud-based diabetes data storage. Our goal is to make it available to third party developers through APIs like I’ve described. Question: Given that this is our intent, should we have a master file for our platform?

Courtney – Master file is an option.

Howard –
If it is a masterfile, since we iterate, what’s the best way to keep it up to date?
What’s our responsibility to monitor how other are using the platform?

Courtney –
Master File has multiple purposes:

1) Giving out to multiple companies, so you don’t have to do it over and over again.
2) Doesn’t require public sharing of information (which doesn’t seem relevant to Tidepool)

The challenge is keeping it updated. You can update it by sending in updates at any point. We won’t review it until someone points to it. They might ask you to update it. If we have questions, we can ask you directly. But usually it’s in the context of the third party leveraging your master file. In this case, it might be a good option because you want people to use it.

Another option is to establish “data standards,” it [the master file] might not even be necessary. In terms of security, integrity, the main issue with these platform would be security of transferring data. We could recognize the standard. The standards we need to think about are in order to enable getting data from your own device, but also moving forward on component devices, [for example] someone who’s developed an artificial pancreas platform, making that more doable for them. They have to show responsibility for that whole system. Communication and security standards would make this more clear.

Howard – Restating: For example, if we said here is a standard set of APIs for you to get data from, you’re artificial pancreas to the cloud and back to you monitoring device; we establish that as a fixed protocol; FDA approves it; then we can give it to the community.

Courtney – That would be Tidepool’s standards; I mean that the community develops the standards.

Howard – [New topic] What is our responsibility for understanding how people use the Tidepool Platform?

Courtney – Your responsibility is to make it clear what this platform is and isn’t. How it does and doesn’t work. If someone integrates your platform into their product, and it should be regulated, it’s their responsibility, not yours.

Howard – If someone uses our platform, which does store glucose data, and they use it to store and retrieve that data in real time, is that their responsibility or ours?

Stayce – That’s their responsibility. Just don’t advertise that people should be using your product for that purpose.

Howard – Last topic is about open source and volunteers. On top of 9 employees, we have volunteers. They do things like write code, UI designs, usability testing, verification and validation. I included a document modeled after other open projects: a volunteer/contributor license agreement. I want to make sure that involving volunteers doesn’t cross the line of [commercial] distribution. What is your feedback?
[For clarity: Volunteer contributor/testers are using development/test software, not for patient use.]

Courtney –

Let’s talk about things at *are* regulated (not enforcement discretion). Research, investigation, commercialization with claims. It doesn’t sound like the things you described are regulated.

[In general] if someone is using a device in a study, they might need approval from us for the study if there is significant risk. Your beta testers might be investigational (part 812) but it seems

like what you are doing is non-significant risk [so no IDE required]. There are very few things you have to do. Most important is to be very clear, e.g. if you were developing something higher risk, like controlling a pump with your platform. Under enforcement discretion you don't need to do anything.

Brendan – "Investigation" is interesting word. These volunteers aren't subjects, they're contributors. You're not distributing to them for device use or medical decision making.

Courtney – Is it research or investigational? It might not hurt to say it's for investigational.

Brandon Arbiter - You said you wanted to talk about Blip and the Uploader up front, then Nutshell later.

Courtney - No. Nutshell and Blip were together. They would fall under MMA or the new Class 1 (like Dexcom Studio). But we had more questions about Uploader, which it seems is pretty clear it's MDDS. We'll follow up with about it after more internal discussion.

Courtney – Wrap-up comments: FDA's concerns are always about the "back end" of data processing. Apps with analysis might be under MMA, not MDDS. Uploader is MMDS, apps are MMA. You have to register with FDA, if you are not MMA/MDDS.

Howard – (1) Tidepool has to analyze our software with respect to MMA/MDDS enforcement discretion vs. Class 1 like Dexcom Studio and determine our regulatory requirements, then do internal documentation. (2) Tidepool will do quality system documentation as required.

Courtney – You guys can help us. We have leverage sometimes with the industry if we know what to push on.

Sheila – Was there something about a public meeting?

Howard – I'm on the panel. I'll fill you in.

Stayce – Follow ups for us: talking about the Uploader and Reverse Engineering.

Courtney – you can help us by letting us know what challenges you see and what blockages need to be unplugged.