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Abiy Desta
Lance Harmer
United States Food and Drug Administration

November 7, 2024

RE: C230014
Product Name: Dr MOOVES A&D App – A Children’s Suicide Prevention App
Suicide Instinct theory to address the Suicide Epidemic in the USA
Update on de Novo Field Study

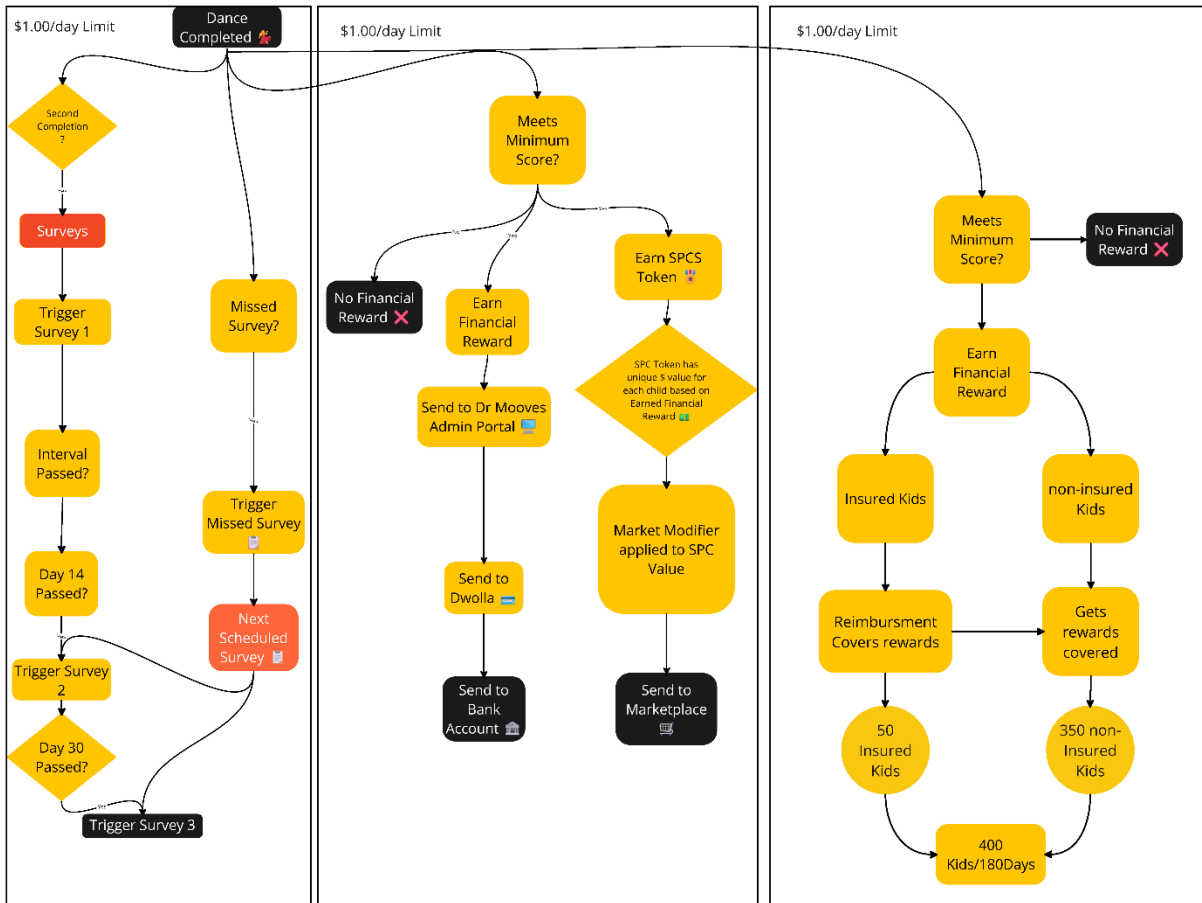
Contact information:	Playing Forward 954 Lexington Ave. #247 New York City, NY 10021 Contact: Victor Talbot Phone: 310-963-9938 E-mail: vtalbot@playingforward.com
Q-sub Type:	Submission Issue Request (SIR)
Method of Feedback:	Meeting
Meeting Information:	
Draft Agenda:	1. Have FDA approve change to design of field study and grant app permission to bill (30 minutes)
Meeting Format:	In-person (Dr. Talbot will travel to FDA offices)
Preferred Dates/Times	November 13, 14, or 15, 2024
Planned Attendees	Victor Talbot, Official Correspondent from Playing Forward & Dr.MOOVES, INC and principal creator of the Dr. MOOVES A&D app

Dear Abiy and Lance,

Purpose of Q-sub: This letter serves as a follow-up to our meeting that took place in September 2024, where you advised me on how to respond to a letter I had received from Dr. David P. McMullen at the FDA. In that meeting, I described a field study we are conducting using the experiential children's movement app Dr. MOOVES A&D. The purpose of the Dr. MOOVES A&D app is to prevent suicide. Our de Novo field study examines subclinical indicators, including moods A&D (Anxiety&Depression). I am writing this letter to provide you with an update on a design change for our field study and ask you for a certain immediate approval before we proceed.

Device Description. Here is a quick recap of the functionality of the app. [Dr. MOOVES A&D](#) is aimed at latency age children (aged 5 to 12). Many users will likely find the Dr. MOOVES A&D app from being online www.drmooves.com. Parents will discover the Dr. MOOVES A&D app and have their children start using it. When we met, I told you that we would be targeting a subclinical population – meaning all US latency age children including those not participating in mental health treatment - because they have not been identified clinically.

Intended Use. As we discussed, Dr. MOOVES A&D guides the users through experiential Dance Styles that serve as movement therapy. When a dance is completed, the app rewards points to the user commensurate with how much cognitive effort and how accurately they completed the movements in the dance. The app also provides micro bank rewards (up to \$1.00 limit per day) and SPC (Suicide Prevention Credits) based on cognitive effort. Presently, the micro bank rewards are deposited into the user's bank account, and fiat-flagged SPC (Suicide Prevention Credits) will be allocated to an online marketplace. Indicators of moods A&D are measured on a schedule of 14 days, 30 days, 60 days, 90 days, and 180 days since onboarding (see schematic).



Schematic: Field Study Design with Micro Bank Deposits and SPC (Suicide Prevention Credits)

Regulatory History. We are currently gathering real world evidence (RWE) to eventually present to the FDA to demonstrate efficacy. In order to demonstrate clinical efficacy, it is anticipated that we require a sample size of 400 users regularly efforting using the app over 180 days.

The Dr. MOOVES A&D app has been designed to bill for the therapy it provides. We have done experiments with the Dr. MOOVES A&D app in 2021-2022 where we have successfully billed health insurance and have been paid (for more than 40 claims). Users may opt into establishing a medical record with Dr. MOOVES A&D or not. If they do, they complete an enrollment form. The user provides their health insurance information. If they are insured, as they complete the movement therapy, billing claims are automatically sent from the app to the health insurance electronically. However, this will only work at reaching all US latency age children if there is a unique National Provider Identification (NPI) number assigned to the DR. MOOVES A&D app.

Specific Questions: We are asking the FDA to grant Dr MOOVES A&D permission to conduct this billing as part of the field study temporarily (for 6 months). We want you to grant us a temporary NPI for the Dr. MOOVES A&D app. I also need you to make this approval in order to cover more children in our field study so that we can obtain the necessary Case size quickly to demonstrate that the app works. This way, it will be available to all therapists so we can aim to cover the 35 million latency age children in the US (see schematic).

Please advise as I am the Official Correspondent from Playing Forward & Dr.MOOVES, INC and principal creator of the Dr. MOOVES A&D app

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Sincerely,

Victor Talbot

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Chief Medical Advisor



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