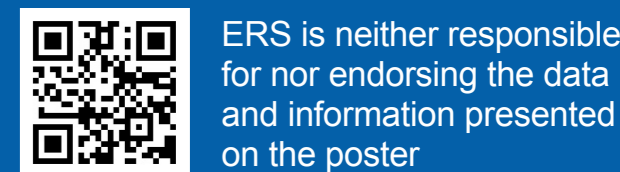


# Interactive Tablet Application for Self-Report of Asthma Symptoms and Impacts in Young Children



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## AIMS

- Asthma burdens an estimated 330 million people worldwide and has a greater prevalence in children than any other chronic disease.<sup>1,2</sup>
- A patient-reported outcome measure that allows for self-report of concepts related to asthma symptoms is needed for use in clinical trials with children.
- A digital application, the electronic pediatric asthma symptom diary (ePASD), was developed to assess the severity and proximal impact of daily asthma symptoms while enabling self-report among children aged 6-11 years without the need for caregiver/proxy reporting or multiple questionnaires.<sup>3</sup> The ePASD also assesses daily rescue medication use.
- Here we describe the early prototype development of the ePASD digital application on a tablet with child participants across 5 countries. This novel, interactive asthma symptom and impact monitoring tool will facilitate self-report during clinical trials with children aged 6-11 years.

## METHODS

- We conducted an observational qualitative study with a constructive research design.
- Participants (i.e., children aged 6-11 years with asthma and their caregivers) were selected for interviews using a purposive sampling approach.
- Participants were then presented with a digital application that included an animated character reading questions aloud while visually and audibly demonstrating asthma symptoms or the impacts on daily activities.
- Round 1 in-person interviews were conducted in New York City, New York, United States (US) and aimed to understand whether kids aged 6-11 years had the skills to self-complete the ePASD (i.e., questionnaire efficacy), how the diary may be integrated in the daily routine of the child participant and their family (i.e., routine integration), how to leverage long-term engagement (i.e., engagement), and how to be well received by both the child and the caregiver participants (i.e., acceptance).
- Round 1 global remote interviews to address cultural variability were conducted by a local moderator in the participant's native language in China, India, Russia, and the United Arab Emirates. A translator provided simultaneous English translation to the researcher who was taking notes, observing, and providing input to the local moderator.
- Findings from round 1 were used to develop the user flows of the ePASD, which were then tested in round 2 in-person interviews conducted in Chicago, Illinois, US.
- Each of the two user flows corresponded to a daytime and nighttime diary component of the ePASD.

## RESULTS

### Round 1: US Participants

- 15 children and their caregivers participated in the round 1 interviews conducted in the US.
- All child participants understood the questions, demonstrated the cognitive skills to correctly interpret questions, and chose answers without needing to be guided by an adult.
- All child participants also understood the animations and related them to the associated symptoms and impacts on daily activities. The child participants provided valuable feedback that helped further refine the animations (Figure 1).
- Daily routines were flexible enough to accommodate the few minutes required for the diary completion twice daily.
- Both human-like (Asthma Buddy) and creature-like (Asthma Monster) character design directions were well received by children across ages and genders. While the human character was mostly appreciated for its ability to establish a relationship with the child, participants liked the look of the creatures and perceived these characters as being "cool" with fun attitudes (Figure 2).
- The Asthma Monsters were less age and gender sensitive than the human Asthma Buddy. Many child participants identified themselves with the human character while seeing the monsters as something completely different. Child participants paid greater attention to the gender and age of the human character than to the monster characters, for which these aspects did not seem to matter.
- Some child participants expressed a strong preference for a character that visibly spoke to them as opposed to an external voiceover. The children empathized with this form of personal communication. Also, we observed that a speaking character allowed child participants to better follow the experience from start to finish and kept their attention focused on one specific part of the interface while preventing distractions. Accordingly, we made the character address the user directly when speaking by ensuring its mouth moved with animation.
- Based on round 1 child participant feedback, a single, nonhuman character was developed for testing in round 2 with the following attributes: relevant body parts (torso, arms, hands, neck, face, etc.), a happy personality in its neutral state/when talking directly to the child, appropriately and credibly represents each concept assessed by the ePASD, does something fun during transitions between questions, is physically active when not demonstrating the concept, and carries some type of cool gear or accessory.
- Older child participants valued the diary as a tool to assess their asthma and to communicate to others how they are feeling. Caregiver participants valued the diary as a management and communication tool. The diary also increased the caregivers' awareness of how asthma symptoms impacted their children.
- Many caregiver participants saw potential in the diary as a tool to empower communication with their child.

### Round 1: Global Cultural Variability

- Round 1 interview global participants included children from Russia (n = 6), China (n = 6), India (n = 6), and the United Arab Emirates (n = 5).
- The diary questions and their visual representations were clear across all 4 countries. Child participants with reading difficulties easily understood questions due to the animations.
- Familiarity with the symptoms was related to the child's personal experience and not cultural aspects.
- All readers, including nonproficiency readers, found it easy to understand response options. All child participants could interpret the smiley faces, which they recognized as a familiar and universal language. Nonreaders understood what the different faces in the response options referred to.
- These findings showed that a different design was not needed for different countries; therefore, 1 prototype was sufficient for round 2 interviews.

### Round 2: US Participants

- 14 child participants and their caregivers participated in round 2 interviews.
- All child participants self-reported their symptoms and demonstrated the cognitive skills necessary to complete the diary.
- Some child participants required a few clarifications when reviewing the flow. Clarifications were needed when terms were new or unclear, participants had never experienced a particular symptom, or participants were not sure about which type of inhaler to report. Once clarifications were provided, all child participants were able to answer with confidence.
- Child participants correctly interpreted animations with respect to the concepts they meant to show (Figure 3). Children often referred to their own way of experiencing symptoms and pointed out similarities and differences between themselves and the character without letting it interfere with their ability to understand what the character was acting out.
- 5 different response scales were tested (Figure 4). Numeric scales and yes/no scales were very easy for all children to interpret. Child participants were familiar with smiley faces, but younger children sometimes struggled to clearly define the differences between severity levels (e.g., "hard" vs. "very hard") with respect to a specific symptom. These participants understood the differences in severity level after explanations and self-reflection on the meaning of the scale.
- All child participants managed to self-complete the diary from the first time they tried the application. They had no problems understanding how to navigate the application: how to select and change an answer, how to go back to the previous question, how to proceed to the next question, how to replay the animation, and how to mute the application.

- Many child participants gave positive feedback regarding the character, its appearance, and tone of voice. A few older children considered it too "childish" for them but nevertheless considered the experience with the diary positive and useful (Figure 5). No child reported particular interest or concern for the character's gender. When asked, they all affirmed that it did not matter.
- Caregiver participants reacted very positively to the diary and commented on the importance of the tool as a way to teach their children about asthma and its signs.

Figure 1. Refinement of Characters Based on Round 1 Feedback

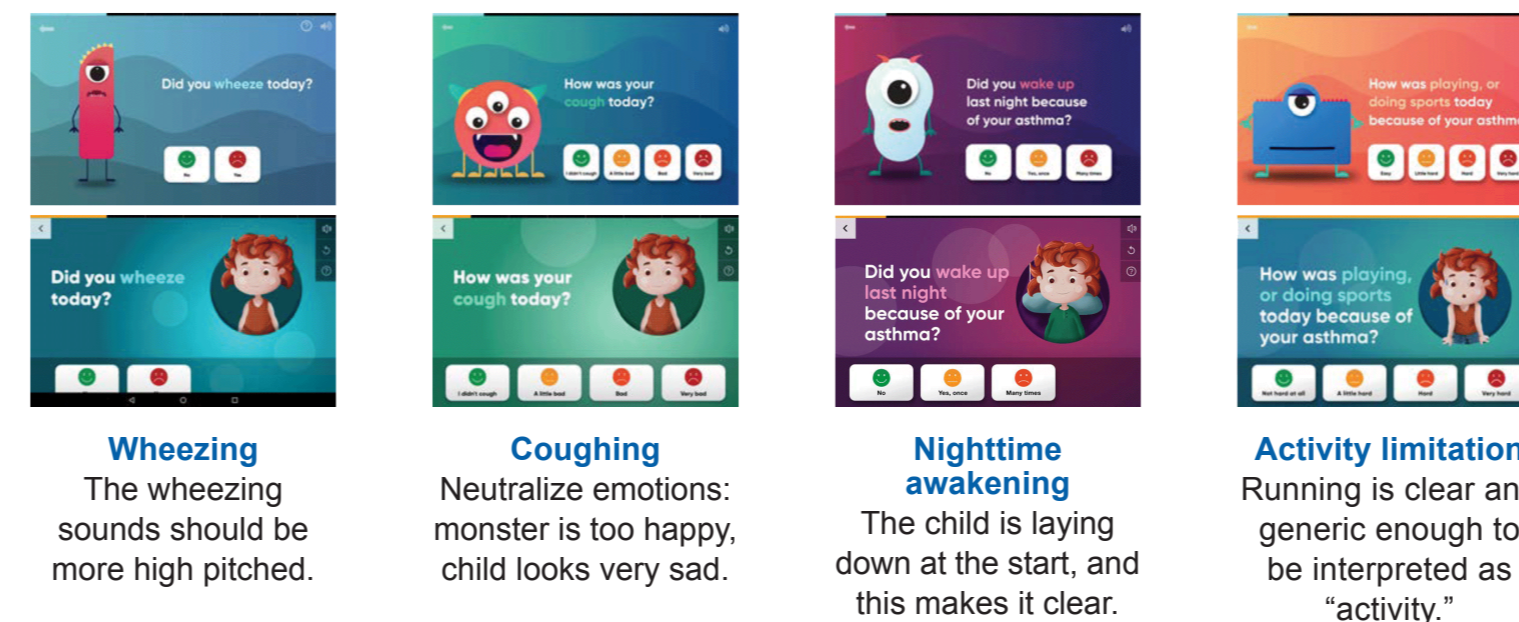


Figure 3. Concept Animations

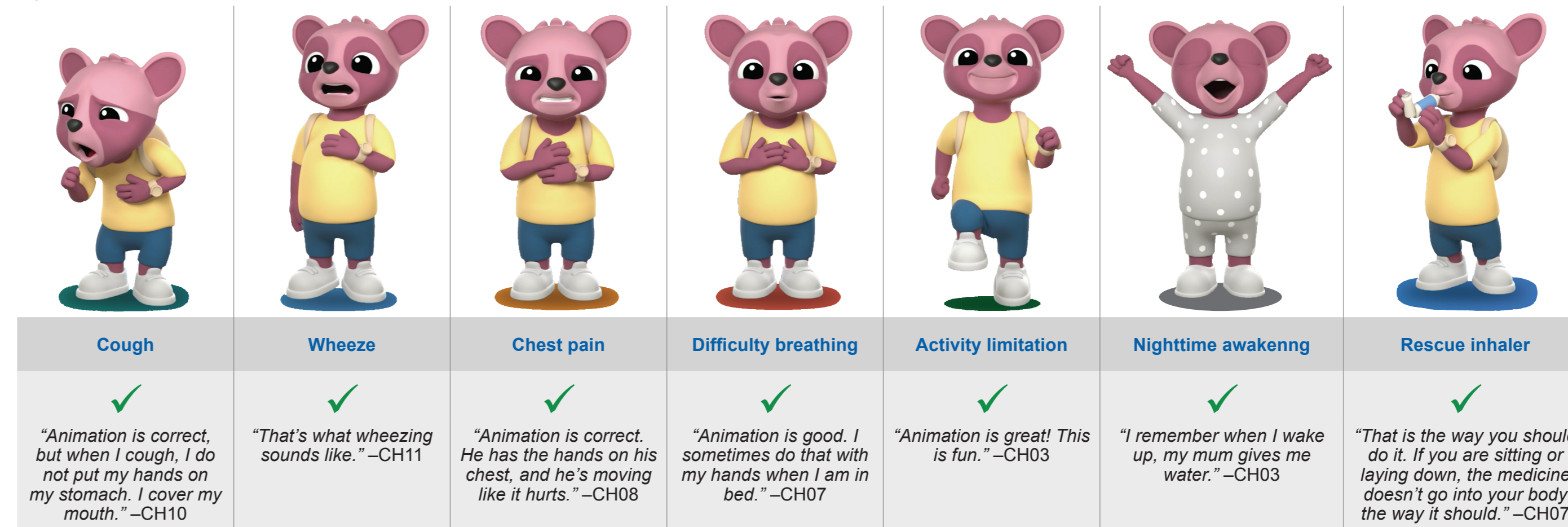


Figure 4. Response Scale Variations

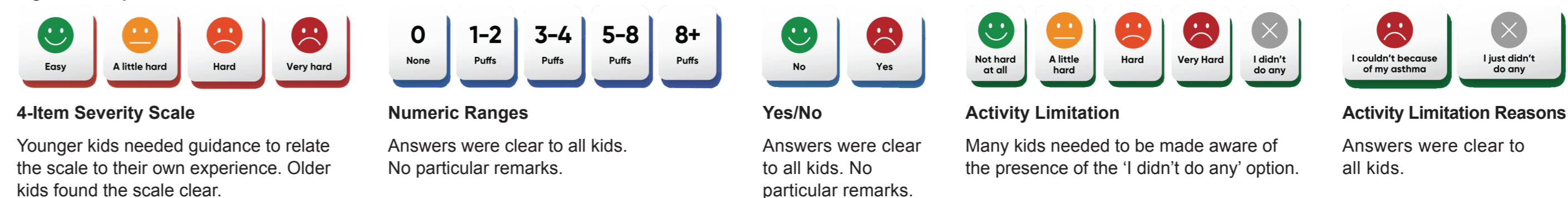
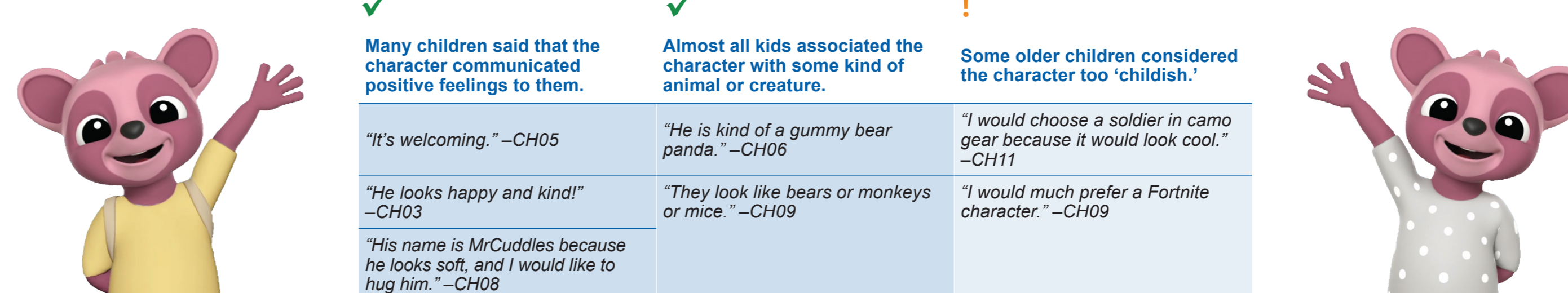


Figure 5. Character Feedback



## CONCLUSIONS

- All child participants aged 6-11 years across 5 countries successfully interacted with the ePASD application and used all of its features to self-report asthma symptoms and impacts on daily activities.
- Almost all families foresaw an easy integration into their routines.
- The final character was a creature with humanoid body parts and a happy personality that spoke directly to children. The character for the evening ePASD wore daytime clothes and a backpack to indicate the questions related to daytime concepts, and the character for the morning ePASD wore pajamas to indicate the questions related to nighttime concepts.
- The use of this character to visualize asthma symptoms and impacts on daily activities engaged children of all ages.
- The smiley faces used for response options acted as a universal language that allowed children from all countries to interpret response options correctly. Personal interest guided the child participants' preferences for characters.
- Details of the content validation of the ePASD are presented in Clark et al.<sup>3</sup>
- An independent, longitudinal psychometric validation study has already been completed, and further longitudinal validation in a clinical trial is currently planned for the ePASD.
- Based on the feedback from children aged 6-11 years and their caregivers during this development phase, the final prototype of the ePASD digital application on a tablet is anticipated to provide a feasible, acceptable, and fun tool for children aged 6-11 years, with or without the ability to read independently, to self-report on their daytime and nighttime asthma symptoms and impacts on daily activities.

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## CONFLICTS OF INTEREST

JM, CB, KG, KK, FE, FP, CN, and FSG are employees and shareholders of Novartis Pharmaceuticals. OG, ZR, and RL are employees of frog, a global design and innovation consultancy. MC, CR, OOA, DW, and RC are employees of RTI Health Solutions, an independent nonprofit research organization that does work for government agencies and pharmaceutical companies.

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