

*US Consent*

**TITLE:** BURDEN initiative  
“Bronchiectasis Understanding & Research on Daily Experiences & Needs”

**PROTOCOL NO.:** Exempt

**SPONSOR:** Insmmed Incorporated

**PROTOCOL VERSION AND DATE:** Version 1.0, May, 14<sup>th</sup> 2024

**PRINCIPAL INVESTIGATOR:** Sunjay R Devarajan, M.D.  
7200 Cambridge St  
Houston, TX 77030  
United States

**RESEARCH-RELATED PHONE NUMBER(S):** Engage Health at 651-994-0510  
612-940-7852 (24 hours)

### **Why is this research being done?**

The objectives of the BURDEN initiative are:

- Increasing awareness on the impact of bronchiectasis on the lives of those affected.
- Enhancing quality of research, care, and information materials.
- Empowering the bronchiectasis community.
- Generating patient relevant insights/ evidence that may be considered by health care decision makers globally.
- Demonstrating disease burden to healthcare decision-makers globally by sharing information delivered by people living with bronchiectasis and those who care for them.

The sponsor for the BURDEN initiative is Insmid Incorporated, a global biopharmaceutical company committed to focusing on serious or rare diseases. admedicum organizes this research. In the US the interviews will be conducted through Engage Health on behalf of admedicum. In no case will our work with you describe or directly or indirectly recommend any products.

### **Why are the interviews being done?**

The interviews are being conducted as part of the BURDEN initiative to learn more about the impact of bronchiectasis (without cystic fibrosis) on everyday life of affected people and their caregivers. The findings from your participation will be used to inform the creation of a larger online survey which will be conducted by admedicum at a later date via a browser-based online survey tool. Your interview participation will help us to consider all relevant topics. The goal of the interview is to better understand the disease burden including the needs and experiences of people living with bronchiectasis (without cystic fibrosis) and people who take care for them in their daily, social and work life.

### **What personal information is collected?**

In order to determine if you qualify and in preparation of the interview, admedicum collected so-called personal data prior to the interview by the online registration. These include, above all, information about you, such as the country you are living, age, sex, status (patient, caregiver), disease(s), disease status and history. admedicum also collected your telephone number and your email address in order to inform Engage Health that you qualify for the interview and to allow them to schedule the interview.

All your answers in the interview, which can be by telephone, will be recorded by Engage Health, who will then share the recordings with admedicum. The sound recording will only be used for the purpose of documentation and transcription in the context of the project described above. For transcription your sound recording will be transferred to the transcription service provider called Rev.com Inc. Under no circumstances will it be passed on to Insmid Incorporated.

After the interview Engage Health will send you a link to an online form to provide your bank details and personal information that admedicum only needs to transfer the compensation (see below). admedicum will not use your personal data outside of the described project, except for the purpose of contacting you and complying with legal regulations (see below).

### **Who sees your personal information?**

Employees and representatives of Engage Health and admedicum, who are each bound by strict confidentiality obligations, will see your data (your contact information and your answers to questions) if and to the extent that this is useful and necessary for the fulfillment of their tasks or because of their participation in the interview. For the processing of compensation, admedicum will have access to your banking information. They will also use the data only for the stated purpose.

### **What are the research procedures? What are my responsibilities?**

We estimate that your overall time commitment will be approximately 60 minutes. You are eligible to participate if you are at least 18 years old, with confirmed diagnosis of bronchiectasis (without cystic fibrosis), and having experienced at least one bronchiectasis flare, or exacerbation, in the past year OR if you are at least 18 years old, provide care on a daily basis, and are living with someone who fits the patient description above. Other eligibility criteria may apply. You will be told about any new information that might change your decision to be in this research.

### **What are the risks or inconveniences of the research?**

The interviews can be emotionally stressful for some patients. The time it takes to complete telephone interview may be a possible inconvenience. However, you can interrupt the interview at any time and revoke your consent to participate. Your alternative is to not participate in this research.

Engage Health and admedicum will make every reasonable effort to protect the interview data.

Submitting personal data over the internet always involves some risk, however. We cannot guarantee that servers are 100% safe from illegal tampering or “hacking”. Once each research

vendor receives research data and enters it into the database, said data has the same protection that they extend to their own confidential information.

**Are there costs to participate?**

There are no direct costs to participate in this research.

**What are the benefits of the research?**

Beyond receiving an honorarium for your time, you may not receive a direct benefit if you agree to participate. However, we hope your participation in this research may provide a better understanding of how bronchiectasis (without cystic fibrosis) impacts your life/your spouse's/your child's/your parent's life in meaningful ways and possibly help to achieve the objectives of this initiative. People in the future may benefit from the information obtained from this research.

**How will my personal information be protected?**

Interviews in the US will be conducted by Engage Health and will take place with approximately 20 individuals in the US affected with bronchiectasis (without cystic fibrosis) as well as those who care for them. Results will be stored in a locked / secure location and stored on secure, encrypted, and wholly-owned servers. Your records will be "pseudonymized" which means that your name and any information that could identify you will be removed and replaced with a unique code. Information from the interview conversations will be anonymized and summarized (with in total approximately 60 interviews from Europe, Japan, and the USA) in a report (see below).

To review the privacy and data storage policies of Engage Health, Inc. for the U.S. and areas outside of the U.S. please visit <https://www.engagehealth.com/about-us/privacy-policy/>

As admedicum's software systems are hosted in European Union (EU), your data will be also transferred to the EU. Patient data in the EU will be processed in compliance with the General Data Protection Regulation (GDPR) of the EU which is at least as strict as local and national data privacy laws in the USA. By storing your data on a cloud service certified with the highest industry standard ISO27018, admedicum ensures that your electronically stored data is safe from loss, destruction, manipulation, or access by unauthorized persons. Written notes and documents are also digitized and electronically secured. Paper originals are also stored in a secure place.

Your data will be stored for a period of 5 years, e.g. in the event of a legal dispute, to prove that the work we have done for the sponsor is based on correct data collection and evaluation. Under no circumstances will your data be used for purposes other than those described in this agreement. The data storage policies of each of the research vendors are noted in this agreement.

### **Who can answer my questions about this research?**

Take as much time as you like before you decide to participate in this research. We will be happy to answer any questions you have about this research.

In the US; Contact Dr. Sunjay R Devarajan through Engage Health at 651-994-0510 or 612-940-7852 (24 hours) for questions, concerns or complaints about the research or if you think you have been harmed as a result of joining this research. Contact the WCG IRB if you have questions about your rights as a research subject, concerns, complaints or input: 855-818-2289 or [researchquestions@wcgirb.com](mailto:researchquestions@wcgirb.com). WCG IRB is a group of people who perform an independent review of research.

In case of complaints, but also simply in case of questions regarding data protection at admedicum, please contact admedicum's data protection officer at [dataprotection@admedicum.com](mailto:dataprotection@admedicum.com), +49-9921 88229000 or Attn: Jasmin Muhmenthaler-Sturm, Datenbeschützerin GmbH, Unterer Sand 9, 94209 Regen, Germany. In case of any other questions please contact admedicum's BURDEN initiative research team at [BURDEN@admedicum.com](mailto:BURDEN@admedicum.com).

### **What happens to the information collected for this research?**

Information from the conversation with you will be anonymized and summarized in a report on a total of up to 60 interviews with affected people and those who care for them in Europe, Japan, and the USA. The report includes age, sex, disease status and history as well as reported experiences of the interviewed people living with bronchiectasis (without cystic fibrosis) and those who care for them. It will also mention the country the people are from. Individual quotes may be used but will be also anonymized, i.e. no direct personal information such as your name or address, will be

mentioned. This means that your contribution to the content of the report cannot be linked to your name or other personal data and your identity remains unknown to the recipients of the report.

Only the anonymized and summarized report will be made available to Insmmed Incorporated as well as patient organizations and physicians and other vendors who are involved in the BURDEN initiative. A future publication of these results is intended. However, we will keep your name and other identifying information confidential.

You also have the right to revoke the storage and use of your personal data before the work is carried out. Please read the next section.

### **Can I stop being in the research?**

You can revoke your consent to participate in the interview or to for us, the research vendors, to use the data we have collected before the interview begins and without giving reasons. You then have the right to demand the correction, blocking or deletion of all your information/data stored up to that point. We will comply with your request immediately and inform you of the measures taken. For legal reasons, we must reserve the right to receive data under certain conditions regulated by law, e.g. if this data is required as evidence in the context of a legal dispute. We will then consult with you accordingly in order to meet your request as far as possible.

However, we must point out that after the interview due to the anonymization of the data and integration into a summarized (aggregated) report about all interviews, correction, blocking or deletion of your personal data is therefore then only possible to the extent that the data is on our server for the purpose of contacting you and for internal documentation (see above).



In case of a revocation, complaints, but also simply in case of questions regarding data protection, please contact

- Engage Health by sending written notice to [pengel@engagehealth.com](mailto:pengel@engagehealth.com) or Attn: P. Engel, Engage Health Inc., 3265 Lexington Ave. So, Eagan MN 55121. Alternatively, you can contact Engage Health's Data Privacy Officer at [DataPrivacyOfficer@engagehealth.com](mailto:DataPrivacyOfficer@engagehealth.com) to remove your information. Any information collected before you withdraw may still be used.
- admedicum by sending a written notice to admedicum's data protection officer, at [dataprotection@admedicum.com](mailto:dataprotection@admedicum.com), +49-9921 88229000 or Attn: Jasmin Muhmenthaler-Sturm, Datenbeschützerin GmbH, Unterer Sand 9, 94209 Regen, Germany.

#### **Can I be removed from this research without my approval?**

Your part in this research may be stopped at any time by admedicum, the research vendors, or the sponsor without your approval for any reason, including:

- If it is in your best interest
- If inclusion criteria are not met
- You do not consent to potential changes made in the research plan (if applicable); or you do not keep your scheduled appointment for the telephone interview

#### **Will I be paid for taking part in this research?**

In the US; Your participation will be compensated with an honorarium of \$100. You can choose not to be compensated by not providing your account details after the interview. The interview will take about one hour without any need for preparation. If the telephone interview is not completed for any reason, you will not receive the honorarium.

## DECLARATION OF DATA PROTECTION CONSENT

1. I HAVE READ AND UNDERSTOOD THE ABOVE INFORMATION ON DATA PROTECTION. I AGREE THAT PERSONAL DATA COLLECTED DURING THE INTERVIEW WITH ENGAGE HEALTH (E.G. ANSWERS TO QUESTIONS) MAY BE RECORDED ON QUESTIONNAIRES AND ELECTRONIC DATA CARRIERS. RECORDINGS WILL BE SHARED WITH ADMEDICUM. I ALSO AGREE THAT IN A SUMMARY REPORT MY SEX, AGE AND COUNTRY, AS WELL AS INFORMATION ABOUT MY LIFE WITH BRONCHIECTASIS (NON-CYSTIC FIBROSIS) WILL BE MENTIONED IN AN ANONYMIZED FORM AND THAT THIS REPORT CAN BE PASSED ON TO INSMED INCORPORATED AND BE PUBLISHED. OTHER PERSONAL DATA WILL NOT BE FORWARDED OR PUBLISHED BY ADMEDICUM OR ENGAGE HEALTH.

2. I AGREE THAT DURING THE INTERVIEW SOUND RECORDINGS WILL BE MADE. SOUND RECORDINGS WILL BE USED EXCLUSIVELY FOR THE PURPOSE OF INTERNAL DOCUMENTATION AND TRANSCRIPTION, ADMEDICUM REPRESENTATIVES AND THE TRANSCRIPTION SERVICE PROVIDER IN THE CONTEXT OF THE PROJECT DESCRIBED ABOVE.

3. I AM AWARE THAT I CAN WITHDRAW OR CANCEL MY CONSENT TO PARTICIPATE BEFORE THE INTERVIEW IS CONDUCTED AND WITHOUT GIVING REASONS. IF I REVOKE MY CONSENT TO PARTICIPATE, I HAVE THE RIGHT TO DEMAND THE DELETION OF ALL MY INFORMATION/DATA STORED UNTIL THEN. I AM ALSO AWARE THAT AFTER THE INTERVIEW DUE TO THE ANONYMIZATION OF THE DATA CORRECTION, BLOCKING OR DELETION OF ANONYMIZED DATA IS NO LONGER POSSIBLE.

4. YES, I WOULD LIKE TO RECEIVE A COPY OF THE SUMMARIZED RESEARCH RESULTS AS THEY BECOME AVAILABLE AND I AGREE THAT ADMEDICUM OR ENGAGE HEALTH WILL USE MY CONTACT DETAILS TO PROVIDE THIS TO ME. PLEASE TICK ACCORDINGLY:

YES       NO

Initials: \_\_\_\_\_ Date: \_\_\_\_\_