

## **Translational Research in Medical Devices in Brazil - National Questionnaire**

Translational research is an approach that aims to accelerate the process of developing innovative technology based on the requirements for translating basic and applied science into innovation, up to the availability of the product or process to society.

The study "Competencies necessary for the development of translational research in medical devices and health technologies in Brazil: a qualitative study" is a doctoral research project that aims to elucidate, from the perspective of different actors in the National Innovation System (SNI), the profile of competencies, strategies, and conditions necessary for the development of translational research in medical devices in Brazil.

The research has ethical approval (CAAE 65474322.9.0000.5292), and the terms of acceptance of participation and participant rights are detailed in the Informed Consent Form (ICF), which is attached or can be accessed via the link: [link]

The questionnaire has 4 sections and the estimated response time is 20 minutes.

Sections 3, 4, and 5 use a Likert scale of importance from 1-5, where:

1 = Not important

2 = Slightly important

3 = Moderate

4 = Important

5 = Very important

Null = Don't know

If you have any questions, please contact us at **[pesquisa.translacionaldm@gmail.com](mailto:pesquisa.translacionaldm@gmail.com)**

### **Section 1: General Data**

1. Do you agree to participate in the research? \*

- Yes, I agree to participate.
- No, I do not want to participate.

2. State where you work: \*

- AC
- AL
- AM
- AP
- BA
- CE
- DF
- GO
- ES
- MA

- MT
- MS
- MG
- PA
- PB
- PE
- PR
- PI
- RJ
- RN
- RS
- RO
- RR
- SC
- SP
- SE
- TO

3. Indicate your academic background: \*

- Medicine
- Nursing
- Physiotherapy
- Dentistry
- Speech Therapy
- Engineering
- Information and Communication Technology (ICT)
- Design or Industrial Design
- Administration
- Economics
- Statistics
- Mathematics
- Law
- Other:

4. Indicate the area in which you predominantly work: \*

- Development of medical devices (equipment, diagnostic tests, orthoses, prostheses, health products and materials)
- Development of software (embedded software in medical devices, clinical, diagnostic, or therapeutic purposes, processing medical, managerial, demographic, and epidemiological data)
- Development of assistive technologies (communication devices, digital software and applications, walkers and mobility equipment, visual magnifiers, hearing aids, and adapted daily utensils)
- Support for researchers (administrative, technical, regulatory, and legal support)
- Training of researchers (undergraduate and postgraduate training, training, content development, and coordination of face-to-face or virtual courses)
- Project coordination (management and coordination of projects)
- Other:

5. Indicate your degree: \*

- Graduate

- Specialist
- Master
- Doctor

6. Age: \*

- Less than 25 years
- 25 to 34 years
- 35 to 44 years
- 45 to 59 years
- Over 60 years

7. How long have you worked in this area? \*

- Less than 2 years
- 3 to 5 years
- 5 to 10 years
- 10 to 15 years
- Over 15 years

## **Section 2: Necessary Knowledge for Translational Researchers**

This section refers to content or techniques that can be learned for the development of translational research in medical devices and health application software.

8. In your opinion, how important are the following knowledge areas for a translational research team in your practice as a researcher? \*

- Not important
- Slightly important
- Moderate
- Important
- Very important
- Don't know

9. How would you rate your knowledge of the technical standards applicable to your research work (Inmetro, ABNT, ISO, IEC, LGPD, DataSUS, SBIS, etc.)? \*

- No knowledge
- Little knowledge
- Regular knowledge
- Good knowledge

10. In your opinion, how important is it for a team member to have mastery of the ANVISA standards applicable to the research and registration process of a medical device or health use software (RDC 548/2021, 153/2017, 185/2001, NT 04/2012, 657/2022, etc.)? \*

- Not important
- Slightly important
- Moderate
- Important
- Very important
- Don't know

11. How would you rate your knowledge of the ANVISA standards applicable to your research work? \*
- No knowledge
  - Little knowledge
  - Regular knowledge
  - Good knowledge
12. In your opinion, how important is it for a team member to have knowledge of the ethical regulatory framework (CNS Resolutions, CEP/CONEP System, and Plataforma Brasil)? \*
- Not important
  - Slightly important
  - Moderate
  - Important
  - Very important
  - Don't know
13. How would you rate your knowledge of the ethical regulatory framework? \*
- No knowledge
  - Little knowledge
  - Regular knowledge
  - Good knowledge
14. In your opinion, how important is it for a team member to have knowledge of intellectual property legislation (INPI) and asset management (institutional innovation policy)? \*
- Not important
  - Slightly important
  - Moderate
  - Important
  - Very important
  - Don't know
15. How would you rate your knowledge of intellectual property legislation and asset management? \*
- No knowledge
  - Little knowledge
  - Regular knowledge
  - Good knowledge
16. In your opinion, how important is it for a team member to have knowledge of the conceptual model of the disease, problem area, workflow, or process (Care Lines, Usage Protocols, Clinical Protocols, and Therapeutic Guidelines - PCDT, Brazilian Guidelines, Disease Burden, and Medical Society Guidelines)? \*
- Not important
  - Slightly important
  - Moderate
  - Important
  - Very important
  - Don't know

17. How would you rate your knowledge of protocols and workflows? \*

- No knowledge
- Little knowledge
- Regular knowledge
- Good knowledge

18. In your opinion, how important is it for a team member to have knowledge of the technology incorporation process in SUS (economic evaluation studies, cost-effectiveness, budget impact, reimbursement mechanisms for product use, system organization by complexity level)? \*

- Not important
- Slightly important
- Moderate
- Important
- Very important
- Don't know

19. How would you rate your knowledge of these themes? \*

- No knowledge
- Little knowledge
- Regular knowledge
- Good knowledge

20. In your opinion, how important is it for a team member to have knowledge of business plan development for technology (demand, production capacity, suppliers, logistics, and supply chain)? \*

- Not important
- Slightly important
- Moderate
- Important
- Very important
- Don't know

21. How would you rate your knowledge in this area? \*

- No knowledge
- Little knowledge
- Regular knowledge
- Good knowledge

22. In your opinion, how important is it for a team member to have knowledge and use of tools and methodologies to foresee the obstacles to research translation (translational readiness level assessment - TRL, project, and risk management)? \*

- Not important
- Slightly important
- Moderate
- Important
- Very important
- Don't know

23. How would you rate your knowledge of these tools and methodologies? \*

- No knowledge
- Little knowledge
- Regular knowledge
- Good knowledge

24. In your opinion, how important is it for a team member to have knowledge of the design and conduct of validation tests, safety, and pre-clinical and clinical trials (when applicable)? \*

- Not important
- Slightly important
- Moderate
- Important
- Very important
- Don't know

25. How would you rate your knowledge of these themes? \*

- No knowledge
- Little knowledge
- Regular knowledge
- Good knowledge

26. In your opinion, how important is it for a team member to have knowledge of product design, human factors engineering, and usability? \*

- Not important
- Slightly important
- Moderate
- Important
- Very important
- Don't know

27. How would you rate your knowledge of these themes? \*

- No knowledge
- Little knowledge
- Regular knowledge
- Good knowledge

28. Do you suggest any other knowledge as important or indispensable for a translational research team?

29. Comments

### Section 3: Necessary Skills for Translational Researchers

This section refers to the "know-how" that indicates a skill that can be acquired for the development of translational research in medical devices and health application software.

In your opinion, how important is the mastery of the skills listed in this section for a translational research team in your practice as a researcher?

30. Collaborative work (partnerships, technical-scientific cooperation, and exchanges) \*

- Not important
- Slightly important
- Moderate
- Important
- Very important
- Don't know

31. Effective communication with different actors involved in the research \*

- Not important
- Slightly important
- Moderate
- Important
- Very important
- Don't know

32. Interaction with patients, managers, and health professionals to identify unmet clinical or managerial needs \*

- Not important
- Slightly important
- Moderate
- Important
- Very important
- Don't know

33. Team capacity to evaluate the technical, patent, clinical, and economic feasibility of the technology under development, compared to an existing product or process \*

- Not important
- Slightly important
- Moderate
- Important
- Very important
- Don't know

34. Mastery of techniques for horizon monitoring and technological prospecting, frontier knowledge technologies, and/or cost-effective ones \*

- Not important
- Slightly important
- Moderate
- Important
- Very important
- Don't know

35. Do you suggest any other skill as important or indispensable for a translational research team?

36. Comments:

#### **Section 4: Institutional Structure and Capacity**

This section corresponds to the physical or management conditions of an institution or a set of partner institutions for the development of translational research in medical devices and health use technologies.

Considering your practice as a researcher, how important do you consider the structure or capacity that the institution must have or develop in partnership to engage in translational research in medical devices and health use technologies

37. Organization and maintenance of a multidisciplinary team dedicated to research \*

- Not important
- Slightly important
- Moderate
- Important
- Very important
- Don't know

38. Establishment of partnerships for collaborative or networked action linking multiple researchers, research centers, and government \*

- Not important
- Slightly important
- Moderate
- Important
- Very important
- Don't know

39. Continuous training and education of the team in regulatory and technical requirements, funding issues, intellectual property, and other pertinent topics \*

- Not important
- Slightly important
- Moderate

- Important
- Very important
- Don't know

40. Need for partnership with the industry for the development of innovations \*

- Not important
- Slightly important
- Moderate
- Important
- Very important
- Don't know

41. Support for researchers in the management, monitoring, and evaluation of technological development projects \*

- Not important
- Slightly important
- Moderate
- Important
- Very important
- Don't know

42. Support for existing funding sources for each stage of research (government and non-government agencies) \*

- Not important
- Slightly important
- Moderate
- Important
- Very important
- Don't know

43. Administrative, legal, and/or regulatory support \*

- Not important
- Slightly important
- Moderate
- Important
- Very important
- Don't know

44. Mentorship offer from experienced researchers and specialists for beginner researchers \*

- Not important
- Slightly important
- Moderate
- Important
- Very important
- Don't know

45. Engagement of institutional leaders to overcome technical and administrative barriers \*

- Not important
- Slightly important
- Moderate
- Important
- Very important
- Don't know

46. Adoption of good laboratory practices (GLP) and quality management system for the project \*

- Not important
- Slightly important
- Moderate
- Important
- Very important
- Don't know

47. Own or collaborative physical infrastructure for proof-of-concept development and in vitro tests \*

- Not important
- Slightly important
- Moderate
- Important
- Very important
- Don't know

48. Own or collaborative physical infrastructure for prototype development under good practice conditions \*

- Not important
- Slightly important
- Moderate
- Important
- Very important
- Don't know

49. Own or collaborative physical infrastructure for pre-clinical and clinical research \*

- Not important
- Slightly important
- Moderate
- Important
- Very important
- Don't know

50. Development of an environment in the institution conducive to entrepreneurship, startup creation, and technology transfer or licensing \*

- Not important
- Slightly important
- Moderate
- Important
- Very important
- Don't know

51. Do you suggest any other organizational capacity as important or indispensable for the development of translational research?

52. Comments:

Thank you for collaborating!