Clinical Evaluation of Medical Devices - IMDRF

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ANVISA
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Working Group

Medical Device Clinical Evaluation

Improve the effectiveness and efficiency of the pre-market review process by promoting increased global harmonization.

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Objectives

- *Improve the efficiency of pre-market evaluation by promoting greater global convergence in the approach and requirements for producing and evaluating available clinical evidence,*
- *Reduce the number of redundant clinical trials, integrate post-market clinical follow-up principles and real-world evidence, as applicable, and*
- *Accelerate the introduction of new medical devices/technologies that are safe and effective for patients.*

Documents

IMDRF MDCE WG/N55 FINAL:2019 - **Clinical Evidence – Key Definitions and Concepts**

IMDRF MDCE WG/N56 FINAL:2019 - **Clinical Evaluation**

IMDRF MDCE WG/N57FINAL:2019 - **Clinical Investigation**

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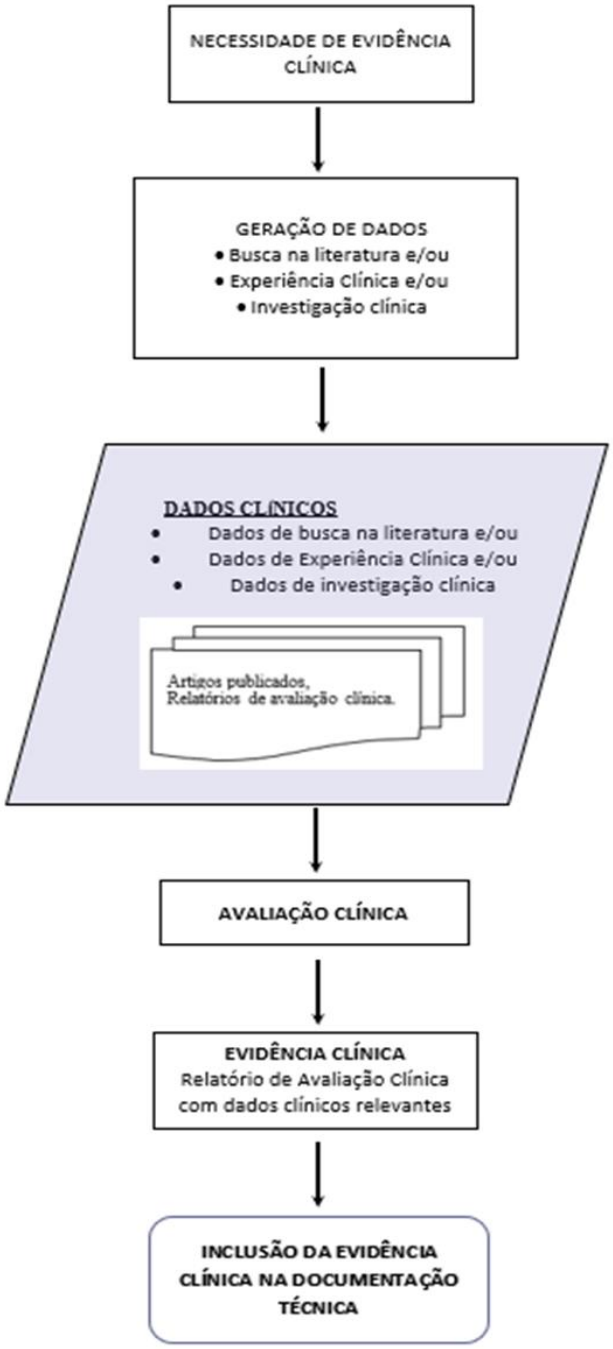
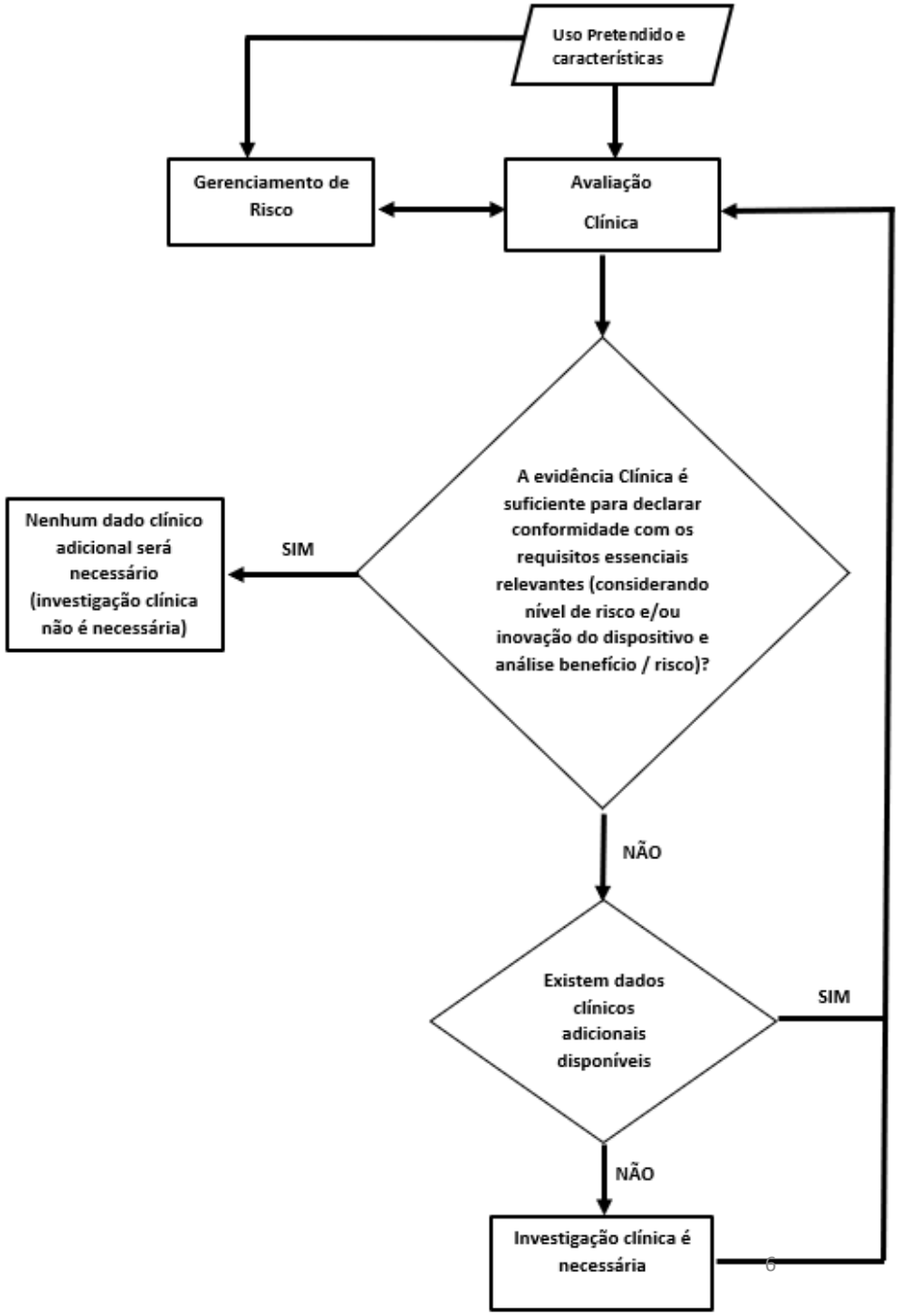
Overview of the data generation process and clinical evaluation



Key Considerations to guide the need for Clinical Investigations



Obrigado!

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