Decision Map: Digital Health Product Classification

Step 1*
Establish intended use and indications for use

Step 2
Determine the novelty

Step 3
Find a "similar" product in the market

Step 4
Identify an FDA medical specialty

Step 5
Find the FDA product code

NEXT STEPS
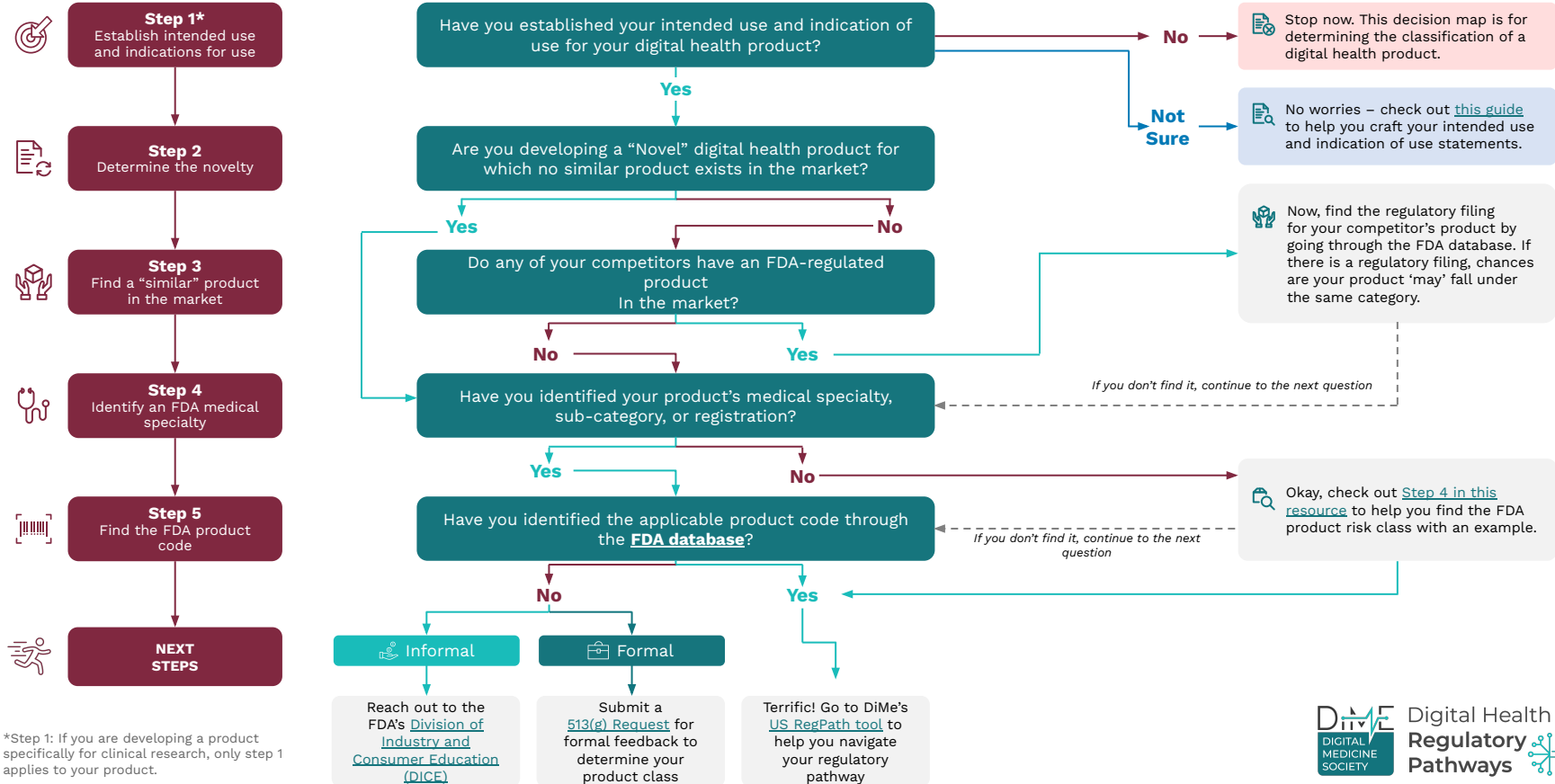
*Step 1: If you are developing a product specifically for clinical research, only step 1 applies to your product.

Have you established your intended use and indication of use for your digital health product?

— **No** → Stop now. This decision map is for determining the classification of a digital health product.

— **Not Sure** → No worries – check out this guide to help you craft your intended use and indication of use statements.

Yes ↓

Are you developing a "Novel" digital health product for which no similar product exists in the market?

— **Yes**

— **No** → Now, find the regulatory filing for your competitor's product by going through the FDA database. If there is a regulatory filing, chances are your product 'may' fall under the same category.

Do any of your competitors have an FDA-regulated product In the market?

— **No**

— **Yes**

If you don't find it, continue to the next question

Have you identified your product's medical specialty, sub-category, or registration?

— **Yes**

— **No** → Okay, check out Step 4 in this resource to help you find the FDA product risk class with an example.

Have you identified the applicable product code through the **FDA database**?

If you don't find it, continue to the next question

— **No**
  - Informal → Reach out to the FDA's Division of Industry and Consumer Education (DICE)
  - Formal → Submit a 513(g) Request for formal feedback to determine your product class

— **Yes** → Terrific! Go to DiMe's US RegPath tool to help you navigate your regulatory pathway

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Digital Health Regulatory Pathways