USE CASE Mastering SaMD Development: Five Fundamental Principles for Success

JAMES GRAVESTON

Principal Business Consultant

Zühlke

zühlke
empowering ideas

zühlke
empowering ideas

Mastering SaMD Development

Five Fundamental Principles for Success

Dr. James Graveston
Principal MedTech Consultant

MedTech and SaMD have huge potential, but it isn't being realised.

Some big failures:

babylon

PEAR THERAPEUTICS

Greater use of health technology 'could save 20,000 lives a year'

The health benefits and business potential of digital therapeutics

January 27, 2023 | Article

By Chirag Adatia, Ralf Dreischmeier, Samarth Shah, and Kirtika Sharma

Share Print Download Save

Digital-native start-ups and healthcare incumbents can both play important roles in building and scaling digital therapeutics to improve the management of chronic health conditions.

TECH

Why digital health has been such a disappointment, and how to change that

We consult on and build MedTech

zühlke
empowering ideas

CUTISS
personalized skin

NHS COVID-19

breathonix

Cognetivity Neurosciences

NOVARTIS

myoswiss

AO

AOT
Advanced Osteotomy Tools

avaco

LiDCO
Hemodynamic Monitoring

Prevented 1 million infections

44,000 hospitalisations

9,600 deaths in 12 months

zühlke
empowering ideas

What I'm not talking about....

ISO13485

EN62304

Disclaimer:

The examples are from experience and heavily anonymised. If they describe your product, I'm sorry!

5 key points you must cover when developing or evaluating potential SaMD

zühlke
empowering ideas

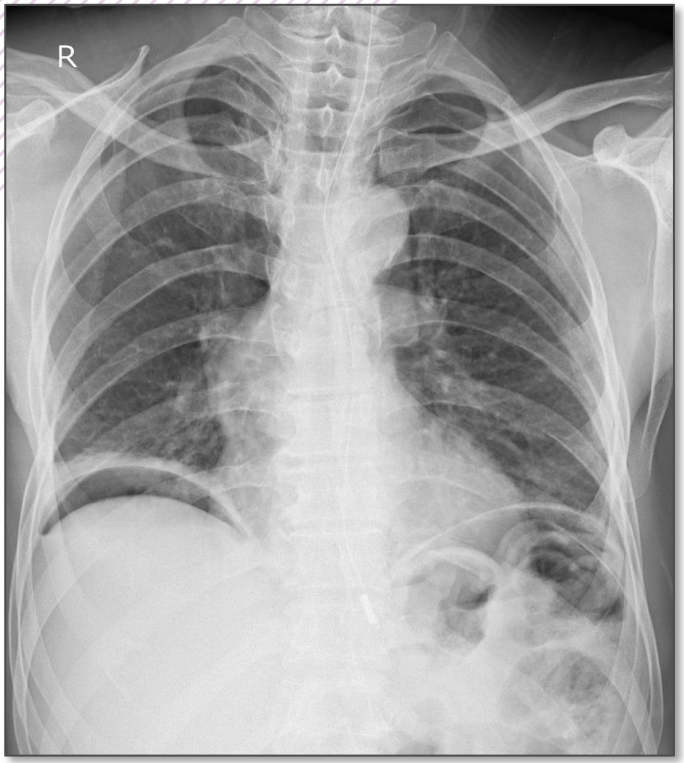
01 Solve a whole problem

02 Understand both the user and data journeys

03 Ensure you can prove it works

04 Make sure you can scale

05 Don’t wed yourself to being a SaMD



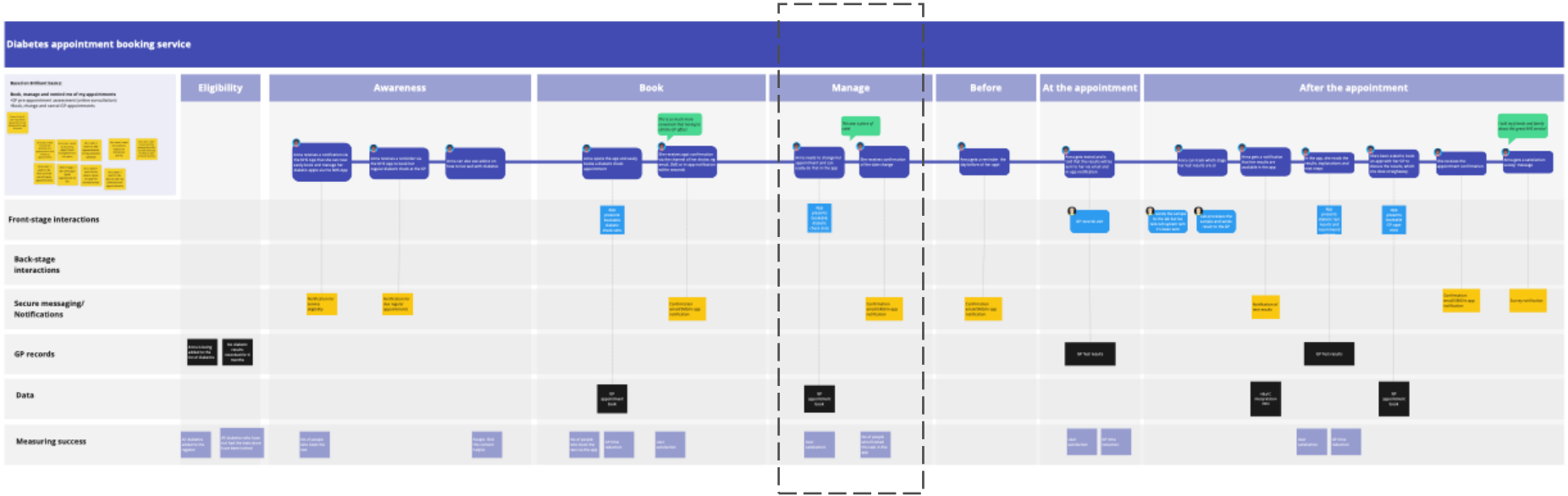
zühlke
empowering ideas

01

Solve whole problems

Why point solutions don't often release time

02 Understand the whole context, not just your part



Don’t just focus here

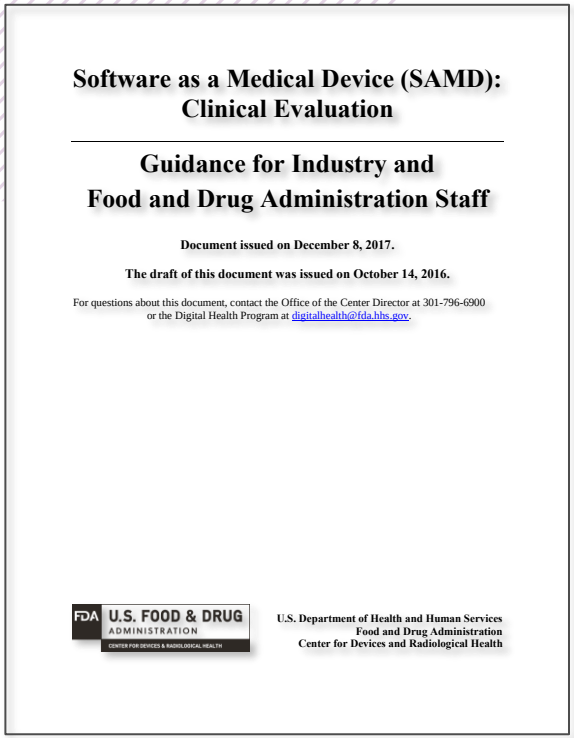
zühlke
empowering ideas

When you don’t understand the user journey, you may find you don’t provide value

zühlke
empowering ideas

- Can you get the data to make it run AND prove it works?
- Is there an API?
- Is the data you can get to prove it works representative?
- When is the data available, is it timely?

… and how data flows in and out of your solution?



Software as a Medical Device (SAMD): Clinical Evaluation

Guidance for Industry and Food and Drug Administration Staff

Document issued on December 8, 2017.

The draft of this document was issued on October 14, 2016.

For questions about this document, contact the Office of the Center Director at 301-796-6900 or the Digital Health Program at digitalhealth@fda.hhs.gov.

FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES & RADIOLOGICAL HEALTH

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

03

Just because it works, doesn't mean you can prove it!

zühlke
empowering ideas

Validating black boxes can be very hard

TA

What is the likely diagnosis for a teenage boy with a blocked nose and recurrent nosebleeds

A blocked nose and recurrent nosebleeds in a teenage boy can be caused by several conditions. One possible diagnosis is nasal polyps, which are noncancerous growths on the lining of the nasal passages. Another possibility is allergic rhinitis, which is an allergic reaction to airborne allergens that causes inflammation in the nose.

TA

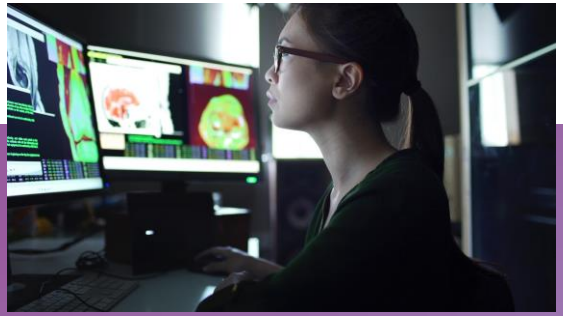
What is the likely diagnosis for an adolescent boy with unilateral nasal obstruction and recurrent epistaxis

Unilateral nasal obstruction and recurrent epistaxis (nosebleeds) in an adolescent boy can have several possible causes, but one possible diagnosis that should be considered is Juvenile Nasopharyngeal Angiofibroma (JNA).

zühlke
empowering ideas

Proving things can take a long time

04 Scaling is not a technology problem



Processes

IT Systems

Data Quality & Formats

05

Can you make a difference without being a SaMD?

5 key points you must cover when developing or evaluating potential SaMD

zühlke
empowering ideas

01 Solve a whole problem

02 Understand both the user and data journeys

03 Ensure you can prove it works

04 Make sure you can scale

05 Don’t wed yourself to being a SaMD

» Build the right thing..
…then build it right

Dr. James Graveston
Principal MedTech Consultant

INTELLIGENT HEALTH UK 2023

Breaking down the barriers between tech and healthcare