# Diabetes Update

Streamlining Regulatory Approaches
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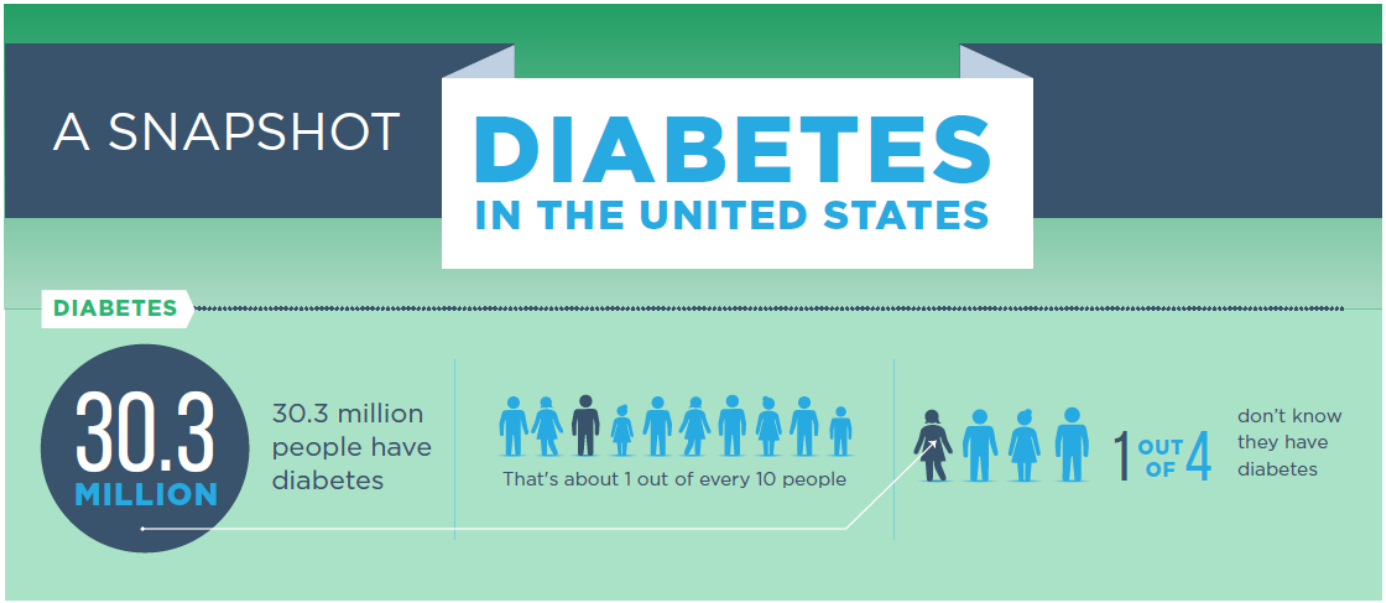
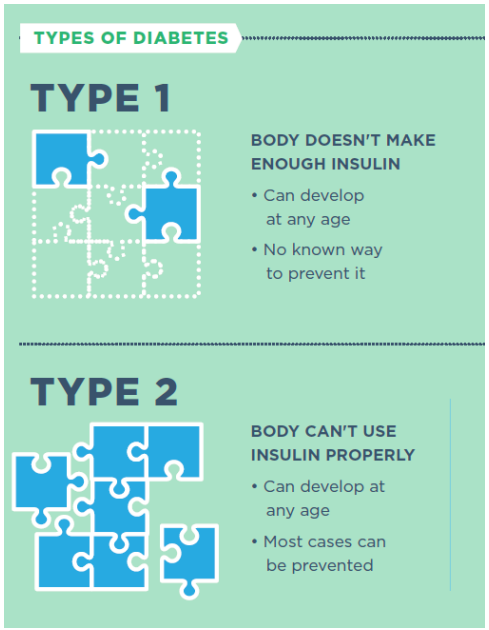
# Facilitating interoperability: a streamlined regulatory approach


- Context and challenge
- Regulatory approach
- iCGM and ACE-pump *de novos*
- Benefits and expected outcomes
- Beyond diabetes devices





https://www.cdc.gov/diabetes/pdfs/library/socialmedia/diabetes-infographic.pdf

# Diabetes Devices


Glucose Meter


Insulin Pump


Continuous Glucose Monitoring System (CGM)

# Automated Insulin Dosing (AID) Systems

Insulin Pump

Class II

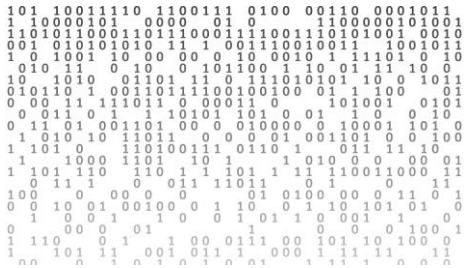
+

CGM

Class III

+

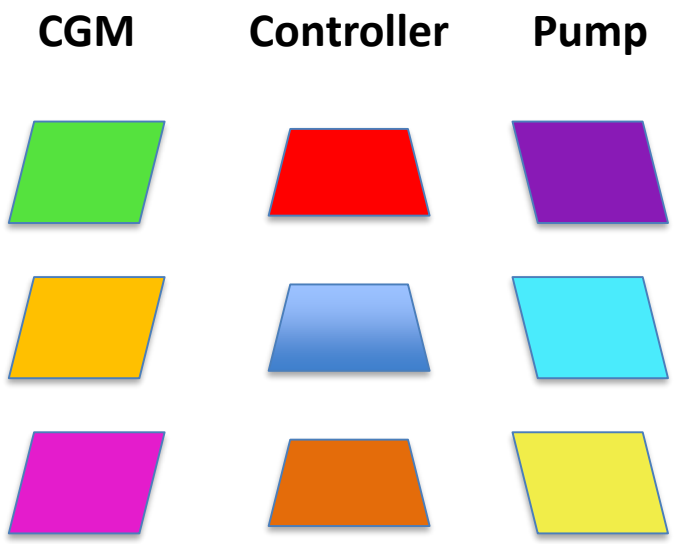
Controller



= **AID**

Class III System

# AID challenges



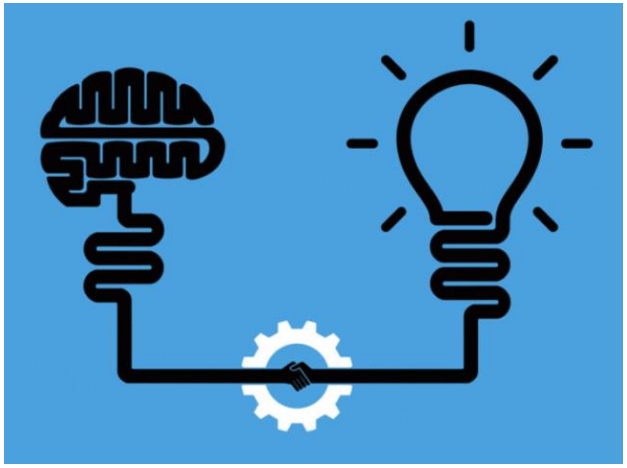

- Multiple permutations
- Different manufacturers/ versions

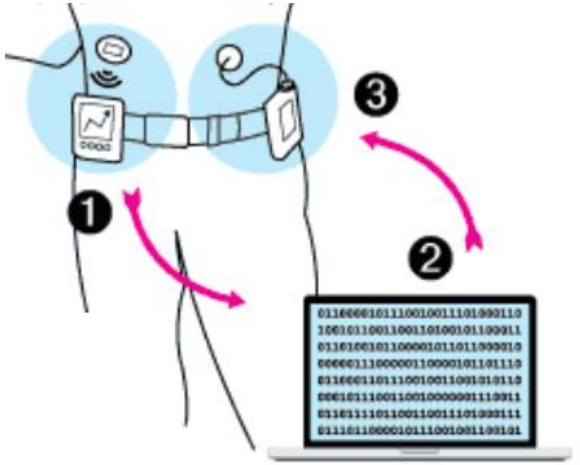
- Class III device
- Regulated as complete system
- Regulatory burden for updates
- Challenging for small companies

# Too much: regulatory and contractual burden

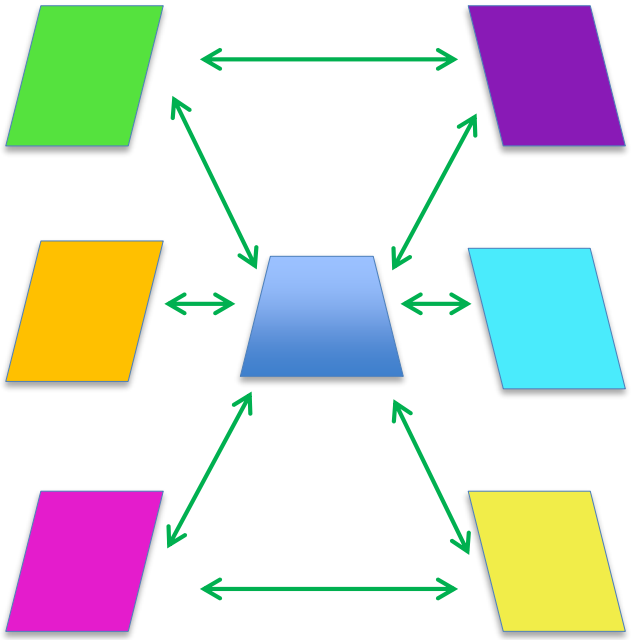


# Not enough: innovative devices to patients





# Goal: Greater AID component Interchangeability



- More efficient regulatory pathways
- Faster innovation
- Streamline combination of different devices
- Enable faster incorporation of new devices and versions

## iCGM

# FDA authorizes first fully interoperable continuous glucose monitoring system, streamlines review pathway for similar devices

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**For Immediate Release** March 27, 2018

## ACE-pump

# FDA authorizes first interoperable insulin pump intended to allow patients to customize treatment through their individual diabetes management devices

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**For Immediate Release** February 14, 2019

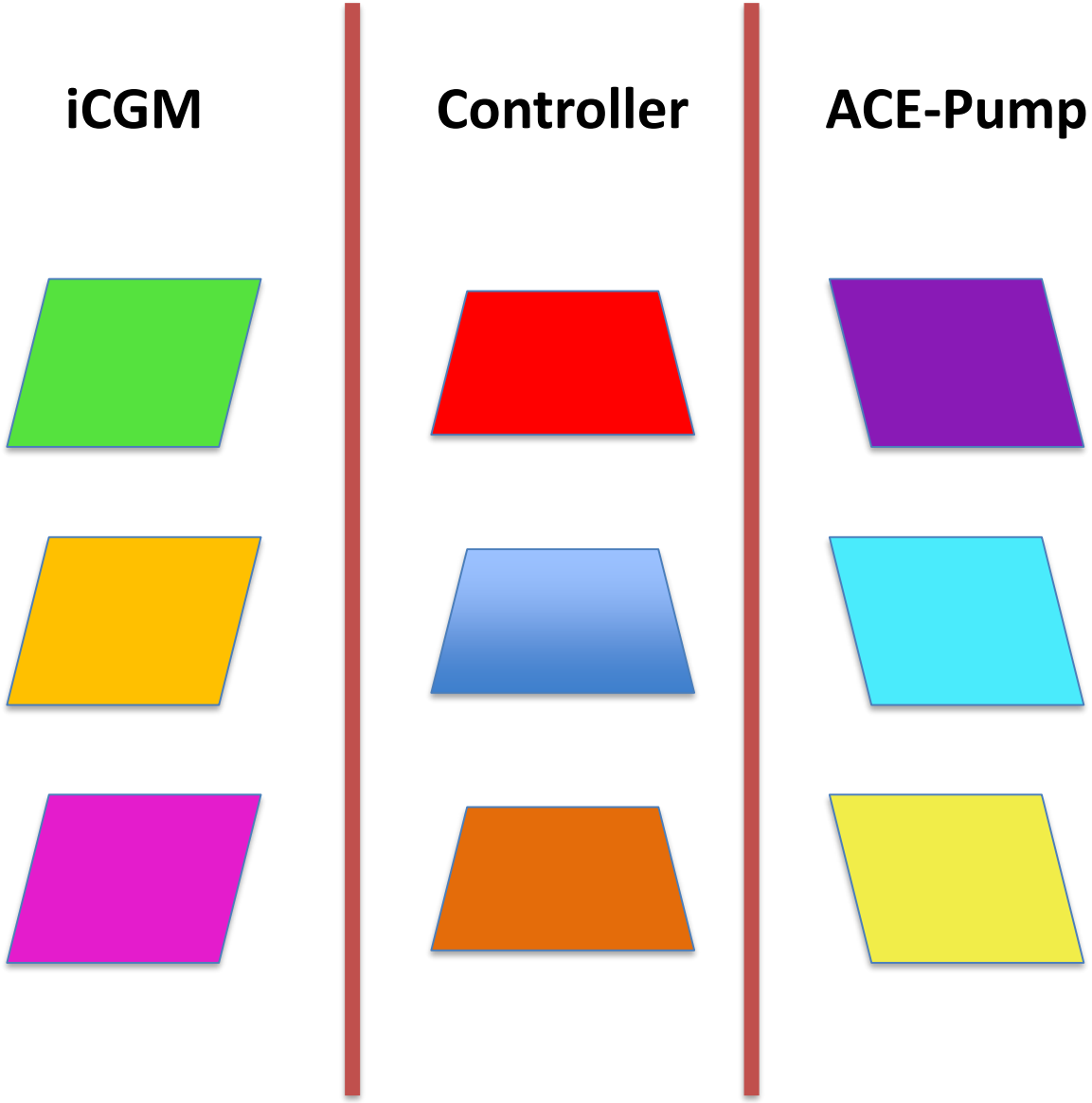
An **integrated continuous glucose monitoring system (iCGM)** is intended to automatically measure glucose in bodily fluids continuously or frequently for a specified period of time. **iCGM systems are designed to reliably and securely transmit glucose measurement data to digitally connected devices**, including automated insulin dosing systems, and are intended to be used alone or in conjunction with these digitally connected medical devices for the purpose of managing a disease or condition related to glycemic control.

**Class II (special controls)**

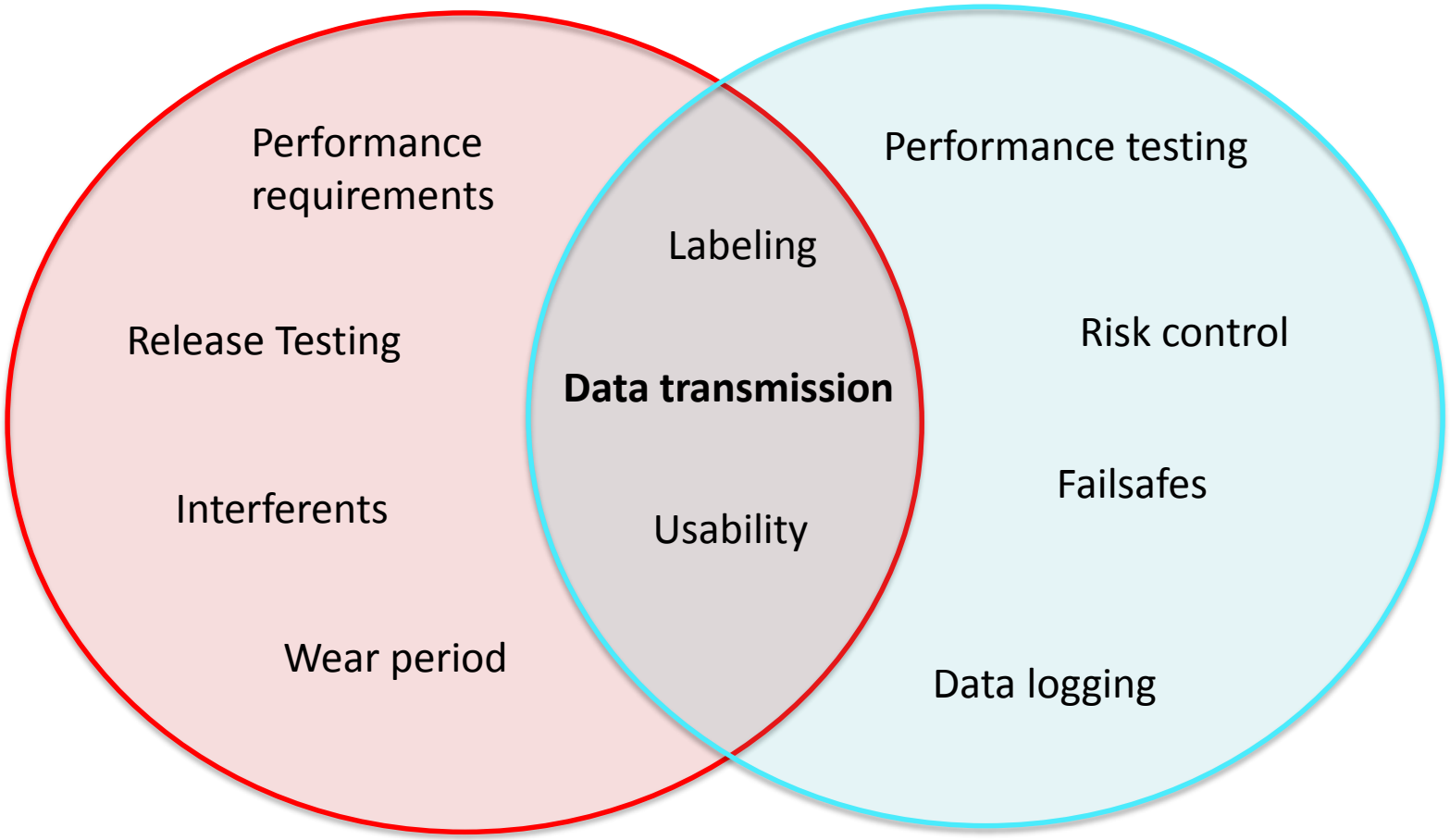
An **alternate controller enabled infusion pump (ACE pump)** is a device intended for the infusion of drugs into a patient. The ACE pump may include basal and bolus drug delivery at set or variable rates. **ACE pumps are designed to reliably and securely communicate with external devices**, such as automated drug dosing systems, to allow drug delivery commands to be received, executed, and confirmed. ACE pumps are intended to be used both alone and in conjunction with digitally connected medical devices for the purpose of drug delivery.

**Class II (special controls)**

# Separation of responsibility



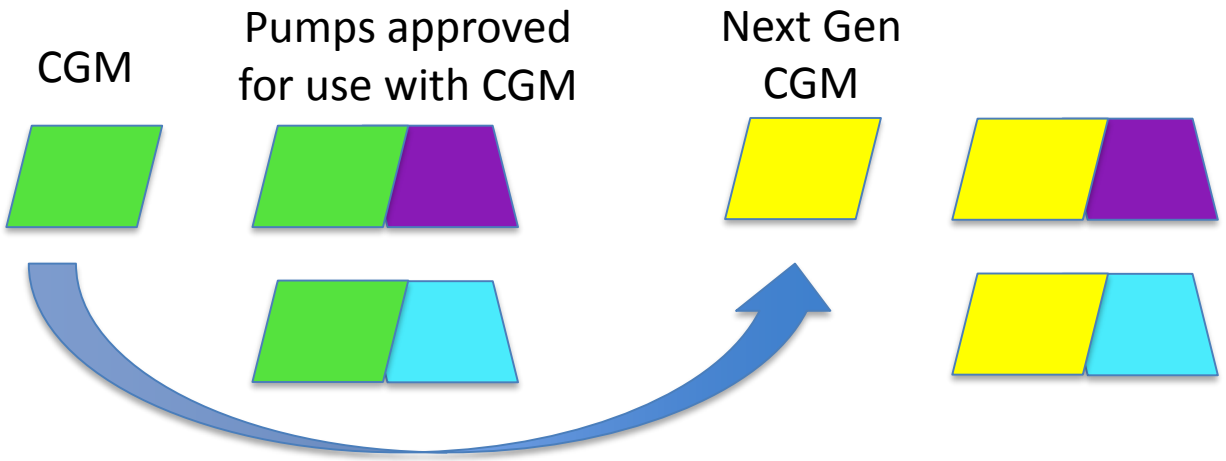
# Special Controls Highlights



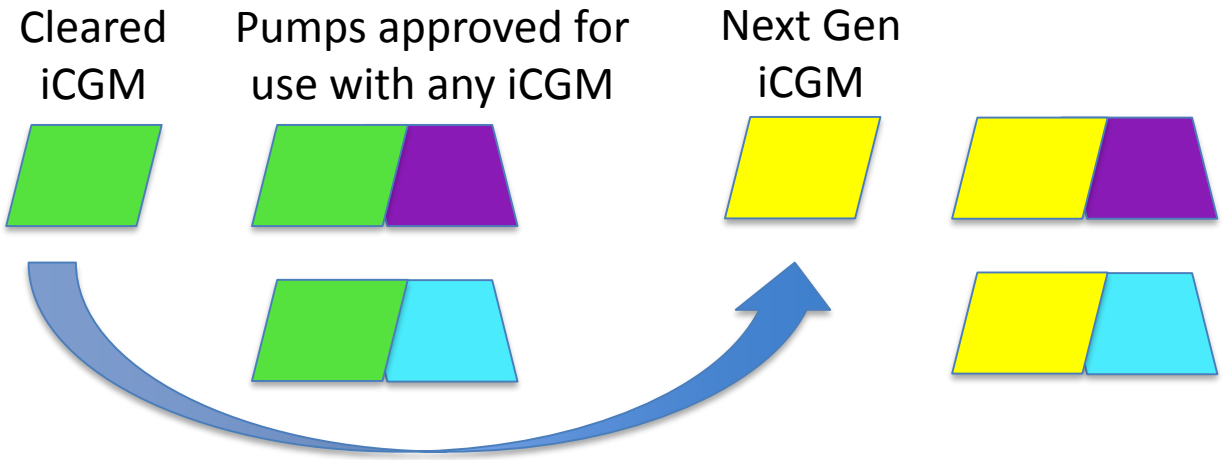
# Data transmission

- **iCGM** = "**strategy** to ensure secure and reliable means of iCGM data transmission…"
- **ACE-pump** = "…**process and procedure** for sharing the pump interface specification with digitally connected devices and for validating the correct implementation of that protocol.

# **Reviewing a plan** facilitates future change




- Three Class III systems
- 3 separate PMAs
- Possible time delay
- Regulatory burden
- Not good for patients




- Three Class II devices
- 1 CGM 510(k) submission
- **Pumps rely on approved integration process**
- Labeling updates
- Change is more efficient
- More rapid innovation


- Makes iCGM and ACE-pump upgrades/modification availability more efficient
  - Reduces the need for duplicative regulatory submissions
  - Separates the CGM and pump from the rest of the system
- Allows connected systems to be updated more quickly and with a predictable process
- Works for many different business models (from open to closed systems)
- More opportunity for patient choice
- Regulatory advantages may incentivize technology development

# Beyond diabetes


Shelf life testing

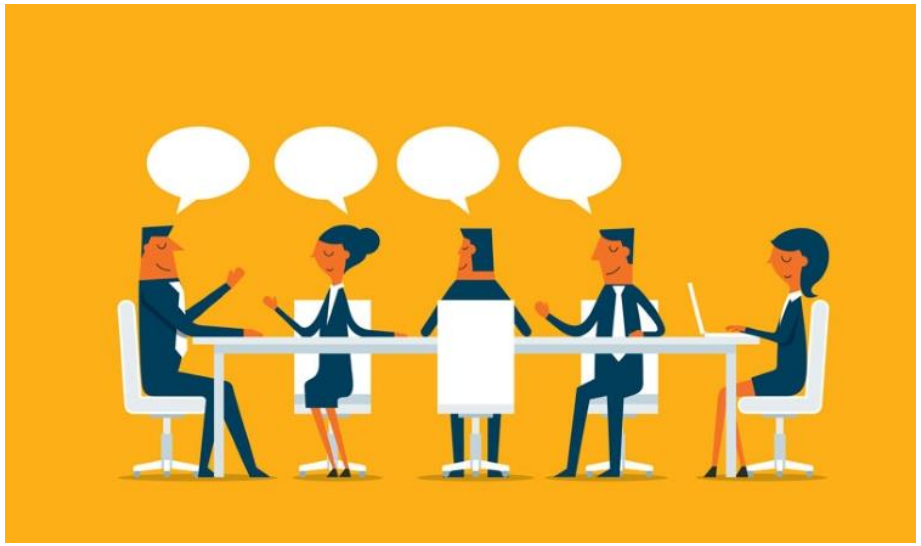
Genetic testing

# Other possibilities for change process review

- Example of adding a new compatible matrix (dependent on assay/analyte)
- Review of protocol and acceptance criteria
- Execute protocol and meet criteria allow updated labeling
- Would only send 510(k) for changes to protocol or acceptance criteria

# Conclusions

- Streamlined regulatory approach for enabling diabetes device connectivity
- Incorporates **review of plans** to facilitate future changes and device integration



- Potential for further exploration
- Talk with FDA if you have proposals for clearance/approval of change processes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