Summary of Topics

1. **Software (SAMD - Software As a Medical Device)**
    a. Regulatory pathway
        i. Local
        ii. International
    b. Application process
2. **Comparative Technology**
    a. BD Veritor / Scanwell Health
    b. Gauss-Cellex Exa App
3. **AI/ML**
    a. Clinical performance validation

Software

Regulatory Pathway

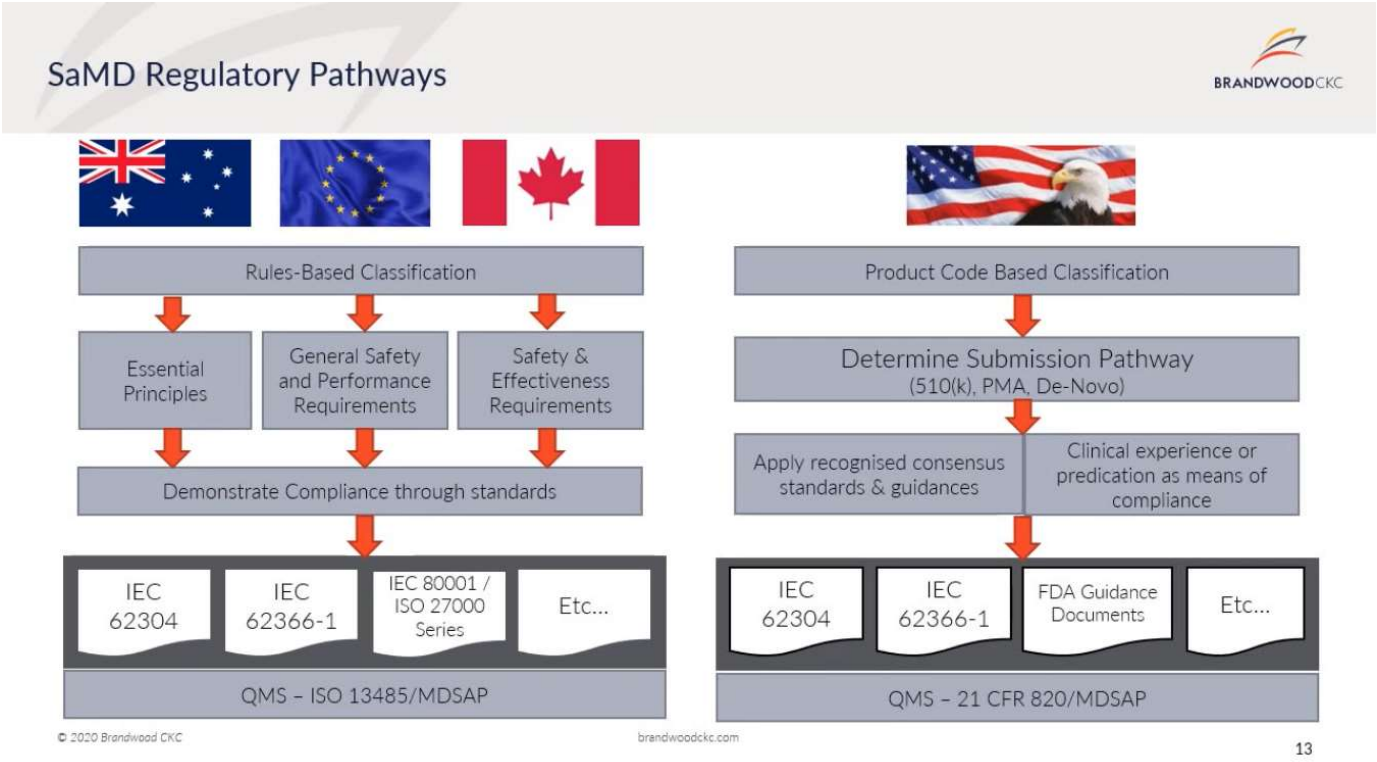
Local

- Pure Guard's technology has an intended purpose which classifies it as a medical device.
- This device is categorised as Class D.
- The process of developing software is identified as manufacturing and is subject to performance testing.
- Testing is performed as a clinical evaluation of a medical device.
- First step to clinical performance testing is a MD022 Application.
- There are 13 parts to the application process and a myriad of requirements for consideration. These requirements before applying can be viewed here.
- Cost for the application is R9 900. Cost to develop the trial and relevant outcomes are dependent on appointed stakeholders in the process. (Eg - Ethics Committee, Investigators, Subjects, Technical Testers)
- Time for processing an application is 6-8 weeks. The process needs to be mapped out in the requirements above before commencing with clinical testing.
- There is no time frame indicating how long acquiring a (FDA equivalent of approval) license may take. There are, however, two opportunities to re-submit information should SAHPRA reject information contained in the trials.

Notes: We have reached out to key contacts at SAHPRA regarding clinical evaluation. At present, no valuable feedback has been received.

International

- International framework for SaMD approval is driven by FDA and European Commision
- Typical process includes categorising the software based on risk and all elements included.
- The list of requirements is extensive and aligned with FDA/EC standards.
- To date, no self testing antigen tech solutions have received full FDA approval. The only approval issued under FDA is "Emergency Use Authorization" for SARS-COV-2. This approval will rescind based on demand under COVID action plans.
- The process looks at the entire lifecycle of the software.



Process flow for SaMD via US/EU/AU/CA channels

Comparative Technology

Self testing with computer vision mobile application

- **BD Veritor - At home COVID-19 test.**
    - Approval issued under FDA as "Emergency Use Authorization" for SARS-COV-2.
    - Does not currently have FDA approval.
    - Utilises an app called Scanwell Health.
    - Can be viewed on the IOS store here.
    - A 1 min video of the process can be viewed here.
    - BD is one of the largest global medical technology companies in the world focusing on medical discovery, diagnostics and the delivery of care. BD and its 70,000 employees have a presence in nearly every country.

Source

- **Gauss & Cellex - At home COVID-19 test. (Rebranded now as Exa)**
    - Engaged in advanced clinical trials in the US. Results have demonstrated nearly 90% sensitivity and 100% specificity in early trials.
    - Does not currently have FDA approval.
    - The COVID-testing app uses facial recognition software to confirm that test-takers correctly swab their noses. The app provides step-by-step instructions and timers. After 15 minutes, an algorithm based on thousands of sample tests interprets the result
    - Gauss is the leader in computer vision in healthcare. Founded in 2011, Gauss's mission is to
    - digitally augment clinicians with software that radically improves diagnostic accuracy and leads to improved patient safety and clinical outcomes.
    - CNBC snippet on Gauss Cellex approval here

Source

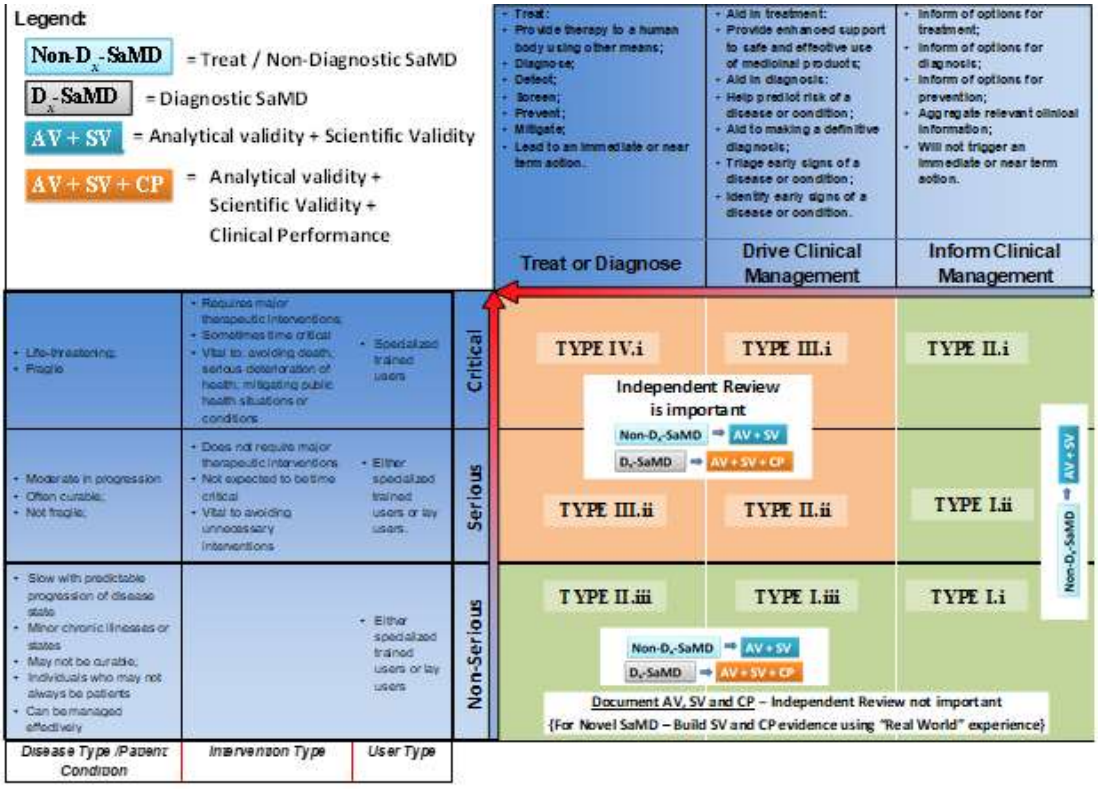
AI/ML

Clinical Performance Testing requirements

- There are 3 main areas that AI/ML tech will be evaluated on based on the International Medical Device Regulators forum.
    - **Scientific validity** – showing with evidence the association of the output to a clinical condition/physiological state;
    - **Analytical validity** – showing with evidence the technical performance related to accuracy, reliability, repeatability and reproducibility;
    - **Clinical performance** – showing with evidence the ability of a SaMD to yield a clinically meaningful output associated with the target use of SaMD output in the healthcare situation or condition.

Source

- Visually, this is the process flow that will be followed to test our AI/ML (at least one of the frameworks that will need to be adhered to).



- The FDA provides very clear guidelines for validation of AI algorithms in SaMD applications.
- The following documents give steer to the testing process in theory.

Validation of AI Algorithms in Guided Imaging Applications

Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD)

Artificial Intelligence/Machine Learning (AI/ML)-Based. Software as a Medical Device (SaMD) Action Plan