eeDAP MDDT

Dr. Brandon Gallas is submitting eeDAP to the FDA MDDT program (the medical device development tool program). He introduced this effort to the WSI WG (link to blog announcement) and offered to document the process, share submission materials and feedback, and involve other groups and individuals on the submission.

- Link to eeDAP MDDT updates
- Link to eeDAP studies group page, home of the eeDAP MDDT effort

What is eeDAP?

an evaluation environment for digital and analog pathology

eeDAP is a software and hardware platform for designing and executing digital and analog pathology studies where evaluation regions of interest (ROIs) in the digital image are registered to the real-time view on the microscope.

For more information, please visit:

- Link to presentation
- Link to paper
- Link to software

What is the MDDT program?

- The FDA's Medical Device Development Tools (MDDT) program page.
- Link to a presentation summarizing the program

"An MDDT is a scientifically validated tool – a clinical outcome assessment (e.g. patient-reported or clinician-reported rating scales), a test used to detect or measure a biomarker (e.g. assay for a chemical analyte or medical imaging method), or non-clinical assessment method or model (e.g. in vitro, animal or computational model) – that aids device development and regulatory evaluation. Qualification reflects CDRH's expectation that within a specified context of use1, the results of an assessment that uses an MDDT can be relied upon to support device development and regulatory decision-making."

The MDDT submission and qualification process are not drastically different from a medical device submission, except the purpose of the MDDT is to *support* regulatory decision-making (an MDDT is not a medical device). An MDDT gets reviewed by FDA/CDRH pretty much like a medical device would get reviewed.

"Once an MDDT is qualified for a specific context of use, FDA's expectation is that it can be used by any medical device developer for that context of use. CDRH reviewers should accept the MDDT for the qualified context of use without the need to reconfirm the suitability of the

MDDT.”