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Dear Plcc Alliance

If you'd like to learn more and contribute, please join us for virtual project sessions on HER2-Low and PCCP.

HER2-Low: Friday, April 7 at 1:00-2:00 PM Eastern Time

Add event to calendar



PCCP: Friday, April 14 at 12:00-1:00PM Eastern Time

Add event to calendar



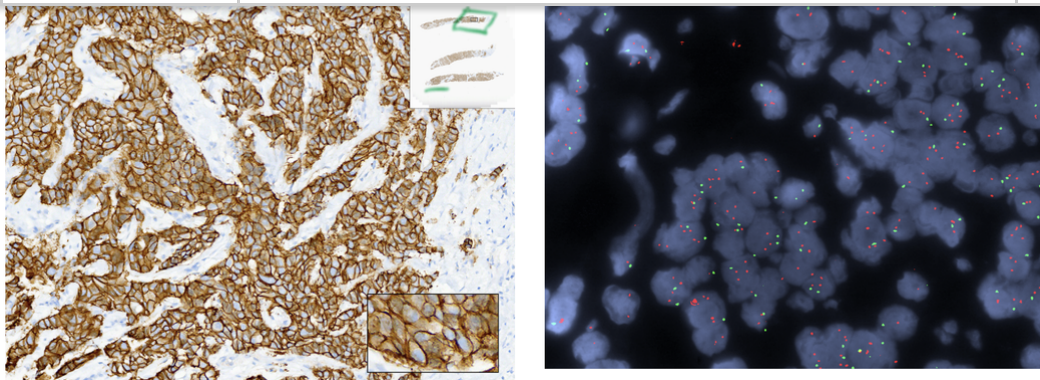
HER2-Low

Curious about the topic, but can't make the session? Find an overview with additional resources on the website project page. As always, a recording of the session will be posted and accessible following the meeting.

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Currently Approved Assays

Diagnostic Name (Manufacturer)	Indication - Sample Type	Drug Trade Name (Device) / NDA / BLA	Biomarker(s)	Biomarker(s) (Details)	PMA / 510(k) / 513(f)(2) / IDE (Approved / Clearance / Grant Date)	Manufacturer(s) (Details)	Chemical / Grant Date
Roche Diagnostics HER2 IHC System (Litho Biosystems)	Breast Cancer - Tissue	Herceptin (trastuzumab) BLA 101792	HER2 (HER2)	HER-2 protein overexpression (IHC) (IHC213)	P000115 (04/18/2012)	Roche Diagnostics (Roche)	HER-2 protein overexpression (IHC) (IHC213) (04/18/2012)
Herceptin Test (Dako Denmark A/S)	Breast Cancer - Tissue	Herceptin	HER2 (HER2)	HER-2 protein	P000118	Roche Diagnostics (Roche)	HER-2 protein (IHC) (IHC213) (04/18/2012)
FoundationOne CDx (Foundation Medicine, Inc.)	Breast Cancer - Tissue	Herceptin (trastuzumab) BLA 101792	HER2 (HER2)	HER2 protein overexpression (IHC) (IHC213)	P000115 (04/18/2012)	FoundationOne CDx (Foundation Medicine, Inc.)	HER2 protein overexpression (IHC) (IHC213) (04/18/2012)
FoundationOne CDx (Foundation Medicine, Inc.)	Breast Cancer - Tissue	Perjeta (trastuzumab) BLA 101792	HER2 (HER2)	HER2 protein overexpression (IHC) (IHC213)	P000115 (04/18/2012)	FoundationOne CDx (Foundation Medicine, Inc.)	HER2 protein overexpression (IHC) (IHC213) (04/18/2012)

Here's an example of what you'll find on the website project page. Visit it [here](#).

PCCP

Last week, a draft guidance on Predetermined Change Control Plan was released by the FDA. Find the document along with additional resources and links on the project page.

approach to regulate predetermined change control plans. The document includes **Predetermined Change Control Plan (PCCP), Authorized Predetermined Change Control Plan (Authorized PCCP), Modification Protocol, as well as Impact Assessment.**



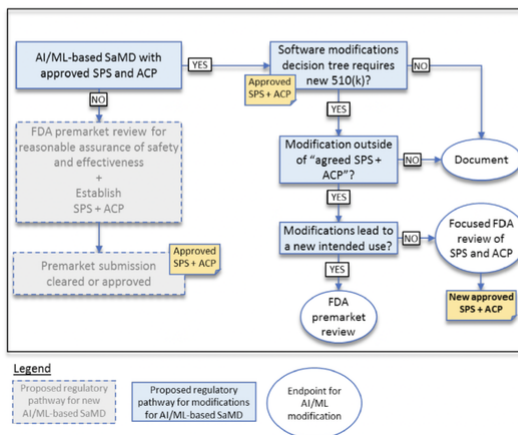
We will host a session to review the draft guidance.

Background

One of the key elements in the proposed regulatory approach to AI/ML is the so-called **Predetermined Change Control Plan (PCCP)**.

A PCCP allows manufacturers to specify the types of anticipated modifications for the software and the associated methodology being used to implement those changes

The PCCP framework will likely entail that a manufacturer defines and submits a PCCP to the FDA in a premarket submission. Under the anticipated framework, the manufacturer can then use the PCCP to make modifications that are within the bounds of the PCCP



Another example of what the project page contains. Visit it [here](#).

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See you at the meetings.



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