# GUIDANCE:
# VALIDATION OF INDUSTRY SPONSORED ELECTRONIC SYSTEMS FOR REGULATED CLINICAL TRIALS

## What is a 'Regulated Clinical Trial'?

Health Canada regulates the conduct of clinical trials with drugs, biologics, devices and natural health products with human participants through regulations, guidance and inspections. The overall purpose is to ensure the safety of participants, data integrity and adherence to regulations and guidance.

## What is 'Validation of an Electronic System'?

From Guidance Document: Part C, Division 5 of the Food and Drug Regulations "Drugs for Clinical Trials Involving Human Subjects" (GUI-0100):

> The validation of an electronic system is performed to confirm that the system's specifications meet the goals and requirements for the clinical trial in a consistent manner. These include, but are not limited to, completeness, credibility and accuracy of recorded information as well as reliability of the system. Therefore, any electronic system used to capture, process, manage and/or archive clinical trial information should be adequately validated and evidence of validation should be kept for the required record retention period and should be readily available for inspection by Health Canada's Inspectors (Health Canada, 2019, pp. 63-64).

## Why is Validation Required?

Validation of electronic systems used to support clinical trials is a Sponsor's legal requirement outlined in the Canadian Food and Drug Regulations, Good Clinical Practices, C.05.010 and ICH Guideline for Good Clinical Practice, Sponsor, 5.5 Trial Management, Data Handling, and Record Keeping.

In addition to the regulatory requirements, validation confirms that a system can be used as created for its intended purpose, reliably and consistently. With this confirmation, validation ensures data integrity through consistent, accurate and reliable data along with participant safety.

## What Systems are Affected?

All electronic systems that are used to support a clinical trial require validation. Examples of electronic systems used in an Industry Sponsored clinical trial are, but not limited to:

- Electronic applications (apps)
- Electronic data capture (EDC) systems
    - Electronic Case Report Form (eCRFs)
- Electronic Devices
    - Tablets
    - Diaries
    - Wearables
- Interactive web response systems (IWRS)
    - Drug accountability
    - Participant randomization

**When to Confirm Validation**

1. Before the start of the clinical trial

    Prior to the beginning of a clinical trial, the Qualified Investigator should request validation documentation for all electronic systems from the Sponsor. Using an electronic system without appropriate validation documentation risks the integrity of the data.

2. After Updates to the Electronic System

    Validation documentation will also need to be requested with every updated version of the system as well.

**Elements of a Validated and Approved Electronic System**

Documentation that supports the validation of an electronic system will contain the following elements:

- Name of the Vendor
- Name of the Sponsor
- Name of the electronic system
- Version of the electronic system
- Confirmation of promotion from User Acceptance Testing (UAT) to Production (PROD)
    - UAT is when the Sponsor has completed its own testing to ensure that the electronic system, that they requested the Vendor to build, is fit for purpose
    - PROD is when the electronic system is put into use or activated
        - This can also be known as ‘software configuration order’ or ‘production release’
- Sign off from the Sponsor’s Quality Assurance/Quality Control
    - Name(s) and signature(s)
    - Date of sign off

## References


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