

## Predetermined Change Control Plan (PCCP)

PCCP is a framework that enables **predefined changes** to be **implemented without separate approval**



### Purpose

Enable continuous learning and improvement of AI/ML models within a regulated environment



### Includes

Change types, evaluation methods, implementation protocols, monitoring plans

### Elements that should be included in PCCP

#### 1. Description of Modifications

- Scope and types of permitted changes

#### 2. Methodology

- Methods for implementing and validating changes

#### 3. Impact Assessment

- Analysis of effects on safety and effectiveness

#### 4. Monitoring Protocol

- Real-world performance tracking and reporting system



### Permitted Changes

Performance improvements, data updates, algorithm optimization



### Restricted Changes

Changes in intended use, addition of new indications



### Reporting Requirements

Regular change logs and performance reports



**Key Point:** PCCP strikes a balance between innovation and regulation, enabling continuous improvement of AI technology while maintaining patient safety