In the case of a delay in the reporting time frame specified in Article 273* of the Regulation for Enforcement of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices

- Identify the cause of the delay and develop and implement measures to prevent recurrence.

- Submit a report that includes the following:

  Background of the delay

  Cause/reason for the delay

  Recurrence prevention measures

＊ Article 273 of the Regulation for Enforcement of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices ：When finding any of the following matters concerning test drugs, a clinical trial applicant or a clinical trial performer must report the finding to the Minister of Health, Labour and Welfare within the period specified by each of the following items:
Source: Japanese Law Translation HP (https://www.japaneselawtranslation.go.jp/ja/laws/view/3215)

PMDA HP：https://www.pmda.go.jp/review-services/trials/0023.html