# Availability of Key Information Required in Protocols and Pharmacy Manuals for Investigational Drug Services

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## Purpose

- Investigational drug services (IDS) rely on the study protocol and pharmacy manual for their management of study drugs.
- Oftentimes, key information is missing.
- Obtaining answers and precisions leads to delays for study start-up.

## Objective

- To quantify the presence of key information for IDS in protocols and pharmacy manuals.

## Method

- Retrospective descriptive study conducted in the IDS of a 500-bed mother-child university health center.

**Inclusion/Exclusion criteria**

- All studies open for recruitment as of April 14, 2023 in the IDS were included.
- All study drugs were included, but other support medications were excluded.
- The latest version of documents were consulted.

**Data collection**

- General and key information was determined by three IDS staff during a brainstorming session.
- Data collection method was pre-tested by two IDS staff
- Data was extracted by one IDS staff between June 28 and July 14, 2023.

**General information**

- Type of sponsor, patient population, phase of research, type of dose and route of administration was collected in the protocols.

**Presence or absence of key information**

- In the protocols: prohibited medication
- In the pharmacy manuals: dose, storage requirements, concentration and packaging, drug preparation

**Analysis**

- Data was analysed in terms of study drugs.
- Descriptive statistics are presented.

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## Results

**General information**

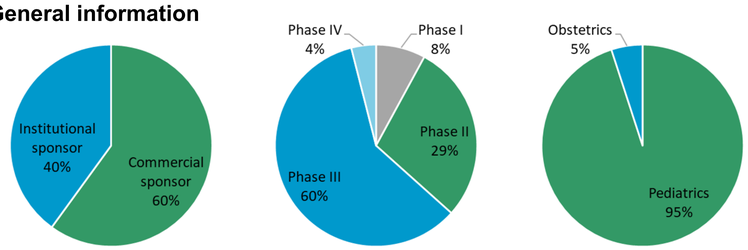


**Figure 1** Type of sponsor, phase and patient population.

- Most of the drugs were intended for oral administration (60%), then for intraveinous (15%), subcutaneous (14%), intramuscular (3%) and other routes of administration (9%).
- The study drugs were products with a pre-defined dose based on weight range (26/60, 43%), a fixed dose (15/60, 25%) or a variable dose (19/60, 32%).
- Half of the study drugs (30/60, 50%) were to be stored at room temperature, for most this was 15-30°C (17/30, 57%) and for some 15-25°C (8/30, 27%).
- Twenty-eight (47%) study drugs required further preparation before administering to the patient.

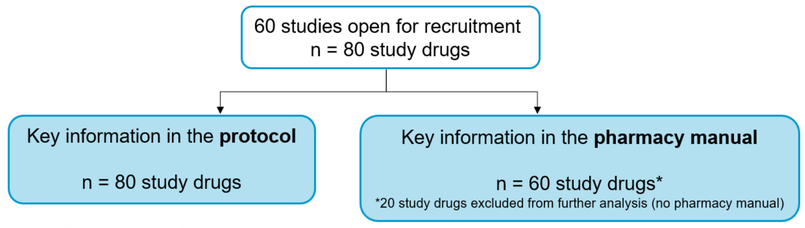


**Figure 2** Origin of the collected data.

**Key information**

- The dose was specified for all study drugs in the pharmacy manual (60/60, 100%). For the products with a variable dose, key information was not always included (**Table II**).
- The same goes for drugs that require preparation prior to administration (28/60, 47%) (**Table II**).

**Key information**

**Table I** Presence of key information in the protocol

| Prohibited medication | n/N (%) |
|---|---|
| How information is provided | |
| -List of specific prohibited medication | 28/80 (35) |
| -Broad categories of prohibited medication | 43/80 (54) |
| -No information on prohibited medication | 9/80 (10) |

**Table II** Presence of key information in the pharmacy manual

| Dose — variable dose only (n=19) | |
|---|---|
| Maximum dose | 14/19 (74) |
| Rounding rules (dose or volume) | 3/19 (16) |
| **Storage requirements** | |
| How information is provided | |
| -Specific temperature range | 52/60 (87) |
| -Reference to the product label | 4/60 (7) |
| -No information on storage requirements | 4/60 (7) |
| Acceptable temperature deviations | 7/60 (12) |
| **Concentration and packaging** | |
| Concentration or strength | 55/60 (92) |
| Type of packaging | 59/60 (98) |
| Quantity per unit of packaging | 56/60 (93) |
| Dimensions of packaging | 4/60 (7) |
| **Drug preparation — preparation required only (n = 28)** | |
| Final storage temperature | 21/28 (75) |
| Beyond-use date | 24/28 (86) |
| List of required material | 24/28 (86) |

## Discussion

- A pharmacy manual was not available for 25% of the study drugs. Having one reference document that contains all necessary study drug management information is of utmost importance.
- A list of specific prohibited medication was provided for only 35% of study drugs. This can make it difficult for pharmacists to identify possible drug interactions.
- When the dose was variable, for example in mg/kg, the maximum dose was not specified in 26% of the cases. This information is crucial for safety reasons. Rounding rules were specified in only 16% of the cases. Unclear dose rounding rules may lead to inadvertent protocol deviations and unintended variability between subjects.
- Detailed storage requirements with a specific temperature range are needed to confirm study feasibility. This information was not specified for 13% of the study drugs.
- Acceptable temperature deviations are important to avoid unnecessary placement of the study drug in quarantine, especially when a participant is on site to receive it. This information was only available for 12% of the study drugs.
- Dimensions of packaging were only specified for 7% of study drugs. This information is also helpful for feasibility reasons, especially when the site has limited storage space.
- Drug preparation information is required prior to study start-up. Missing information can lead to delays.

## Conclusion

- This project highlights key elements that are needed for IDS to manage study drugs.
- Having complete pharmacy manuals will expedite study start-up and be beneficial for sponsors and study teams.
- Some key information that ensures the safety of participants was missing in pharmacy manuals, such as the maximum dose.
- This information will help sponsors develop study documents that contain all necessary information for the safe and effective management of study drugs by IDS.
- Further work could investigate the presence of other key information in protocols.