Add the following:

▲⟨1079.1⟩ STORAGE AND TRANSPORTATION OF INVESTIGATIONAL DRUG PRODUCTS

INTRODUCTION

Clinical trials are drug studies that are performed to determine if an investigational medicine meets the effectiveness and safety criteria as has been outlined in the protocol for the clinical trial. Investigational drug products (IDPs) are products not commercially available for the indication or dosage being tested; there may be situations when a commercially available product may be used in a clinical trial as a positive control (comparator), a new indication, or a rescue medication. The term IDP is used throughout this document. Where IDP is used, others may be more familiar with the European Union term investigational medicinal product (IMP). The definition of an IMP is provided in European Commission Directive 2001/20/EC, Article 2 (d), as "a pharmaceutical form of an active substance or placebo being tested or used as a reference in a clinical trial, including products already with a marketing authorization but used or assembled (formulated or packaged) in a way different from the authorized form, or when used for an unauthorized indication, or when used to gain further information about the authorized form". For the purposes of this chapter, we will consider the two terms as equivalent. The pre-commercial nature of IDPs means the manufacturing ingredients, including active pharmaceutical ingredients (APIs), excipients, the clinical trial dosage, and any associated stability and packaging components may not be as defined as the final approved finished product. The Food and Drug Administration (FDA) current Good Manufacturing Practice regulations for finished drug products apply equally to commercial products and IDPs.

IDP distribution differs from commercial distribution in that the quantities for IDPs are often small (e.g., as little as one or two bottles or unit dose packages) and there are numerous final destinations, such as clinics and remote clinical settings. Another difference from a commercial drug product is the known stability of the IDP that is often a new chemical/molecular entity in the early stages of clinical trials and has not been through the robust stability program of commercial products. The IDP also creates a unique challenge when compared to a commercial product, which is ensuring the proper distribution of every packaging system, because a temperature excursion may jeopardize the entire clinical trial outcome.

SCOPE

Due to global security issues, regulations may vary and/or change for the distribution of drug products and for IDPs as well. Sponsors, clinical trial site personnel, or their designees are responsible for control of IDPs and should maintain an understanding of the current country distribution requirements. This chapter will address the aspects of storage and distribution that are unique to IDPs (e.g., unblinding, comparators, and academic studies); other chapters of interest may be *Monitoring Devices—Time, Temperature, and Humidity* ⟨1118⟩, *Good Storage and Distribution Practices for Drug Products* ⟨1079⟩, and *Good Distribution Practices for Bulk Pharmaceutical Excipients* ⟨1197⟩. This guidance chapter applies to all IDPs, including drug device combinations as well as non-commercial clinical IDPs, but does not apply to medical devices. The non-commercial clinical trial may have limited financial commercial return and is often performed in an academic setting or by a compounding pharmacy with limited industry participation (see *Figure 1*).

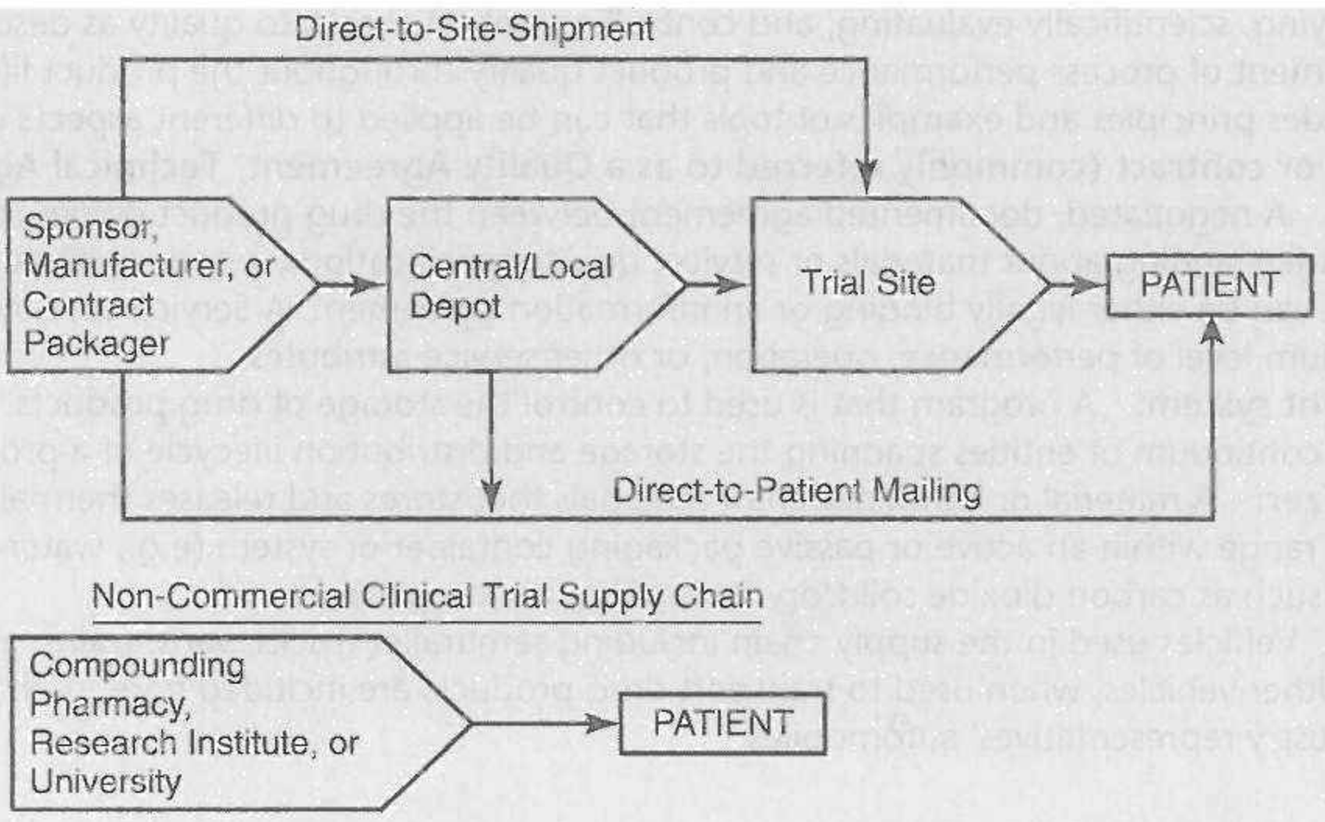

Figure 1. IDP supply chain scheme for commercial and non-commercial clinical trial studies.