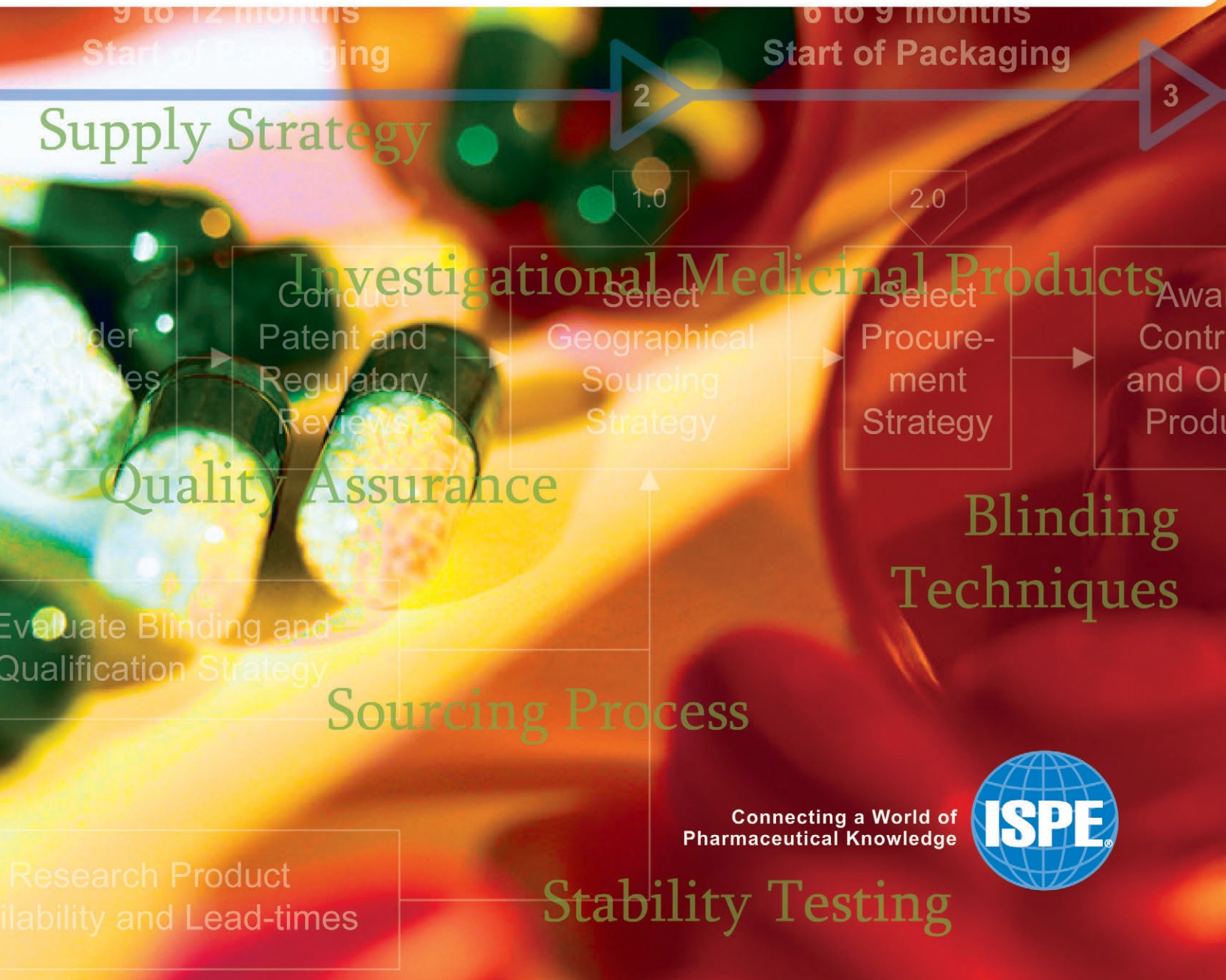
Good Practice Guide

Comparator Management



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Comparator Management

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Preface

The Purpose of the ISPE Good Practice Guide: Comparator Management is intended to establish strategic and tactical considerations when sourcing and procuring comparators for use in a Clinical Trial.

The information provided in this Guide reflects the cumulative knowledge and experiences of the authors, editors, and reviewers with input from members of the ISPE Investigational Products (IP) Community of Practice (COP) and general membership.

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1 Introduction

1.1 Overview

A comparator drug, also known as a reference drug, is one that is included in a clinical study for the purpose of making comparisons of its performance in a defined population. Comparisons may be made in terms of a combination of factors such as:

- efficacy
- safety
- ease of use
- patient compliance

Comparators should not be confused with placebos. (Placebos are inert representations of an investigational compound designed to eliminate psychosomatic effects from statistical analyses.)

Comparator drugs are usually sought for the purpose of comparing a drug from one organization (the sponsor organization's proprietary investigational drug) with existing marketed products from other organizations. The objective of the comparison is to demonstrate the benefits of the sponsor organization's drug, based on factors such as those listed. This is intended to allow legitimate claims regarding, e.g., greater efficacy or an improved safety profile, for the sponsor organization's drug.

The sourcing of comparator drugs is, therefore, usually conducted confidentially by the sourcing organization based on commercial sensitivity. For example, if Company A learns that Company B is planning to take over the position of their drug within a particular market segment, Company A may change their pipeline strategy or make new plans in response to this information.

There is a global trend regarding the increasing importance of comparative trials. Data from comparative trials have been the focus of healthcare technology appraisal organizations worldwide. Such organizations can provide guidance on the medication that doctors from their country should be prescribing. This can be based on available evidence relative to the benefits, and may be described in terms of functional outcomes and improvements in quality of life versus the comparative costs of the drug and its alternatives.

Comparative effectiveness is expected to help deliver better value and lower costs as part of an overall healthcare reform effort. At the time of publication, a major initiative is underway. The American Recovery and Reinvestment Act of 2009 [1] has invested $1.1 billion to begin the work of Comparative Effectiveness Research (CER) and the US Department of Health and Human Services has established a new Federal Coordinating Council to help coordinate research and guide investment. Physicians, pharmacists, patients, and purchasers of healthcare, including employers, health plans, and the government, are seeking evidence regarding the comparative effectiveness of drugs in order to make more knowledgeable and informed decisions.

1.2 Scope

1.2.1 Comparator Sourcing Process

The ISPE Good Practice Guide: Comparator Management discusses:

- selection of a comparator: branded or generic version