

Sample content/features, Alladex Drug Development Self-Study Course

Learning objectives are stated at the beginning of each chapter

Example:

3.1 Learning Objectives

In this section you will:

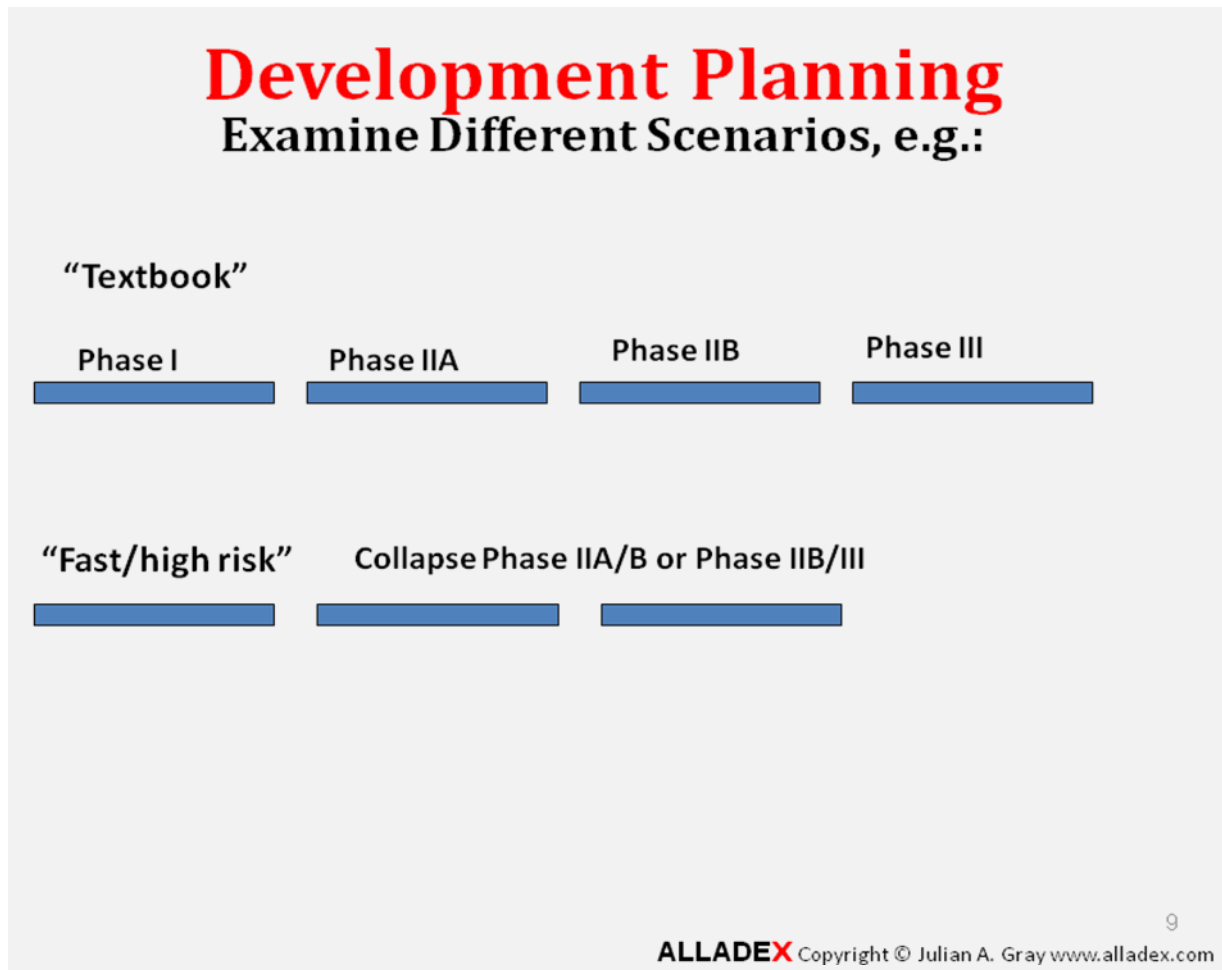
- Understand the basic principles of conducting **clinical research**, ie **Good Clinical Practice**
- Understand the classical phases of drug development; the **learn-confirm** concept of Sheiner
- Understand the key activities and steps involved in running clinical studies
- Understand the importance of being able to collaborate effectively with third party organisations including CROs.
- Understand how **data are managed** in clinical studies
- Understand basic principles of **statistics**
- Understand the concepts underlying drug **safety** in clinical studies including key topics such as ECG abnormalities and liver function test abnormalities

Text uses extracts and illustrations from Alladex Rapid Learning **Tools**. Technical terms are explained as they are introduced, with list of abbreviations for later reference

Example

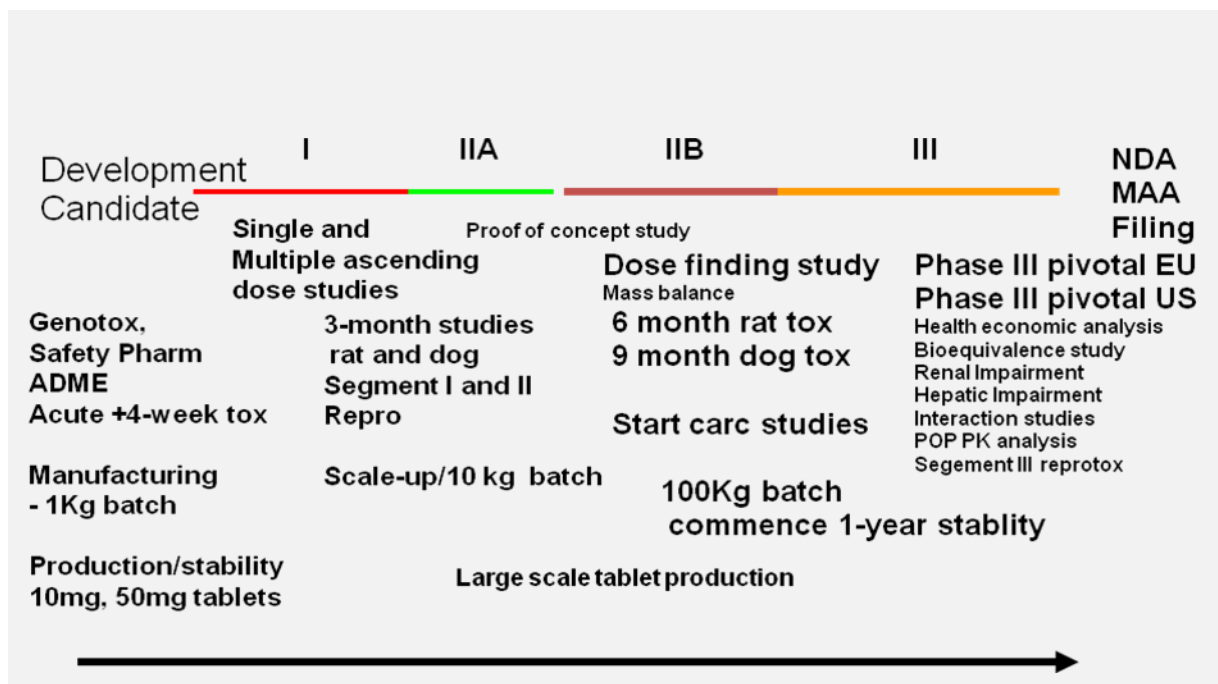
Decision points/milestones must be built into the plan – usually after each major clinical study, e.g. after phase I, proof of concept (i.e. end of Phase IIa), end of Phase II, pre-filing etc. **Go-No Go Decision Criteria** must be set with the aim to advance the project only if the target profile is confirmed going forward.

At least three development scenarios should be outlined of varying degrees of “aggressiveness” in terms of timeline, and the relative risks and costs of each assessed. Management may tend to support scenarios with aggressive timelines but should be made aware of the inevitably higher risks associated with such plans.



Project Management

Project Management should be handled by a professional, coordinating the various cross-functional activities (see chart below for an example from Drug Development Clearly Explained and the Alladex Course) and using project management software (e.g. Microsoft Project, second example below, with parallel activities displayed as a “Gantt chart” and key rate-limiting steps i.e. the so-called “**critical path**” analyzed).



Text interspersed with examples from Alladex case study

Eg

.....after multiple meetings with experts on Alzheimer's disease attended also by a marketing consultant , to understand the available treatment and unmet needs of the patients/market MacKnight sets the target profile as follows:

- Efficacy: at least 50% slowing of the progression of the symptoms of the disease over a period of a year
- Tolerability: well tolerated by the elderly target population, no serious adverse effects which would prevent its prescription by non-specialists
- Once daily oral administration
- No clinically significant interactions with other medications taken by this population.

In addition to this main profile they also set a "minimal" acceptable profile (in this case reduction of symptom progression of only 25%) and an optimal("dream" profile).

Frequent self-assessment questions (answers provided)/exercises

eg

Preclinical testing usually requires toxicology testing in both rodents and non-rodents

True/False

ICH guidelines apply only in Europe

True/False

Connect the left and right columns as appropriate

Phase I	Dose finding in patients
Phase IIA	Large confirmatory pivotal studies
Phase IIB	Proof of concept studies
Phase III	Studies of pharmacokinetics and safety usually conducted in healthy volunteers
Phase IV studies	Post marketing studies