### How Venn Life Sciences can help you draft and implement your

# Drug Development Plan

General background: Venn Life Sciences has been part of the Open Orphan PLC Group since 2019. The Open Orphan group includes several companies that specialise in drug development. The two largest companies in the group are Venn Life Sciences and hVIVO.

Our sister company hVIVO is based in London and is the world leader in testing vaccines and antivirals using human challenge studies. To conduct these studies, it uses the name

FluCamp – Clinical Trials Recruitment. They have two quarantine units in Whitechapel with a capacity of 43 beds and their own laboratories.

Venn Life Sciences provides the services you are used to and currently consists of two offices. The first office is located in Breda and specialises in CMC, Clinical PK & Pharmacometrics, Non-Clinical Development, Medical Writing & Regulatory Affairs. In addition to the office in Breda, we have a second office in Paris. Our team in Paris specialises in Data Management, Statistics, Study Design & Methodology. By combining these unique specialisations, we can provide all the services a client needs to move from Discovery to Market Access, such as Drug Development Consultancy and Trial Management, as well as training courses tailored to the client's needs.

#### Why do you need a good Drug Development Plan?

Developing a drug is a long-term process that requires the involvement of numerous disciplines. Drawing up a good development plan, the so-called Drug Development Plan (DDP), is an essential success factor in the development of a drug. The Drug

Development Plan should ideally be made at the earliest possible stage and consist of the following elements:

- Overview and analysis of existing data and information
- Defining, along with the Target Product Profile, the goals for the development of the product
- Mapping out the project plan to achieve these goals, including timing and budget estimates for each phase.

To develop the DDP, Venn Life Sciences employs various experts from a wide range of disciplines, namely Chemistry, Manufacturing and Control (CMC), Non-Clinical/Preclinical and Clinical.

All this is done within the appropriate Regulatory Affairs framework, aiming at the future approval of the product by authorities such as the

Food and Drug Administration or the European Medicines Agency EMA.

### **Commercial benefits of the DDP**

A good DDP documents the different phases of the drug development process. It maps out the various milestones along with timings and costs. As a result, the start-up or early stage biotech can use it as the basis of its pitch to attract investment. Through our experience we have helped many clients in the past to raise funds with the help of a Venn Drug Development Plan. This allows companies to continue their projects.

add value and ultimately attract even more investors.

## Why work with expert consultants?

Venn's consultants have built up an extensive background and expertise at biotech companies, Big Pharma, CROs, CMOs and academic institutions. Each client is assigned a single point of contact, who is the main contact and coordinates the internal Venn team. Thanks to our integrated approach, we have the necessary knowledge and expertise to optimally develop your Development Plan. Venn can also take on the coordination and project management of the various development activities. This takes the stress out of managing different suppliers. This can only improve efficiency and lead to shorter project timelines and lower costs.

#### What are Venn's plans for the future?

Venn Life Sciences will continue to provide flexible, customer-oriented services as you have come to expect. We will also be sharing more information by writing blogs, articles & whitepapers and holding webinars and hopefully kickstart events again in the near future. We hope to meet you again soon! The first step has already been taken! As of this month, our new website www.vennlifesciences.com is online!

