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Human health lessons for veterinary data packages

Time is money when developing data packages for new products. The animal health industry could learn from best practice in human health, argues Triveritas consultant Germán Graff DVM MBA.

Every time an animal health company reaches the stage of planning the safety and efficacy field study of a new product, at least five years of product development and often millions of euros might have been invested in the project. R&D project managers are usually under extreme pressure.

Delivering a reliable data package, including the data produced as a result of a well executed clinical trial, to the regulatory affairs team is crucial in order to compile the dossier for submission as soon as possible and launch the product according to schedule.

A ROI is expected and frequently, at this stage the project budget may be under pressure and the sales' team is looking forward to having something new to boost their productivity. Nevertheless caution must be used because, data reported on the basis of a trial having a badly designed statistical plan, a weak protocol or poor field data could easily threaten the whole project's viability.

An event that could, depending on the size of the investment, seriously affect the future of the company.

This scenario is not new, neither for the animal health sector nor for the human health industry. Both face this kind of challenge frequently.

However, the significant difference in resources and margins between these industries is not only well recognized but is also growing with time, which offers a greater challenge to the companies involved in developing animal health products.

Even so, many things can be learnt and even adopted from the Human Health industry.

Launching a new product on to the market requires vital investments in R&D. The first few years of sales will be crucial in order to pay back the capital and pave the way for new investments.

In the current economic climate, the product's price is less likely to be a variable when looking to reduce the time for return of the main investment and maximizing the targeted market currently might be an easier way to go.

Historically, companies based in Europe would launch their products first in the EU market and

a couple of years later in the Americas; North American and Asian companies can follow an equivalent sequential pattern. This strategy has been reviewed by the human sector and there have been many products being launched globally over the last decade.

Considering that marketing means can be tailored to target as many markets as desired and distribution channels can be built over commercial agreements and alliances, the only piece missing could be a globally regulatory approved product.

Most countries would accept US or EU regulatory standards and both administrations have been working relentlessly since 1996 towards an harmonized regulatory environment (VICH).

Therefore creating an application document compliant with these harmonized standards would create easier access to 65% of the world's market (EU and US) and facilitate entrance into the remaining 35% (in some cases, using a relatively abridged application based on major market's regulatory requirements).

Meeting this aspiration seems impossible for SMEs and even improbable for some of the larger companies since it's assumed that a much higher investment in R&D would be needed.

It's expected that in order to comply with US and EU regulations, two different field studies could need to be conducted to produce tailored data packages, resulting in more time and money.

This is where a lesson from the human health industry might be learnt: think globally from the beginning. From the product concept, all the way through pre-clinical tests up to the field studies, the opinion and comments from the regulatory authorities are fundamental.

For the final clinical stage, another innovative strategy tried and tested by the human industry could be followed.

Nowadays, technology in the form of electronic data capture (EDC) systems allows us to follow a study in real time, accessing preliminary results remotely, resolving data errors as they occur, amending the protocol and ensuring that its data capture forms (DCFs) can be used anywhere (e.g. including different languages).

Computers and internet interfaces are probably the most international language ever spoken and a web-based EDC system compliant with current data validation regulations and based on expert-designed DCFs can simplify the conduct of a global field study enormously.

Internet and desktops or laptops (not to mention i-Pads, blackberries, i-Phones, etc) are available in almost every veterinary practice and many farms, making access to these web-based EDC systems ubiquitous and relatively cheap (as no specific hardware is required).

In addition, a 21-CRF-11 application like the Prelude Dynamics "Vision" evaluated and selected by Triveritas guarantees data quality and efficiency by delivering a verified database to the study statisticians up to three months earlier than the paper-based method.

Finding the right mix of experience and expertise required to ensure all of these ideas work for your development could be the final lesson to be taken in from the elder sister industry.

Outsourcing some key tasks whilst remaining in absolute control of the helm would bring enough flexibility and budget control. Comprehensive expert CROs would be able to accomplish the task by the agreed date and deliver a cost-effective service. This is a new partnership alternative for the exciting experience of creating a new animal health product.