

Xenotransplantation of Biotech Companies to Bridge the One Health Divide

The concept of One Health is essentially the collaborative work across all sectors affecting public health in order to improve outcomes. Animal health is a cornerstone of public health through provision of animal products, risk of zoonotic infections and the positive impact of animals on our wellbeing. Where synergies exist in disease and treatment modes, it would appear to make a lot of sense to develop diagnostics and therapeutics in concert. This begs the question why is it not more commonplace for biotech to develop co-incidentally in both human and animal health? This article explores both the benefits and the barriers to a One Health approach in diagnostic and therapeutic research and development.

Mutual Gains

Healthier animals lead to healthier people, and vice versa. In the field of medicine, there are advantages to collaborative working across the species barriers and transferring tech between the spheres of human and animal health. The concentrated genetic pool within species, and breeds within those species, can aid genetic target discovery. This may have reciprocal benefit where the genetics are conserved from animals to humans. Shorter lifespans of many animals reduce the time to end point for clinical trials. For example, canine cognitive dysfunction shows many pathological similarities with Alzheimer's disease. Treatment outcomes are similar for dogs with CCD as they are for people with AD, making dogs a useful therapeutic model. Reduced regulatory barriers in animal health increases speed to market delivery and financial returns. Why, therefore, does parallel research and development not happen more frequently where there is shared physiology? Let's look at the benefits and challenges of these comparable markets and discuss why companies should consider both in their strategic plan.

Reducing Uncertainty

The degree of uncertainty of the future of medicine is growing, driven by the exponential growth of molecular technologies, digital health tech, AI and big data. There is also a shift in emphasis from 'sick' care to 'health' care, focusing on wellbeing, prevention and early intervention. Both human patients and animal owners are demanding increased personalisation, accessibility and convenience for their healthcare, with a growing C to B relationship, rather than the historic paternalistic B to C model. This is driving the emergence of smart health communities to improve efficiency in innovation and delivery, increase access and affordability, and improve quality. Surely, as the degree of both uncertainty and consolidation rise it makes sense to de-risk by having a foothold in both markets? Streamlining tech development should prove more efficient, while protecting against jolts in the human market as animal health tends to lag behind.

Market Size

The size of the global animal health market is approximately \$150 billion¹. The size of the human health market is an order of magnitude greater at around \$8 trillion². Continued healthy industry growth rates of 5–7% annually predicted to continue for both markets. The global population continues

to rise and live longer, and with it an increased demand for animal products and pet healthcare.

The companion animal sector has seen huge growth, thanks to the humanisation of pets seen increasingly as valued family members. This has driven consistent year on year increased spending in the pet and animal health segments. The size of the pet expenditures in the US grew from \$43 billion in 2008 to \$73 billion in 2018³. Multiple data points suggest sustained strength in companion animal markets. These include continued rising pet adoption and prescription trends, increasing spend per pet, and healthy pet insurance markets⁴. Ironically, as we value our companion animals more, we value our individual production animals less with the rising demand for cheap meat driving intensive farming. Meat consumption per capita is on the rise, alongside growing populations. The sands are shifting, however, with increasing concerns over welfare and environmental impact gaining traction in the Westernised world. It will be interesting to follow these trends, which also champion local higher welfare and more natural farming methods, for which people are increasingly prepared to pay premium prices.

	Human Health	Animal Health
Market size	\$8 trillion	\$150 billion
Annual growth rate (CAGR)	5-7%	5-7%
Trial process	Multiple species steps	Direct to species
Approval process	Better than an existing standard of care	Better than a placebo
Avg number of years for a new drug to reach the market	12-15 years ⁵	5-7 years
Development costs	>\$1 billion	<\$100 million

Table: Human and animal health industry comparisons

Barriers to Market Entry

The size of the markets may be the headline, but ease of accessing a market share is more important in delivering returns. While the potential gains are significantly less in the animal health sector, it is de-risked with fewer barriers to entry, reduced regulatory time and costs, and fewer competitor products and companies. Product lifecycle development from new concept to market is 5–7 years compared to 12–13 years for human drugs¹. In addition, the approval barrier for an animal therapy is to outperform a placebo, but the bar is set higher in human health to beating an existing standard of care.

The animal health industry is largely free from the constraints of healthcare reforms, direct reimbursement models and generic conversions. There are vastly reduced R&D costs (see table) and fewer onerous regulatory hoops to jump through compared to human drug development. Access to the market is much more direct and efficient, rather than the complex, indirect routes to buyers in human health.

Venturing Into the Unknown

So, what deters companies from developing parallel tech? Is it the act of venturing into the relative unknown? Concerns and considerations over species differences? Lack of funding to pursue both avenues? Or is it the bottom line of a contracted animal health market seeming less worth the investment? The smaller overall industry market



size is a crude guide to potential returns, as the size and profitability of different sectors varies greatly.

There are additional factors and idiosyncrasies of a market where the end user (owner/farmer) is an intermediary between the professional (vet) and end target patient (the animal). In the companion animal sector, there is a large emotive component to consider with messaging and positioning within the market. It is important to thoroughly research not only the potential number of targets, but also the receptiveness of both veterinary professionals and, ultimately, owners to the type of treatment. The therapeutic focus shifts more from maximising longevity to preservation of quality of life. A deep understanding of the factors influencing animal care not only informs strategy and direction, but also the avoidance of faux pas and negative brand associations which can be hard to shake off. A true understanding is needed to avoid marketing pitfalls, such as throwing sticks for dogs, or using images of extreme breed types. Portfolio marketing with an audience-centric go-to-market strategy, incorporating deep buyer insights, creating messaging that resonates, and taking a strategic approach to launch, should develop alongside product R&D. Fostering and maintaining customer relationships will influence customer decision-making on new market entrants.

For the production animal sector, the situation is somewhat different. Economies of scale drive down the value of the individual animal, and only cost-effective treatments will be adopted on a large scale. This will need to be reflected in pricing strategy. The role of the veterinarian in food animal medicine and technology should not be under-estimated. They will need to be convinced of the value to their clients, in addition to ensuring high welfare is maintained. There is the need for substantial, robust, and compelling performance, efficacy and economic consequences for food animal products.

Risks

With the current Brexit uncertainty and global trade deals to be done, the future influences on the UK human and animal health markets is uncertain. Globally, these markets are extremely resilient. Despite being historically similarly

resilient, socioeconomic conditions are more likely to impact the animal health market. Trends and concerns about food animal production and sustainability may potentially offset the continuing trend for higher demand for animal protein. Unexpected downturns in macroeconomic conditions could negatively impact consumer discretionary income, i.e. spending on their pets. The rise in online pharmacies and telehealth are changing the traditional models of pet care, necessitating a more anticipatory approach to regulation.

Factors affecting both markets include the consolidation of larger health companies, intensifying competition and making it harder for smaller players to gain a foothold.

How to Succeed

For start-ups wanting to succeed, it's vital to understand the potential role of the technology, technically and financially, for both markets. This involves undertaking due diligence necessary to have rational and credible pricing and sales projections for the products (and regulatory where applicable). Competitor analysis and anticipating that others are developing similar competing products should drive a healthy sense of urgency. A detailed manufacturing plan should be considered, with contingency planning for potential hurdles in terms of regulatory, delays and additional costs. Distribution channels need to be considered, bearing in mind exclusivity arrangements and the rise of buying groups.

The landscape for animal health distribution is changing dramatically. Direct to consumer online channels and home delivery platforms continue to disrupt traditional distribution channels through veterinary practices. To counter this and improve efficiency, buying groups of distributors and both private and corporate practices continue to grow. Remaining agile and responding to distribution trends will be important as the world increasingly moves online.

Suck It and See

In both farm and companion animal sectors, the method of product administration is also a much more significant factor than in human health. Poor palatability or in-appetence can be huge hurdles in oral drug delivery. Frequency of dosing is an important consideration,



especially in farm animals where handling is both time-consuming and causes stress and potential injury (both to the animals and their handlers). Remote dosing in drinking water or feed leads to unpredictable intake within groups of animals, necessitating high safety levels. Drugs must also be safe for human handlers and the environment, and disposed of appropriately. The issue of drug residues is also important for animal products, and ideally withdrawal periods should be short. Effect on performance must be taken into account with competitive sport horses and racing greyhounds.

The Funding Dilemma

Traditional large pharma R&D is being increasingly augmented by increasing numbers of innovative start-ups. This means there are many smaller companies seeking to access funding pots. Few grants exist for the animal health sector unless it directly relates back to public health, such as antimicrobial resistance or zoonotic disease. Many more grants are available for human health projects, and this funding would likely have conditional use in a company working in both fields. Limited available capital may restrict companies to just one market segment. In this instance, the more familiar market with higher potential gains will likely win out.

Alternative funding models, beyond grants and venture capital, are becoming increasingly important to fuel innovation. Angel investors in animal health in the form of practice owners having sold on, provide a growing source of both advice and money. Equity crowdfunding capitalises on growing, engaged online communities. If companies are developing the technology in parallel this opens the door to funding, investments and partnerships from both market segments.

Growth of the One Health Approach

Interest in working within both human and animal sectors is certainly an area of increasing attention and focus. The Humanimal trust was set up in 2014 to foster partnership and join up research efforts between doctors, vets and researchers in fields such as stem cells, oncology, neurodegenerative disease and antibiotic resistance.

Start-ups well on the road to developing cross-over tech include examples of taking tech from human to animal, vice-versa, and in parallel to both markets. An example of animal to human diagnostic is Test&Treat, which has developed point of care tests for the rapid detection of urinary tract infections (UTIs) and subsequent antibiotic sensitivity analysis. The patented technology has been launched into the veterinary market for use in companion animals. The same test can also be used for detection and antibiotic susceptibility of human UTIs and the next stage for the company is to develop diagnostic partners to license the technology for application on the human market.

Human to animal cutting-edge biotech can be seen with the likes of PetMedix, developing monoclonal antibody platforms for dogs and cats, following success of the team



in human drug development. Having seen the change these therapies have made to human health, what started as a PhD project to prove a platform to create fully canine Mabs has led to a rapidly growing enterprise working on multiple targets focussing on unmet clinical needs.

Pregenerate and VisusNano are both developing tech in parallel. Pregenerate combines the expertise of human doctors with an equine orthopaedic specialist in development of their biologic microchip. The wide range of potential applications include arthritis drug development and personalised medicine optimisation. VisusNano's medicated intraocular lenses have potential applications in both canine and human cataract surgery, but are likely to enter the veterinary surgery years ahead of the human clinic.

Conclusions

People and animals have a lot to gain from one another, both in terms of companionship and mutual health and wellbeing. The increasing trend towards efficiency and consolidation to reduce waste, expenditure and time globally is a strong argument for increasing collaboration between human and animal health markets. The potential reciprocal gains for the patients, spread of risk, and revenue from two independent market sectors should encourage companies to fully explore the possibility of developing their technologies in parallel. If this approach can become more commonplace, the network of collaborators will grow, along with familiarity and understanding, and One Health can thrive.

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