Using AI for Biosimilars Market Intelligence

VAMSTAR

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Biosimilars are biological products that are similar to an already licensed biologic, with no clinically meaningful differences in quality, efficacy, or safety, and go through a rigorous process to gain regulatory approval. Biosimilar development focuses predominantly on in-depth analyses to confirm that the product is identical to the originator in terms of structure, composition, and in vitro activity. Therefore, the critical quality attributes of a biological drug that influences clinical safety and efficacy should be carefully assessed.

Biosimilars usually need at least one clinical study to compare pharmacokinetics of bio-originator and biosimilar, and at least one sufficiently large randomised controlled trial to demonstrate clinical equivalence. Once biosimilarity is confirmed, regulators may allow extrapolation to other licensed bio-originator indications, provided efficacy relies on a similar mechanism of action in each one. Consequently, a biosimilar may be approved in all indications for which the bio-originator has been approved, without multiple clinical trials.

Today, Biosimilar drugs are used in prevention and treatment of various severe diseases such as cancer, diabetes, autoimmune diseases, heart attacks, rheumatoid arthritis, oncology, growth hormone deficiency, chronic kidney failure, hematological disease and infectious disease. Since the approval of the first biosimilar to somatropin (Omnitrope) in 2006, over 77 biosimilars have been authorized and 8 of those biosimilars have been withdrawn by the European Commission for use in the EU. Similarly, in the US, of the 29 biosimilars approved, only 18 have so far been launched. (GaBi; Feb 2021)

During the COVID-19 pandemic, Biosimilar adoption and uptake took a setback as most healthcare providers and hospital stakeholders were focusing on taking care of the affected patients and ensuring that adequate supply of beds and PPE is maintained. During this time, most institutions lacked the bandwidth to evaluate complex biosimilar-related decisions and decided to stick with status-quo i.e. the reference product or the existing preferred biosimilar product in key markets. However, as the dust settles and the focus shifts towards cost savings due to significant financial strain on account of pandemic, Biosimilars adoption is taking a strong upward swing.

In this white paper, we highlight the use of Artificial Intelligence in Biosimilar market intelligence and tendering, focusing on supplier bidding strategies and the use of machine learning algorithms. This paper aims to highlight how AI can help improve the efficiency and competitiveness of organisations and is particularly suitable for both suppliers and public procurement agencies. On the one hand, it can help the suppliers identify the most suited Biosimilar tenders (and markets), i.e., those that they should prioritise and reduce their winner's curse. On the other hand, the contracting agency could automatically search companies with a compatible profile for the tender's announcement, e.g., selective tendering where suppliers are only allowed by invitation.

Tracking Biosimilar Markets

Large pharmaceutical companies have been reaping the benefits from dominating and monopolizing the biologics market for decades, but now new players are emerging to take over the biosimilars market landscape. Indian-based generic drug manufacturers and Korean mega conglomerates account for significant portions of European markets in generics drugs and this success offers a template for execution for Biosimilars as well. However, biosimilar launches are unlike any other generic or branded launches, and product uptake varies widely based on the specific dynamics of the medication, market, and competitive landscape.

To further complicate the Biosimilars market dynamics, Emerging Markets (EMs) offer the highest potential for growth due to demographic surge, growing prosperity, and increasing life expectancy, accounting in total for 30%-50% of the global healthcare market. However, the operating environment varies quite drastically in each of these markets, with many differences in terms of size, price levels, contracting conditions, standards of care, pace of growth, disease patterns and many other parameters. Biosimilar expansion strategies have to be tailored to the market specifics and their populations by ways of adjusted product ranges, branding, promotion, patient engagement, and pricing.

Many companies are launching their biosimilars in these untapped markets, despite EM biosimilars presenting unclear and often unquantified threats. Others are entering the biosimilar market based on the same paradigm as firms operating large generics divisions while some are adopting a mixture of these two strategies. Moreover, while opportunities are exciting, there are external risks in doing business in the EMs related to currency fluctuations, geo-political climate, local manufacturing requirements, or pricing caps that can further erode the overall return on investment in these markets. Success will depend on whether you would be in the first wave of launch while ensuring that tender and contracting strategy is in line with a competitive COGS position in the market to grow and maintain market share.

Under these circumstances, it is extremely critical for both domestic/local and international companies to fully understand the scope of opportunities in the market while tracking competitive activity across the market segments. The competitive landscape for biologic drugs is changing. As companies continue to introduce more biosimilars into the market, they need to keep adapting their strategies and positioning in order stay ahead of competitors that are also undergoing adaptation. Effective commercial approaches strike a balance between three different imperatives: making the product more affordable for patients and building tender capabilities to secure volume gains; generating further savings for payers and providers through incentives; and tailoring pricing and channel strategies to individual products and countries to achieve traction at physician level (McKinsey; 2021).

By combining human research and AI based data capabilities in market tracking, companies can easily size the overall markets while ensuring that every tender/contract opportunity is analysed in real-time for optimal price discovery to drive market share. It is essential, especially for these companies, to follow criteria that take into account all aspects of the product, including the supply of active ingredients, the manufacturing process optimization, the regulatory path, the evaluation of the treatment paradigm, the expected level of acceptance by doctors and patients, the situation regarding tenders, the expected level of competition, the portfolio synergies and, over all, company resources and objectives.

COVID-19 and the Supply Chain Transformation

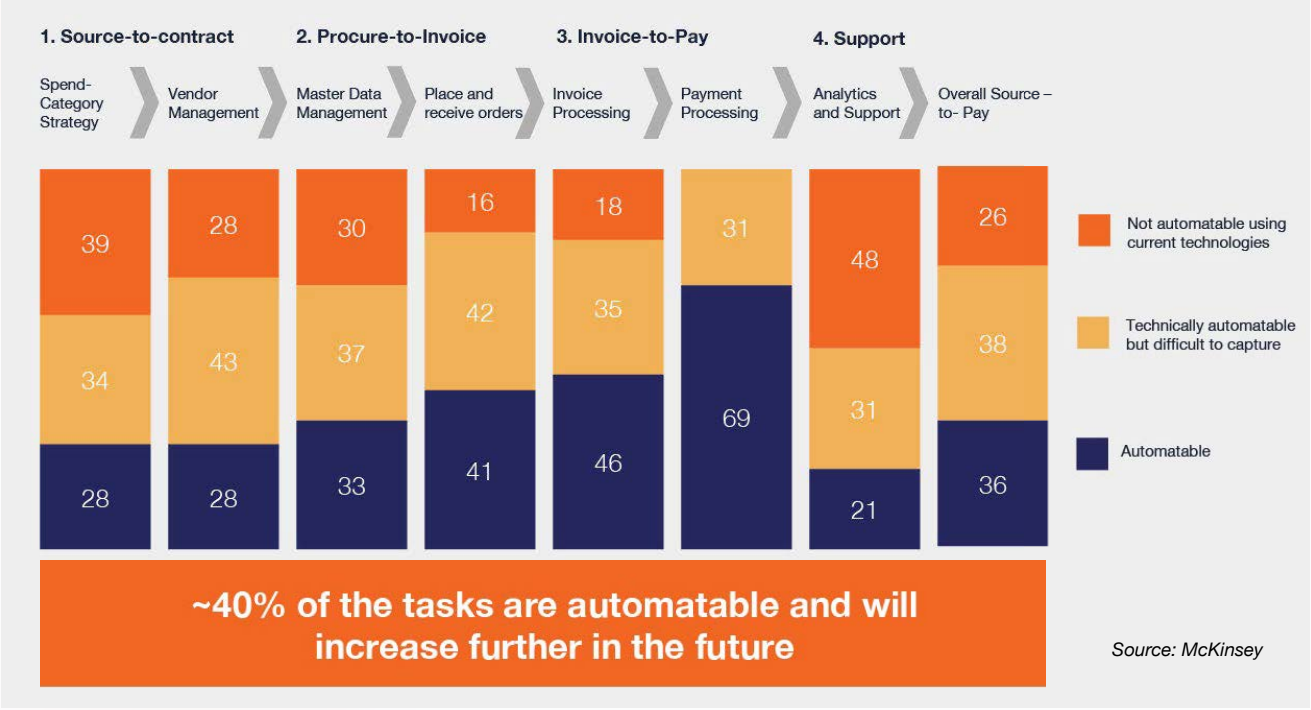
COVID-19 has highlighted the deficiencies in the current supply chain models and has exposed many healthcare organisations' critical vulnerabilities, particularly those with a high dependence on global suppliers. The immediate demand surge of various medical consumables, devices, and pharmaceuticals has led to a cascade effect as the components of complex global supply chains started to fall over, and the availability of necessary materials rapidly dried up. Indeed, some of the critical materials are still in short supply since the start of the pandemic.

The business between healthcare buyers and suppliers has not changed from 20 or 30 years ago, even though processes have improved significantly. Undoubtedly, communication is faster and easier, but still, there are many parts of health systems, even in developed countries where we still need to send purchase orders through the post or use fax to send specification documents to suppliers. Within the industry, and especially within procurement, there are numerous opportunities to improve operational efficiency.

"2018: I am instructing the NHS to stop buying fax machines, and I'm setting a deadline for getting rid of them altogether. Email is much more secure and miles more effective than fax machines. The NHS can be the best in the world – and we can start by getting rid of fax machines - Matt Hancock, Health and Social Care Secretary for NHS in the United Kingdom."

In recent years, there has been some degree of digitalisation of procurement, especially concerning pharmaceuticals and medical devices. Nonetheless, public procurement is still administratively burdensome, costly, and time-consuming, with several complicated forms to be filled out, requiring significant human effort by both the contracting authority and the tenderer.

Moreover, the core procurement processes such as source-to-pay (S2P) or sourcing management have not fundamentally changed. The S2P process is still executed as it has been for generations - an electronic tendering process still almost always follows the tendering 'rules' laid down years ago in the days of pen and paper. According to McKinsey's research, 56 per cent of the tasks associated with the source-to-pay process are entirely or largely automatable using existing technologies.



Tendering in the Healthcare Sector

The pharmaceuticals and the medical devices The pharmaceuticals and the medical devices industry is ripe for many disruptions and is considered a highly competitive environment for bidders within the hospital sector, where the majority of the sourcing happens via tendering. One of the aspects of this competitive environment is the supplier selection process. While different bid allocation methods are used in the overall procurement, the lowest bid (and to a certain extent MEAT based procurement; Most Economically Advantageous Tender) approach is the most commonly used across many countries. The lowest bid means that the procurement contracts are allocated based on a competitive bidding process.

Competitive bidding is considered a legal requirement in the public sector, especially in markets that are primarily taxpayer-funded. For instance, in the public EU and LATAM hospital and ambulatory procurement, such as those funded by the Department of Health or Regional Health Bodies, public bidding and procurement laws require the procurement to be allocated to the lowest price or MEAT based bidder to protect the public against the squandering of public funds and to prevent abuses such as fraud, waste, and favouritism.

It has often been emphasised that tender evaluation and contractor selection is “one of the most critical undertakings performed by buyers, the effectiveness of which is directly related to project success and the achievement of specified objectives”. Making judgments about suppliers and their ability to deliver to the requirements comprises high levels of ambiguity, uncertainty and, sometimes, trade-offs in conflicting objectives. Therefore, criteria supporting the fair and practical assessments of the bids are of great importance (e.g., price, experience, capability, quality, performance).

In terms of Pharmaceuticals, specific considerations are to be made due to some of the products being under patent or other IP rights protection at the time of the tender procedure’s launch. Public tendering entails that competing products are proposed to contracting authorities and are then compared in award criteria. Innovative, patented products can qualify as being protected by exclusive rights, which in certain circumstances allows contracting authorities to have recourse to the (less burdensome) negotiated procedures under the public contracts legislation. However, for this paper’s purposes, we will focus on our efforts on competitive and multisource bidding contracts, including the ones for biosimilars.

Suppliers reflect their desires to provide various pharmaceuticals and Biosimilars by submitting their proposals for an agreed price for an allocated volume. That said, one of the most complex decisions that suppliers face is the bid amount to offer for a given RFP (Request for Proposal). This critical decision significantly influences the supplier company because it needs considerable time and costs to be prepared, requires significant efforts to understand the total demand, and affects the firm's financial status. Suppliers aim to design and submit their bids so that they are the lowest price or the MEAT bidder. The lowest price bidder is the supplier "who fully complied with all of the bid requirements and whose past performance, reputation, and financial capability is deemed acceptable, and who has offered the most advantageous pricing or cost-benefit, based on the criteria stipulated in the bid documents".

The suppliers aim to win tender contracts as much as their capabilities allow for many reasons, including:

1. Increasing earned profits.
2. Minimising losses because they need to keep the firm intacts.
3. Minimising the gains of competitors to have a long-term good competitive position within the market.
4. Discovering new contracting opportunities.

As such, suppliers need to take different important bidding decisions, including (1) the bid or no-bid decision where the supplier weighs many factors that determine the expected benefits from a tender contract win; and (2) the bid value or the markup decision, which is determined based on the bidding strategy.

Suppliers quote a price during the bidding process when all the risks and costs are only partially known, and production delays, demand surges, policy changes, and plant/machinery challenges are not fully factored. Additionally, a supplier should figure out what bid values the competitors will submit to adjust their bid price to win the contract, which is certainly difficult to predict in the competing marketplace. This desire to be the lowest bidder creates the so-called winner's curse. The winner's curse is the situation when the bidder with the most optimistic (low) cost estimate wins the contract due to a submitted bid less than the actual cost and thus will most likely earn negative or, at least, below-normal profits. The winner's curse is very hard to avoid; however, it can be reduced using targeted strategies. Keeping this in mind, when choosing their bidding strategy(ies), suppliers weigh two objectives: (1) increasing the win-rate across tender contracts; and (2) reducing the winner's curse, but this could mean increasing the bid value and thus lowering the probability of winning the contract.

Based on the previously mentioned points, a practical and reasonable bidding model is needed to be used in the supplier's bidding decision-making process to overcome the inherent complexities and uncertainties in the competitive pharmaceutical and Biosimilars bidding environment. One practical and reasonable approach is determining the bid price based on competitors' historic bidding patterns and the price-value archetypes across different buyers. Therefore, we aim to provide a useful algorithmic game theory framework that helps suppliers in their bidding decision-making process by learning from historical bids within the market based on publicly available data that is collected, normalised, and aggregated using structured approaches.

Algorithmic Game Theory and Bidding in Tenders

Game theory is defined as “the study of mathematical models of conflict and cooperation between intelligent, rational decision-makers” (Myerson 1991). A particular area of game theory is algorithmic game theory, a field at the intersection of game theory and computer science to understand and design algorithms in strategic environments (Nisan et al. 2007).

Auction theory is a subdiscipline of game theory. Historically, auctions have been used to sell and allocate various types of goods and services to customers. In today’s world, auctions are of great practical importance in both the public and private sectors. Governments usually use auctions to sell assets, purchase services, and fund their national debt in the public sector. Moreover, in the private sector, auctions are used widely in many areas, such as the utility market and the selling of items through internet auctions. There are two major types of auctions: (1) private value auctions; and (2) common value auctions. In private value auctions, the bidders know, with certainty, their valuation of the auctioned item. Conversely, in common value auctions, all bidders have the same value of the auctioned item, but no bidder knows it with certainty.

Pharmaceutical and Biosimilars bidding is considered a common value auction. In the industry, the base unit cost is regarded as a common variable for different bidders. Suppliers have two sources of incomplete information at the time of submitting their bids: (1) actual (realised) cost; and (2) their competitors’ estimates of the average unit cost. In common value auctions, bidders are subject to the winner’s curse.

For creating a bidding framework and the following model, we need first to understand the different learning algorithms in the bidding decision-making process. These algorithms can help us design the model while allowing for exploitation based on historical bid sequences to decide the best bid value.

Multiplicative Weights Learning Algorithm

The multiplicative weights learning algorithm is one of the most commonly used methods in decision-making processes and prediction applications, and it is widely deployed in game theory and algorithm design. Indeed, this algorithm has applications across various learning and optimisation problems, which makes this algorithm a state-of-the-art learning method. The algorithm assigns initial weights to all possible actions (usually identical initial weights). It updates these weights multiplicatively and iteratively according to the feedback of how well the taken action performed, reducing them in case of poor performance and increasing them otherwise.

Exponential Weights Learning Algorithm

The exponential weights algorithm is considered a universal method used for learning, and thus it is perceived as a state-of-the-art learning algorithm. As compared with the multiplicative weights learning algorithm, the exponential weights algorithm uses a different update rule for the individual weights. In simple terms, given a set of possible actions, the exponential weights algorithm begins with equal weights for each action. For each iteration, the algorithm chooses an action proportional to the weights assigned to all actions. Afterwards, the outcome of each iteration is realised, and the algorithm updates the weights of the actions by multiplying their previous weights by an exponential factor; thus, it is known as the exponential weights algorithm.

Types of bidding strategies

In the current context within the industry, there are two types of bidding strategies at play. The first bidding strategy is winning as many tendering contracts as possible compared to the competitors, with little importance given to reducing the winner's curse. The primary reason for a supplier choosing this strategy is to maintain the market share, form relationships with buyers, and deprive competitors from taking contracts to gain a long-term good competitive position within the market. This is a high-risk strategy and results in either supplier winning the business or losing out entirely. An exciting example of this is on display during the early launches of new biosimilar tenders within Europe.

The second bidding strategy emphasises reducing the winner's curse while sacrificing winning as many tender contracts as possible. Suppliers use this strategy for different reasons, including increasing the total earned profits, minimising contract losses, and minimising dealing with unexpected events or risks during the contract implementation (volume supply or factory capacity) phase. Within this strategy play, the supplier receives a positive reward if they win the tender for a bid value higher than the actual value to deliver the contract (that is, positive profit), the supplier receives a reward of zero if they did not win the tender, and the supplier gets a negative reward (that is, a penalty) if they win the tender for a bid value less than the actual value to deliver the contract (that is, negative profit). This is a risk-averse strategy where suppliers following such strategy leverage not winning a tender contract over winning it with negative profits.

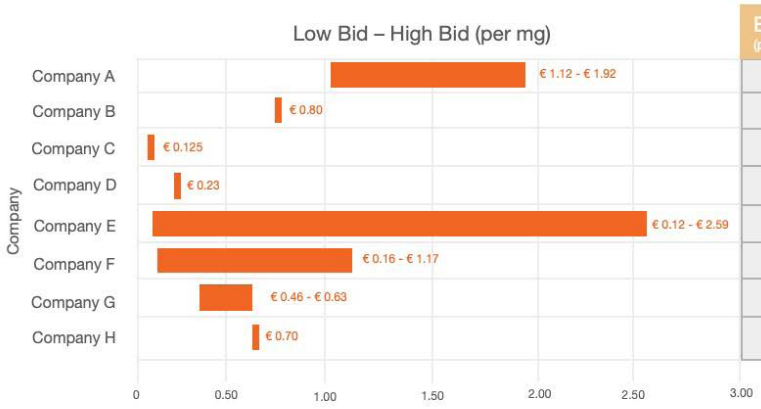
Developing the model

Based on the available knowledge base and the technology, the bidding models can be divided into probability theory and statistical models, multicriteria utility models, and artificial intelligence (AI) based models.

The probability theory-based models aim at defining probabilities of winning in competition, such as within a tender bidding scenario with a select set of competitors. These probabilities are typically estimated based on experimental distributions of the competitor's past bidding behaviour. However, certain assumptions need to made for these types of models to provide a simulated output, and these are: (1) there exists a pattern in each competitor's bidding defined by a particular probability density function; (2) the competitor's patterns are independent (thus the probability of winning in the lowest bid tender is a product of probabilities to beat each of the competitors); and (3) the competitors should be known in advance, though if the identity and number of competitors are unknown – as in real life – some more assumptions on the distribution on the number of bidders were to be made, and the "unknown" competitors' pattern of bidding was advised to be described by averaging patterns of competitors observed in the past).

Predicted Bidding Range of a Biosimilar

(Net and List Price Levels)



Ex-factory List Price (per mg)	Discounts Offered at Lowest Bid (%)
€ 2.33	52%
€ 2.33	66%
€ 2.33	95%
€ 2.33	90%
€ 2.33	90%
€ 2.33	93%
€ 2.33	80%
€ 2.17	70%

For creating a more realistic tender evaluation model that is capable of simultaneously (1) compiling multiple decision-makers inputs, (2) incorporating risk and uncertainty and (3) offering computer interaction that makes a model flexible to any change in the situation, the multicriteria utility models were produced. They work on the theory of combining a utility function and a social welfare function. These types of model have two main steps: step1- evaluating supplier's ability and step2 - evaluating tenders; consisting of three main processes: (1) the supplier ability criteria selection process; (2) the supplier ability criteria balancing/measuring process; and (3) bid price and supplier ability balancing/ measuring process. Supplier's ability criteria across key dimensions include relevant experience, track record, quality, expertise, capability, cost, safety record, and capacity, to name a few. Moreover, based on our research across millions of tender documents (and RFP documentation), cost, quality, safety, ease of adoption, and delivery performance were identified as the most important criteria used during the evaluation and selection process for Biosimilars.

As the competitors' bidding pattern may be difficult to capture by the statistical models, many factors are likely to affect bidding decisions in a particular case. Moreover, in some cases, the objectives of bidding might not necessarily be to maximise profits. In that case, new modelling approaches such as the ones that use fuzzy input to infer the most suitable markup size but base on a predefined range of the margin. Models that use neural networks can be more effective in finding the most optimal bid markup while accounting for more factors that characterise particular tender contracts and are likely to affect both cost and bid values.

Modelling framework

Several e-procurement systems have been designed and implemented by procuring entities to align and execute various procurement activities. To an extent, these systems have solved some of the challenges within procurement processes, such as prequalification and contractors' registration, including for consultants and suppliers, advertisement to tender (ITT), tender submission, the closing of tender, opening of tender, tender evaluation, and contract award notification. However, none of these systems can evaluate tender automatically, ensure conformity to security and legal requirements, and provide complete integration of the front-end and back-end processes.

In recent years, machine learning (ML) has been gaining popularity in aiding decision-making. ML is a technique that applies algorithms in finding concealed trends that humans cannot recognise to make decisions using existing data. Due to the procurement process being data-rich, albeit requiring effective cleansing, it has the prospective to reap from ML.

Until now, there has been no web-based procurement system that considers the entire procurement lifecycle, which has its processes automated with the aid of machine learning. At Vamstar, we are building a system that will recognise and adjust itself when new (and cleaned) data is introduced and modify its performance accordingly to have better efficiency.

One of the critical areas of AI gaining wide acceptance in tendering and procurement is machine learning (ML). ML deals with software agents' training to learn from the large and complex dataset and make an accurate prediction of the future. Specifically, ML uses learning algorithms (like the ones described above) to train a software agent to learn from a data set. Within tendering, different applied AI techniques, such as fuzzy set, knowledge-based expert system, and case-based reasoning, can provide the basis of selecting suppliers.

Additionally, different AI models can be deployed to evaluate and classify tenders. For example, k-means clustering can be used to identify the bidding trends within Biosimialr tendering contracts. Moreover, the applied neural network (NN) and support vector machine (SVM) can be used to classify contract text documents and provide insights about features, value levers, characteristics, and buyer's overall purchasing patterns.

We have identified four steps in the building of an ML model for bidding in Biosimilars tendering. These include: identify data on Biosimilars tenders, including award and bid level data; prepare data; select the ML algorithm, e.g. deep learning; train the algorithm (using created data set); evaluate different models; deploy the model to cloud as part of a software system, e.g. web-based procurement system or an e-procurement system; use deployed model to predict with new data, and finally assess the legitimacy of model's prediction.

The framework for developing a bidding ML model can be grouped into four stages:

1. Identifying the decriptive attributes (or Features) within the historical bidding data.
2. Identifying the target attributes (or Labels) accross each of the product/feature space.
3. Training the machine learning models (using train/test data).
4. Elevating the models (on test live and validation data) and selecting the most suitable one.

Conclusion

Tenders for Biosimilars are increasing in magnitude, and both buyers and suppliers are feeling its impact. In the last decade, many tendering tools and web platforms have organised the bidding process. Still, these remain relatively limited in solving the overall bottleneck, i.e. reducing the overall administrative burden and automating the tasks across the process lifecycle for both buyers and suppliers. In many cases, these platforms have digitised the pen-and-paper process without providing any added efficiency.

Artificial intelligence (AI) and machine learning (ML) are the latest technologies that apply algorithms in finding concealed trends that humans cannot recognise to make decisions using existing data and can significantly improve process efficiency and stage automation.

AI and ML and its derived bidding framework offer the promise and hope to improve suppliers' bidding performance while helping buyers ensure an optimum value-for-money across procurement. This can make Biosimilar tender markets healthy and introduce a level of sustainability, and ensure that a crisis like COVID-19 never hampers our ability to provide goods and services where it is most needed.

Vamstar's Global Biosimilar Tracker

Vamstar provides a comprehensive global biosimilar tracker that assists suppliers, in preparing a global strategy along with tactical support in form of tender management and pricing analytics to maximise revenues & margins.

Global Biosimilar Tracker Includes:

- **Global Biosimilar Market Review - August 2021**
- **Market Intelligence & KPI Reporting**
  + Complementary 40 analyst hours
- **Biosimilar Tender Calendar & Marketplace Platform**
- **Quarterly Updates on Global Biosimilar Market Review + Launch Tracker**

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Praful Mehta is the co-founder and CEO of Vamstar. He has more than 17 years of experience in helping pharmaceutical and medical device companies create effective commercialisation strategies across different therapeutic areas. Mr. Mehta has been a longtime advisor to senior teams on the issues of market access strategies, sourcing and procurement, launch planning, landscape assessments, market competitiveness, and lifecycle planning. He has significant project experience in working with the BRIC-MT and EU-5 nations, as well as the United States and Japan.

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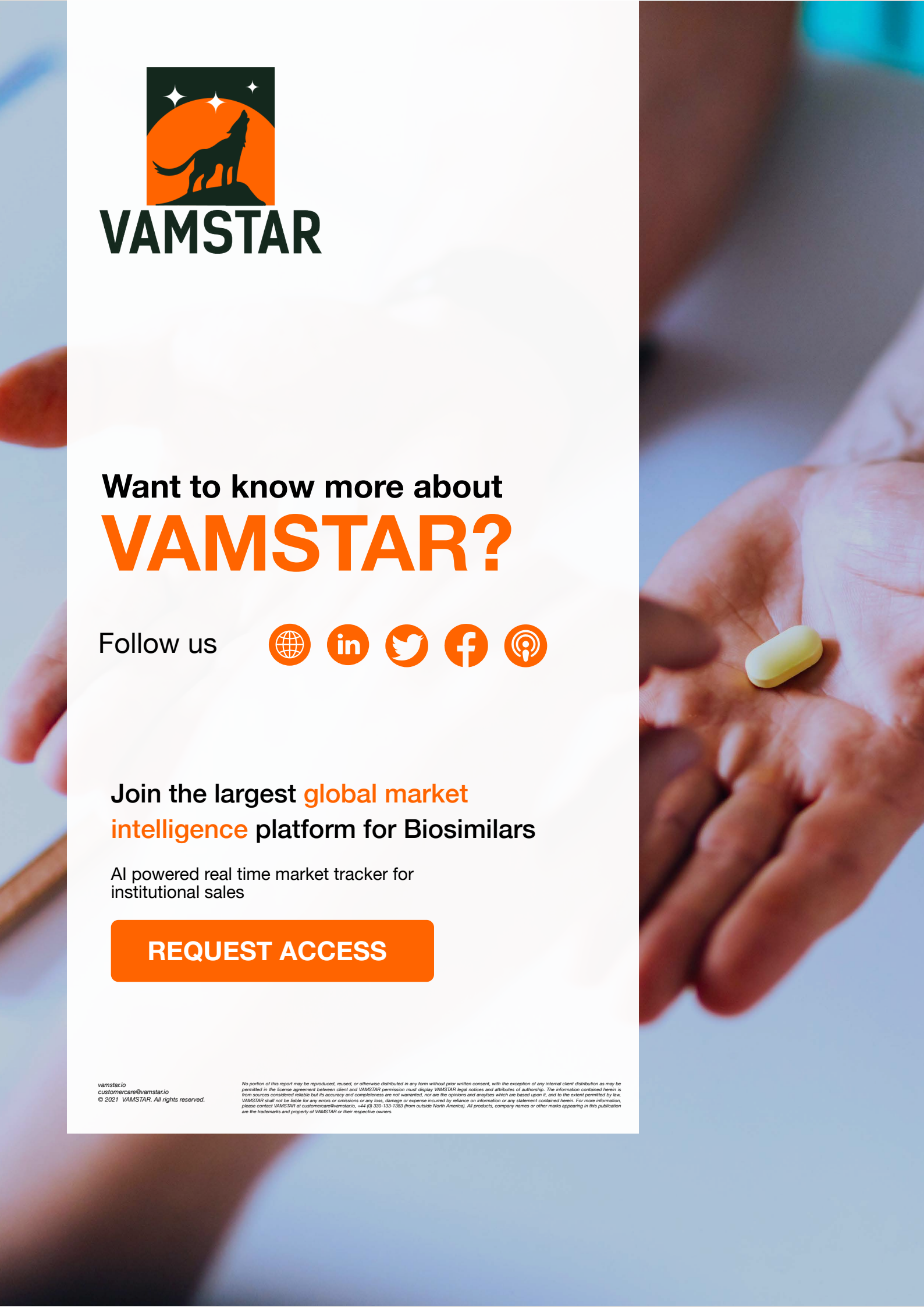
Specializing in health economics, pricing analytics, volume-based procurement, tender strategy, market intelligence, forecasting, Go-To-Market, market access, funding, licensing, portfolio management etc. Worked across cultures with specialisation in key markets of Asia, Middle East, and Europe.



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