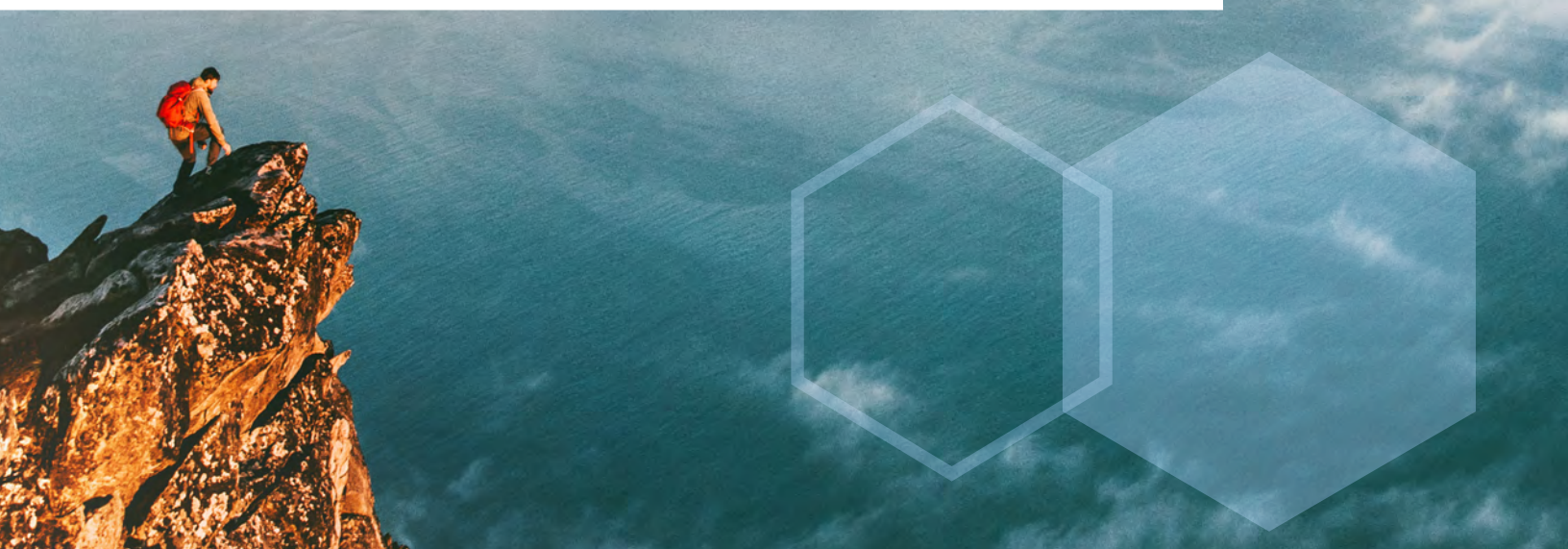
FACET LIFE SCIENCES

YOUR PARTNER IN LIFE SCIENCES PRODUCT DEVELOPMENT

At Facet Life Sciences, we provide tailored scientific and regulatory expertise from concept through clinical trials, FDA submissions (e.g., IND/IDE, NDA, BLA, 505(b)(2), 505(j), 510(k), De Novo, PMA). We work closely with clients to craft compelling scientific narratives, interact with the FDA on their behalf, and address development gaps. Throughout development, we also use market analyses and health economics and outcomes research (HEOR) to help small life sciences companies navigate the critical choices which lead to optimal asset value.

What makes Facet Life Sciences unique is our entrepreneurial approach, rejecting the "big pharma model" to offer customized strategies that align with the budget, staff, and risk constraints of small organizations. We emphasize scientific storytelling and transform complex data into compelling FDA submissions, enhancing approval chances.

For over a decade, Facet has a proven track record of success helping to streamline development and successfully navigate products through FDA. Our services include nonclinical and clinical development, chemistry, manufacturing, and controls (CMC) support, regulatory strategy, medical writing, strategic statistics, and asset valuation and optimization. Let our team of experts help you overcome regulatory and development challenges and find success the first time, allowing you to maximize product value and get to divestiture or the US market faster.



APPLICATION TYPE EXPERIENCE

Facet's FDA application experience incudes (but is not limited to):

- 505(b)(1) NDA
- 505(b)(2) NDA
- 505(j) ANDA
- IND (non-commercial)
- IND (commercial)
- DMF
- Pre-IDE
- 510(k)
- PMA
- De Novo
- Breakthrough
- Orphan
- Fast Track
- Rare pediatric / rare tropical
- Disease
- Small business
- Expanded access

THERAPEUTIC AREA EXPERIENCE

Facet has worked in virtually every therapeutic area with special expertise in:

- Allergy
- Cardiovascular/renal
- CNS
- Dermatology
- Endocrinology
- Gastrointestinal
- Immunology
- Infectious disease
- Inflammatory Diseases
- Oncology
- Ophthalmology
- Pain
- Pediatric
- Radiopharmaceuticals (diagnostic & therapeutic)
- Reproductive health
- Substance Use Disorders
- Ultra-rare diseases

DOSAGE FORM EXPERIENCE

Facet has experience with the following dosage forms:

- Capsules
- Creams/Ointments
- Gels
- Liposomes
- Medical gases
- Microdose powders
- Monoclonal antibodies
- Parenterals (liquid, lyophilized, powder fill)
- Psychedelics
- Overencapsulation
- Patches
- Powders
- Synthetic and semi-synthetic drug substances
- Tablets (IR and ER)
- Toothpaste
- Suppositories
- Swabs
- Vaccines

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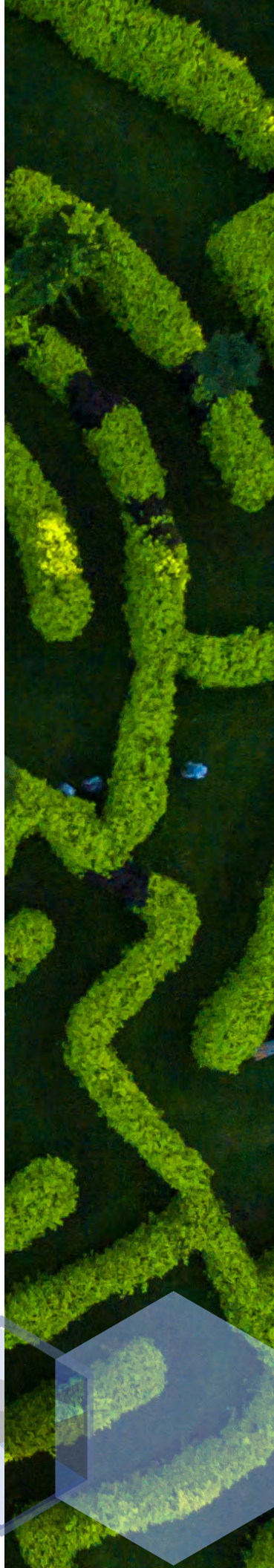
REGULATORY STRATEGY AND FDA SUBMISSIONS

The Facet regulatory affairs and regulatory medical writing teams have advanced scientific degrees and over 300 combined years of experience in the life sciences industry. They help small organizations plan and implement lean and efficient development programs, identify and mitigate risks, discuss programs with FDA, and prepare and submit regulatory applications with the FDA reviewer in mind.

At Facet, we see regulatory affairs very differently than other organizations: Others operate conservatively and don't look to push the regulatory envelope. We specialize in creative, data-supported, aggressive strategies that align with your business objectives. Translating those strategies into flawless execution, Facet helps you to secure regulatory assets and rapidly move your product through FDA milestones. Our seasoned regulatory affairs team members are 15+ year industry veterans with advanced scientific degrees who can help with all aspects of your development program, including nonclinical, CMC, clinical, and regulatory strategies. Our expert regulatory writers are routinely praised by FDA reviewers for providing clear, concise, accurate content that tells a compelling scientific story.

Every company is unique. We develop custom strategies to ensure long-term success for our clients that address their specific scientific challenges and business opportunities. Your goals are our goals and your success is our success. We provide high-impact, scalable services without the overhead of in-house staff, offering the expertise and tools needed to bring your product to divestiture or to market successfully.



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OUR REGULATORY EXPERTISE

U.S. Agent

An experienced strategic liaison with US FDA on your behalf. Facilitates efficient collaboration and leverages hundreds of combined years of experience of successful working relationships with the agency. US Agent services include strategy, planning, and regulatory/scientific strategic and tactical support for all types of FDA meetings with CDER, CBER, and CDRH. Facet has served as US Agent for over 150 applications.

Gap Analysis

An objective evaluation of a product in the context of your company's stated goal (e.g., NDA submission). Gaps from a development, medical, regulatory, and commercial perspective are identified, and potential risk mitigation is suggested. Facet has provided gap analyses for over 50 Sponsors.

Strategic Regulatory & Development Guidance

Generation or review of a carefully designed strategic and tactical regulatory plan (clinical, nonclinical, CMC, and procedural activities) that is designed meet a specific corporate goal for your product. Guidance can be provided on a program or parts of a program (e.g., nonclinical only), as needed. Facet has provided strategic regulatory and development guidance to over 250 developers.

Meeting with FDA

A rigorous strategic and tactical process that facilitates FDA meeting success. Facet recommends the best time to hold a meeting with FDA and suggests the optimal meeting type and format, based on the purpose, goals, and objectives of your meeting. Facet also authors strategic meeting requests and background packages, holds active rehearsals, and can serve in a variety of roles at your FDA meeting. Facet has helped over 100 Sponsors navigate the complex meeting process and obtain clear and actionable outcomes.

Medical Writing of Submission Documents

An experienced team of regulatory medical writers who author, QC/format, and finalize documents for your US IND, IDE, NDA, BLA, or device application. Facet has extensive experience preparing FDA meeting requests, background packages, nonclinical and clinical protocols and study reports, investigator brochures, drug substance and drug product sections, IPSP, and physician and patient product labeling. We also author orphan designations, breakthrough therapy designations, nonclinical and clinical waiver requests, and small business waiver requests. All our documents are written with the FDA reviewer in mind. If desired, we also review Sponsor submission documents for scientific integrity and regulatory compliance.

Regulatory Submission Leadership

Strategic and tactical team leaders who champion your regulatory submission project from inception to submission to the FDA. We manage regulatory submissions creation, review and finalization for new drug/biologics applications, medical device applications, special regulatory designations, and more! Facet has successfully submitted thousands of eCTD, paper, NextGen portal, email, and eSTAR submissions to FDA.

We provide fully integrated solutions for small organizations through carefully selected partners who work with small businesses in the same way that Facet does. Our partners can help you with patents, contract manufacturing, nonclinical and clinical study execution, CDISC/SEND data packages, regulatory submission publishing, and ex-US regulatory support.

STRATEGIC STATISTICS SERVICES

Facet's Statistics experts have advanced degrees in statistics and research methodology and over 60 years of combined experience which they have skillfully applied to provide strategic support for over 100 clinical trials. They develop lean and efficient trial designs, select optimal efficacy and safety endpoints, and use simulations to increase trial probabilities of success, all with an eye toward accelerating development.

Today's trial designs and statistical methods are more sophisticated than ever before. While this is beneficial from an R&D standpoint, only the largest companies have statisticians in-house who are well versed in complex trial designs and statistical methodologies. Companies without expert statistical support are less likely to design optimal research and development programs and are more likely to struggle in FDA meetings when statistical questions or issues arise.

At Facet, we believe that small companies need high-impact strategic statistical support to achieve more with less. Using cutting-edge statistical methods, modeling, and simulation, small organizations can improve trial probabilities of success and expedite development to help bring your product to divestiture or to market successfully.

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OUR STATISTICS EXPERTISE

Trial Simulations

Simulations can minimize costly trial failures and reduce development timelines. They can also provide data-driven insights for go/no-go decisions enabling prioritization of resources. Simulations permit Sponsors to make more confident company and product decisions in the face of uncertainty and allow Sponsors to evaluate a range of possible outcomes and plan for success. Facet has performed hundreds of simulations to support trial design decision-making.

Expert Statistical Representation at FDA Meetings

Statisticians play an important role in drug development and in interactions with FDA. They justify trial designs, sample sizes, and statistical methods. Statisticians also address any FDA concerns about study validity and the interpretability of results and ensure that the design and methodology of studies will fulfill regulatory and business requirements. Facet has provided statistical support for dozens of FDA meetings.

Trial Design and Trial Support

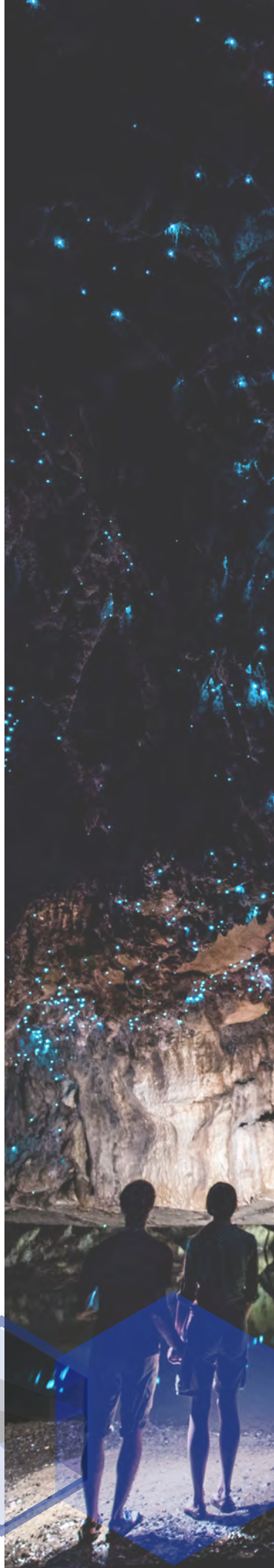
Statisticians develop the statistical framework for trial adaptations, such as sample size re-estimation, dose adjustments, dropping ineffective treatment arms, interim analyses, or early stopping while maintaining trial validity. Traditional and innovative trial designs (e.g., historical control, bucket, adaptive), help small companies to accelerate regulated development. Using our expertise, we write statistical analysis plans, statistical reports, and statistical content for protocols. Facet has provided statistical support for over 50 clinical trials.

CRO Guidance and Support

Facet's statisticians serve as a Sponsor's statistical representative to guide and oversee third-party trial activities. Sponsors obtain peace of mind using Facet statisticians to set the strategy (if desired) and then verify quality, compliance, efficiency, and objectivity in the data management, statistical analysis, and regulatory compliance of clinical trials. Facet's experts have provided CRO guidance and support to over 70 clients.

Validation of Trial Results

Facet provides independent statistical validation of nonclinical and clinical trial results to serve as a safeguard against errors, bias, and non-compliance. Independent validation provides confidence that the results and key messages are accurate, can support presentations, publications, regulatory applications, and can be reproduced by FDA. Facet experts have provided independent validation and key messaging for over 150 clients.



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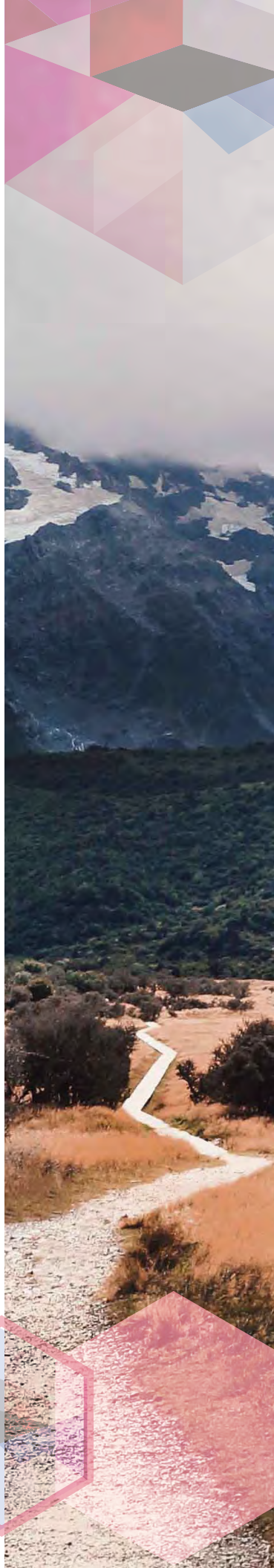
ASSET VALUATION OPTIMIZATION SERVICES

Facet's Asset Valuation team harnesses over 20 years of combined expertise in market analysis, health economics and outcomes research (HEOR, pricing, and reimbursement to help small life sciences companies navigate the critical choices to optimize asset value. Whether your goal is to bring a product to market or prepare for a value-driven divestiture, Facet can help you grow asset value throughout the development life-cycle to achieve long-term financial success.

At the early stage of R&D, companies need to define the clinical and economic value proposition of their product. This early analysis provides the necessary information to help secure investment, guide the difficult nonclinical, clinical, CMC, and regulatory decisions, and drive the publication plan that will influence the future value of the product. Waiting until late-stage clinical development or not updating your strategy as you learn more about your product will lead you to missed opportunities to boost value!

Facet's Asset Valuation team helps you plan for divestiture or post-product market launch strategies for patients, physicians, and payers. Whether you plan to exit early or see your product all the way to commercial launch, our tailored services are designed to transform innovative ideas into market-ready solutions and position you to achieve financial success.



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OUR ASSET VALUE EXPERTISE

Investor Support Pack

Enables Sponsors to know the basic underpinnings of the US regulatory and commercial value of the product at a given stage in development. The purpose of the Investor Support Pack is to help demonstrate why your product is a good investment so that you can secure more money to progress to your next R&D milestone(s). Facet experts have provided key regulatory and business messaging to help over 45 clients secure funding, including private and public grants.

Market Assessment

Enables Sponsors to understand the US market for a product. Includes some or all of the following: Defining the unmet medical need, burden of illness including disease progression/prognosis, the natural history of the disease, current treatment guidelines and competitive landscape, market size and market opportunities, incidence, prevalence, and duration of treatment, efficacy and safety evidence planning, and stakeholder insights and perceived value. Results and expert recommendations from Facet market analyses have helped over 100 clients identify and optimize their development journey.

Asset Value Strategy with Regulatory Focus

Product asset valuation is integrally tied to the regulatory strategy, FDA requirements, and regulatory assets (e.g., orphan designation, breakthrough designation). Combined with a Market Assessment, the asset value strategy enables you to make informed decisions about the best development pathway to increase asset value while moving through FDA milestones. Facet experts have provided market information to help over 30 clients target optimal product indications, secure special regulatory designations, and select clinical trial endpoints.

Health Economics as a Foundation

Facet has used real-world and health economic and outcomes research (HEOR) data to cost-effectively inform clinical trial designs, fill program gaps, satisfy regulatory requirements, and support regulatory decision-making. Develop an Evidence Platform to enhance and showcase the unique value of your product in the post-approval space through strategic analysis of HEOR data. Facet experts have skillfully used HEOR and real-world data to increase asset value for over 25 products.

Pricing and Reimbursement

Understanding target pricing and reimbursement is critical to knowing your asset value early in development. Later in development, optimal pricing and reimbursement strategies are critical to broad market penetration and commercial success. Facet experts have helped over 60 Sponsors take control of pricing negotiations with payers using a strong, data-driven position.

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FOR MORE INFORMATION ABOUT FACET, PLEASE **CONTACT US**!

TEL : +1 610-283-9613
EMAIL : INFO@FACETLS.COM
WEB : WWW.FACETLIFESCIENCES.COM