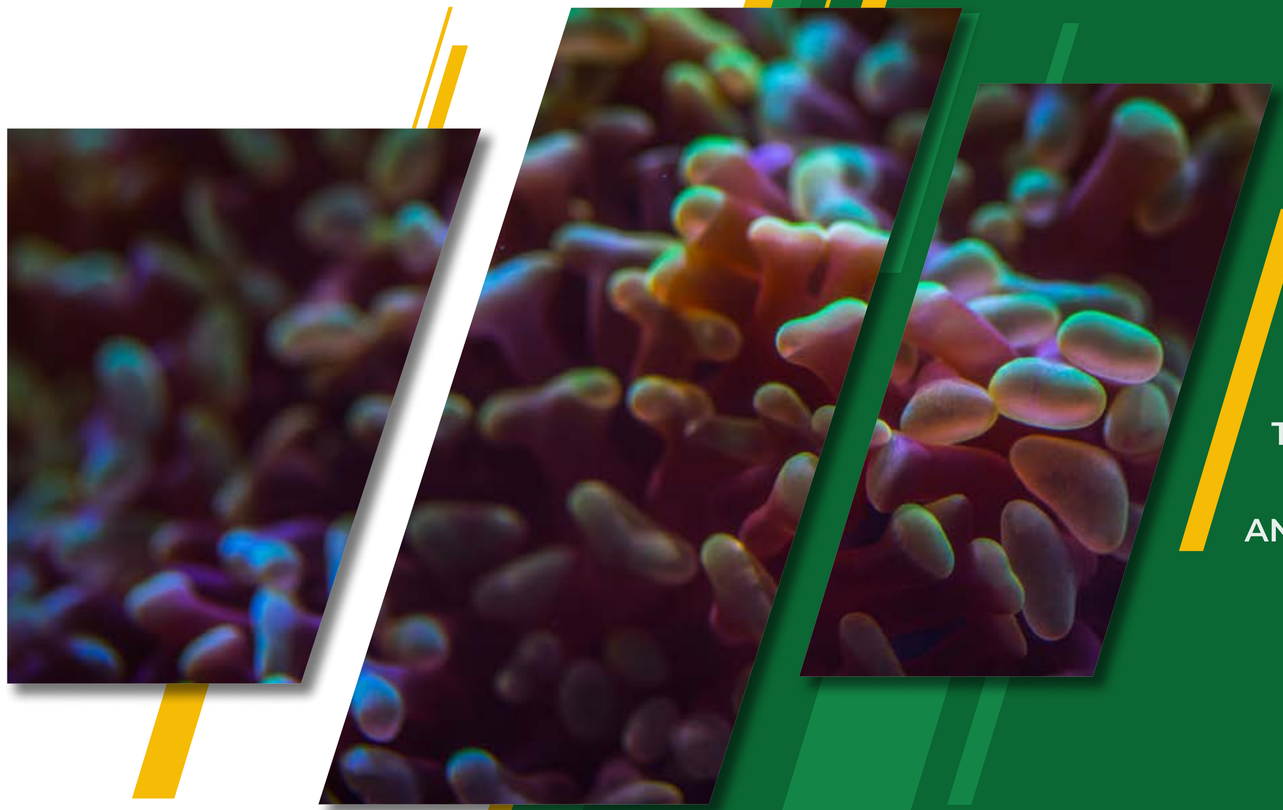
BIOLOGY

2020: A LOOK AHEAD

Part of Proventa International's U.S. Biology Strategy Meetings 2019 InterContinental, San Francisco, CA - 30 October 2019 and Le Méridien, Cambridge, MA - 13 November 2019



ATTENDEE STATISTICS - WHO WENT AND WHAT THEY'RE INVESTING IN

HIGHLIGHTS FROM ALL OUR TRACKS THIS YEAR

TOP STRATEGIC CHALLENGES FOR BIOLOGY, 2020 AND BEYOND

AN EXPERT LOOK AT THE NEXT FIVE YEARS IN BIOLOGY

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INTRODUCTION

Proventa's two U.S. Biology Strategy Meetings recently concluded, with delegates and sponsors in Boston and San Francisco satisfied with both with the unique roundtable format and fantastic networking opportunities on offer.

The events featured expert industry facilitators talking about a wide range of forward-thinking topics in the area. These included an in-depth look at in vitro and in vivo pharmacology, the challenges of DMPK & ADME/Toxicology, and the ever-present difficulty of successfully finding trustworthy suppliers and third parties in outsourcing work.

THIS REPORT - THE FUTURE OF CGT

This report, looking both back over the 2019 Biology Strategy Meetings in San Francisco and Boston and - more importantly - to the future of the sector, contains quality information both for those who attended and those who may attend in coming iterations: it lays out not only statistics showing job titles and the investments of this year's delegates, but highlights from the event roundtables themselves and even our facilitators' impressions of how the biology field will evolve and change over the near future.

We hope you enjoy this report, and take away information that will be of use to you and your company whether you attend our future events or not.

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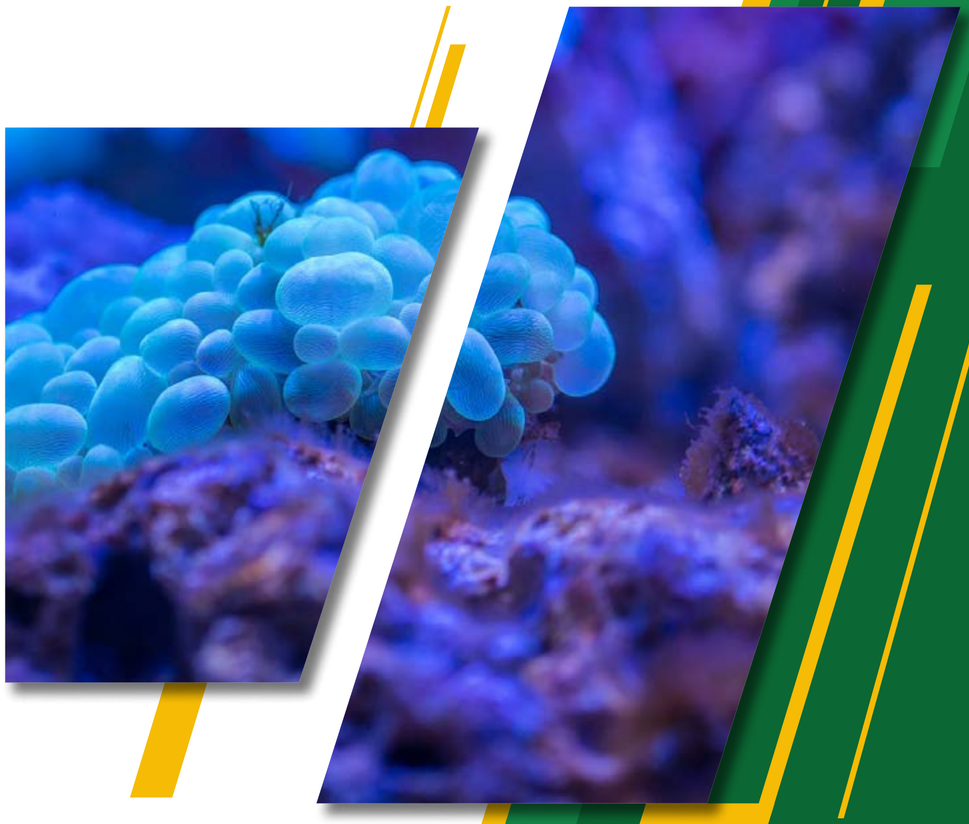

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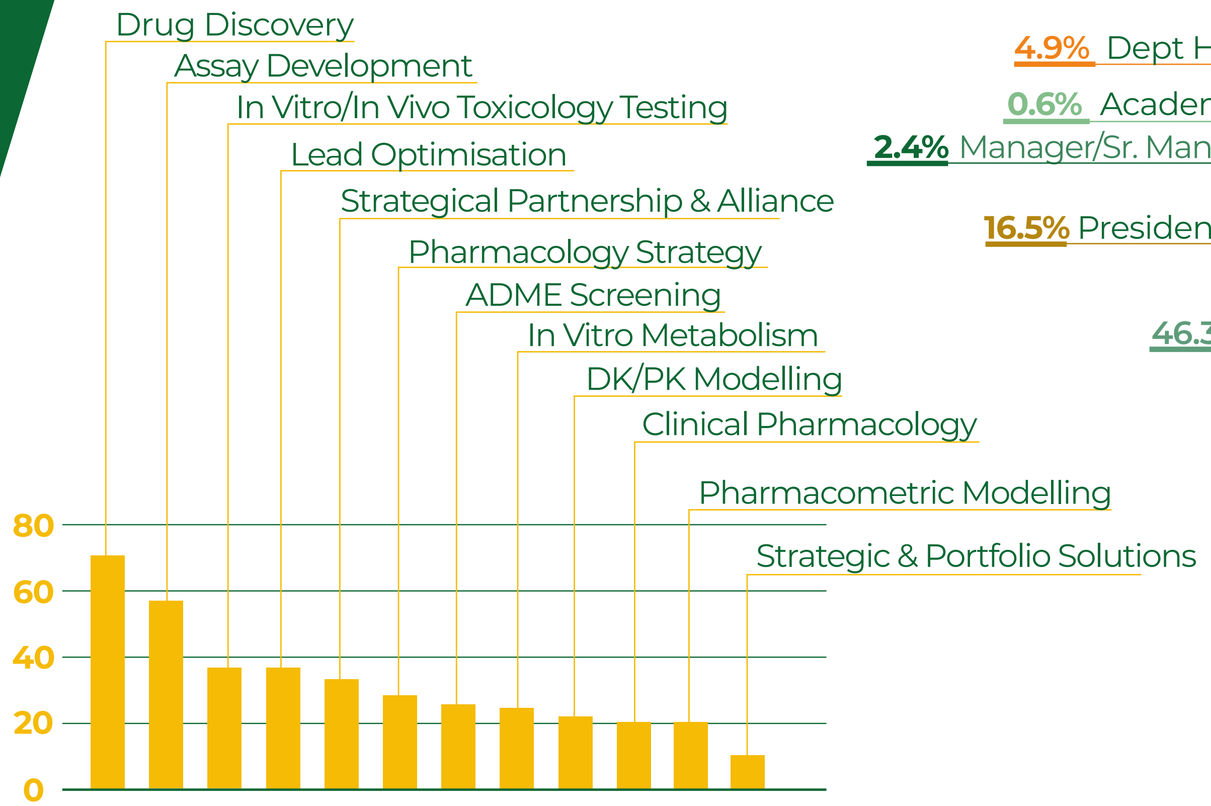
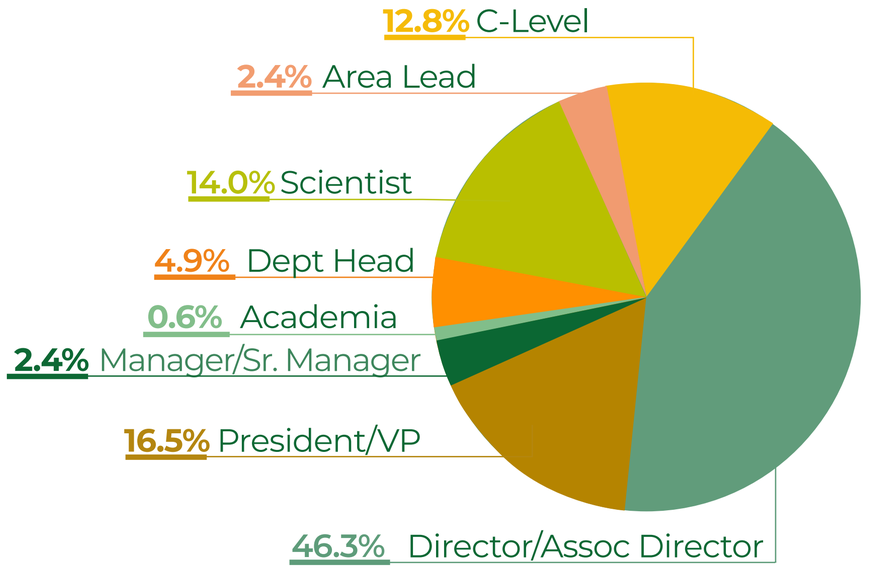
2019 DELEGATES BIGGEST INVESTMENTS



2019 ATTENDEE BREAKDOWN



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2 KEY DELEGATE CHALLENGES

One of the most important resources available to any senior figure in biotech or pharmaceuticals is an understanding not only of the field at present but where the field is going, and the key obstacles that any company in the sector faces.

Proventa International surveyed a number of major players in the field prior to our 2019 events, using expert opinion and insider knowledge to uncover out of the many obstacles on the horizon the major challenges to overcome in the next few years.

MAJOR CHALLENGES - 2020 AND BEYOND

OUTSOURCING AND PARTNERSHIP

The biggest challenge facing delegates, according to Proventa's survey, involved the different elements of outsourcing work and choosing third-party partners: experts said that, among other issues, they had concerns about monitoring the quality of outsourced work, vulnerabilities relating to outsourcing to China, outsourcing crystallography and identifying new strategic partnerships.

TARGET IDENTIFICATION AND VALIDATION

Another major challenge for the coming years revolved around identifying and validating targets: many experts voiced concerns around identifying novel targets, genetic-based target discovery, and NAb assays for new targets.

ASSAY DEVELOPMENT

Assays were brought up repeatedly by experts when discussing future challenges: specific points mentioned included advanced in-vitro assay systems; phenotypic and biomarker assays; assay development for new targets; and DMPK assay refinements.

TRANSLATION

Clinical translation and translational research were big challenges cited by experts for the years ahead. Specific points mentioned included translational toxicity and PK models, gene therapy modelling and translation, identifying translatable preclinical systems to test therapeutic hypotheses, and in vitro and in vivo translation.

PK/PD MODELS

Experts surveyed expressed concerns around PK/PD modelling, largely relating to new models and implementing innovative assays in the space. Outsourcing the work was also mentioned as a potential challenge for the next few years, alongside technologies that could assist with PK profiling.

IND APPLICATIONS AND PROCESS

Issuers surrounding the Investigational New Drug (IND) application were another cause of concern for experts, according to the survey. The speed to IND, as well as filing issues and preparation for the IND process, were all mentioned as common challenges, as was conducting IND-enabling studies.

TOXICOLOGY

Toxicology studies were next on the survey, with many delegates noting that some of their upcoming challenges involved toxicology studies in some form or other. Particular mentions of the process related to in vivo and in vitro toxicology, translational toxicity models, and the field of immunotoxicology.

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DRUG DISCOVERY

The area of drug discovery was next mentioned as a source of challenges for the industry: experts mentioned discovery of biomarkers and antibodies, as well as expanding a portfolio and risk management in early discovery, as areas of concern for the next few years.

COMPLIANCE/REGULATORY

Uncertainty around regulatory requirements, stringent metabolic characterisation requirements from regulators and general submissions all featured as continuing challenges facing delegates, alongside many other fears around the complexity and opacity of the process.

3 A LOOK AHEAD

EXPERT OPINION ON THE FUTURE OF BIOLOGY

Biology is a broad subject, and narrowing down a specific “next five years” in the area seems almost impossible. There are however some certainties - the increasing quantity of big data, for example, and the rapid digitalisation of companies in the area - that can be set out as a given.

As the field advances, it is also important to ensure scientists rethink how traditional drug discovery is performed. Many of the new innovations mean fuzzier datasets, alongside more cell-based, phenotypic, and patient-related multi-parametric datapoints, as scientists grapple with reaching the full potential of the data that is coming in when they don’t know how to focus on new targets or when the information received is singly phenotypic or in terms of a much larger picture than desired.

We spoke to some of the facilitators and experts at our events to find out how the next five years in biology will likely go, and how the industry will react to new technologies and datasets where results are less than black and white.

INTEGRATED PLATFORMS

One facilitator, a VP of biology, suggested that the future would see more integration of biological platforms, such as organ on a chip, organoids and different types of matrices. These would allow scientists to better replicate the physiological environment with multiple cell types, giving higher-density data but less ability to screen a higher number of compounds through it. This trade-off of depth versus breadth will need to be further explored as the technology advances.

IMMUNO-ONCOLOGY

Another major development in science comes from the field of immuno-oncology. One facilitator noted that the field covers half or more of the investments and portfolios currently being worked on by many oncology companies, with money pouring into it. The same is true of the field of oncology with small molecules, which could also affect immune response.

THE MICROBIOME

The VP of Biology noted that while in retrospect the importance of the microbiome is self-evident, the field has until now not had the tools to know its importance. Now that early adopters have pushed this importance forward, a critical mass has been quickly reached, and the near future will see many insights into human health and disease come out of it, alongside treatment options.

DERISKING AND SAFETY

Another facilitator, a VP of early development, noted derisking and safety of drug development as a current area of importance, and particularly the balance of needing safe drugs but also avoiding burdens when creating them. Clarity on regulatory issues will further develop over the next few years, solved by a combination of regulatory and pharmaceutical bodies.

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TARGET VALIDATION

One senior director of biology suggested that, with so many targets failing in the clinic and the steady decline of pharma R&D returns in recent years, target validation is becoming an increasingly vital step in pharma's process. This is particularly important, he said, where companies are working in more genetically-defined diseases where they may have smaller patient populations.

TRANSLATION

He also suggested that another important topic for the years to come is translation - particularly how scientists can translate the biology on the bench to the clinic. While there has been a lot implemented on this in the last five to ten years, it will continue into the future, particularly as companies move more into rare disease. Good translation from dish to animal to patient can improve the success rate of drugs getting approved.

CELL AND GENE THERAPY

When asked about some of the more overhyped innovations for the future, many facilitators mentioned cell and gene therapy and CRISPR. Most thought the area had a great deal of promise, but speculated that it would take longer than currently thought to mature and receive approval.

One facilitator suggested it has not yet entirely made its proof in the clinic as of yet: a great deal is left to do, for example around how to ensure good organ coverage, but with lots of investor excitement he suggested it would only be a matter of time.

Even a facilitator working in functional genomics and CRISPR, who believes the field is growing and potentially very powerful, said it certainly was "over-advertised", receiving much attention but potentially taking a while yet to find its place in biology.

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