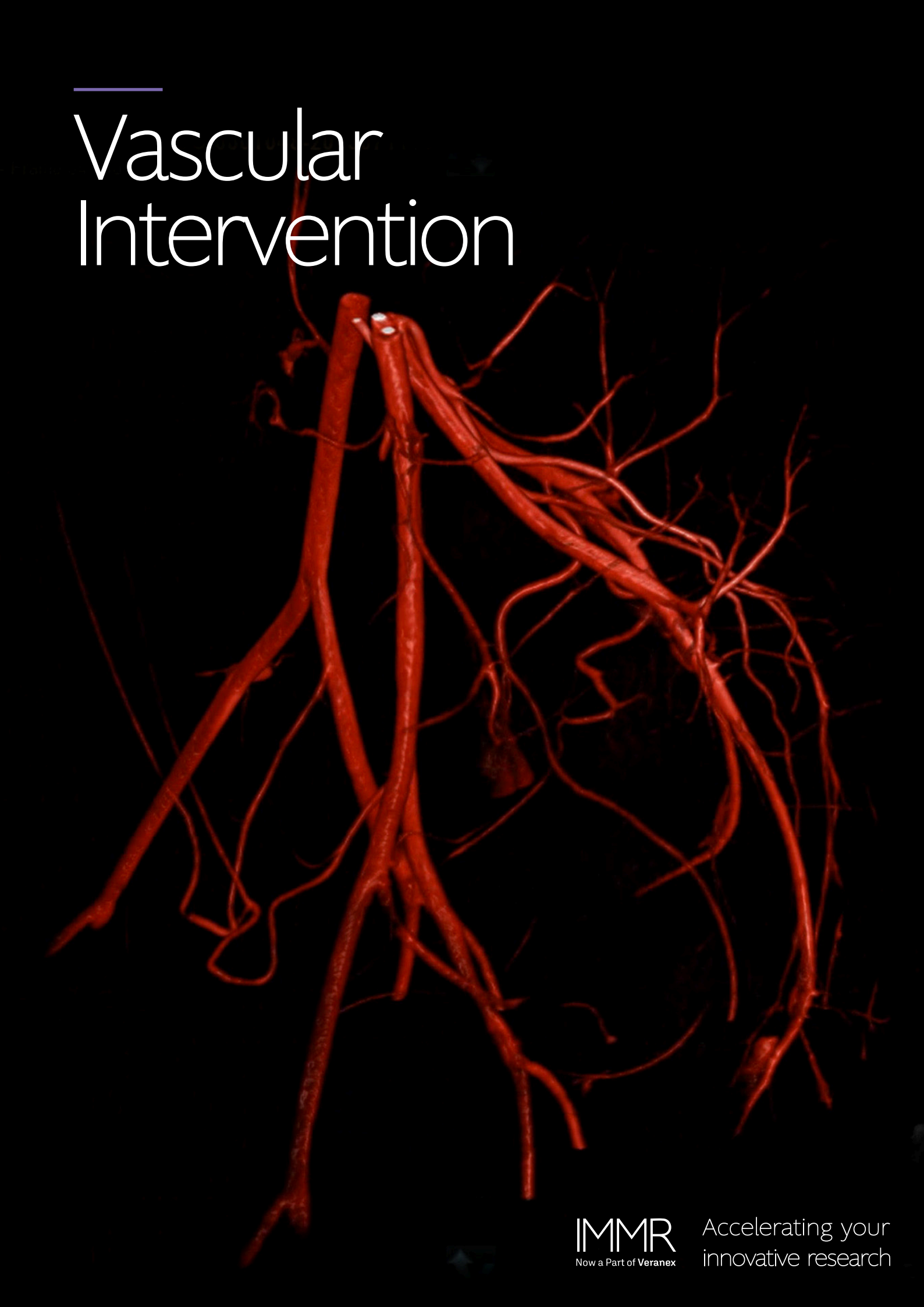
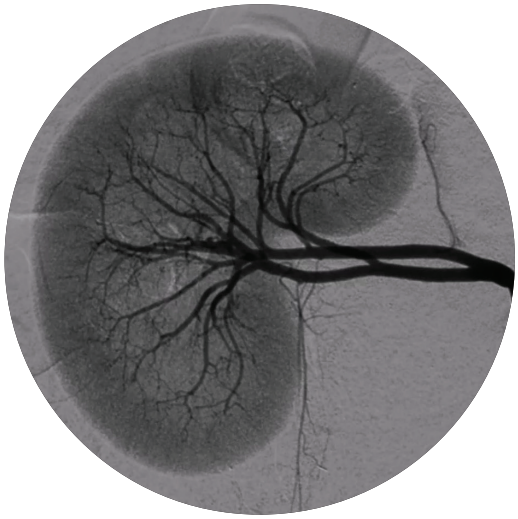
Vascular Intervention



IMMR
Now a Part of Veranex
Accelerating your innovative research



IMMR, now a part of Veranex, is a world-leading, science-driven center of excellence for preclinical research in the important and growing field of Vascular Intervention. The preclinical phase is a critical stage for the development of medical device, biopharma, and biotechnology innovations, beginning at the earliest stages of Proof of Concept and perfection of product design, and continuing through the final assessment of a product's safety and performance. IMMR offers an integrated, comprehensive, state-of-the-art and Good Laboratory Practice (GLP)-compliant portfolio of services that includes **large animal preclinical studies, pathology evaluation and interventional training** for human clinical studies to help propel innovative technologies forward.

IMMR's unparalleled expertise in vascular intervention

Over the past 20 years, IMMR has amassed deep experience in the Vascular arena, working with **Coronary, Peripheral, Carotid** and **Neurovascular** technologies at human scale in normal as well as in pathologic models. Appropriate model selection is a critical success factor for these studies, as there are important species differences in target vessel size and length availability, local inflammatory reactions to biomaterials, and tendency toward early thrombosis and restenosis.

SOME OF THE VASCULAR TECHNOLOGIES WE EVALUATE

> Coronary Stents
> AAA stent Grafts
> Vascular Filters
> Surgical Sealants
> Drug Delivery
> Venous Stents
> Angioplasty Balloons
> Thrombectomy Devices
> Vascular Patches
> Monitoring Devices
> Peripheral Arterial Stents
> Embolization Devices
> Closure Devices
> Bioresorbable Scaffolds
> New Imaging Modalities

EXAMPLES OF OUR PATHOLOGIC MODELS

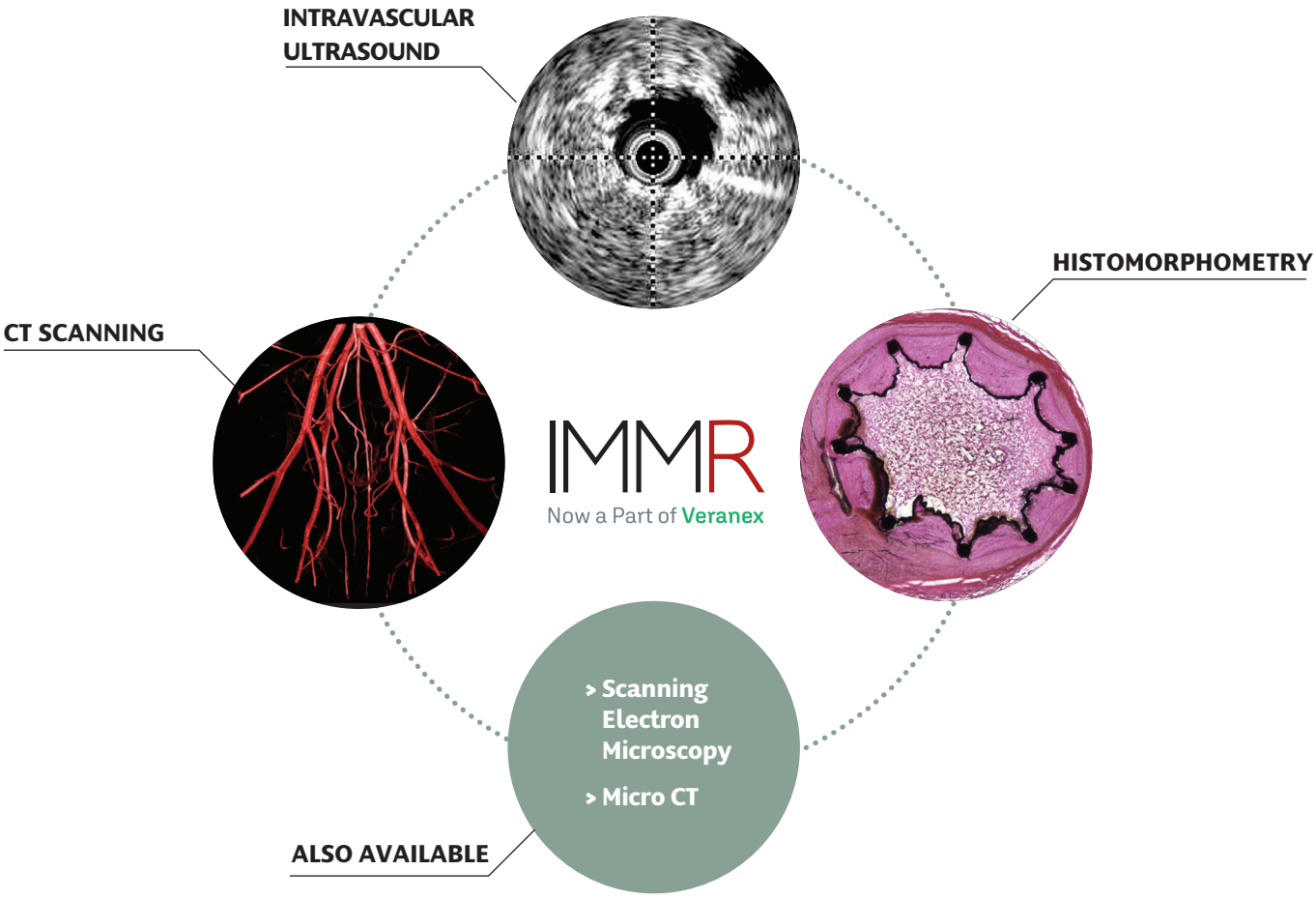
Aortic Aneurysm

Acute Deep Vein Thrombosis

Chronic Deep Vein Thrombosis

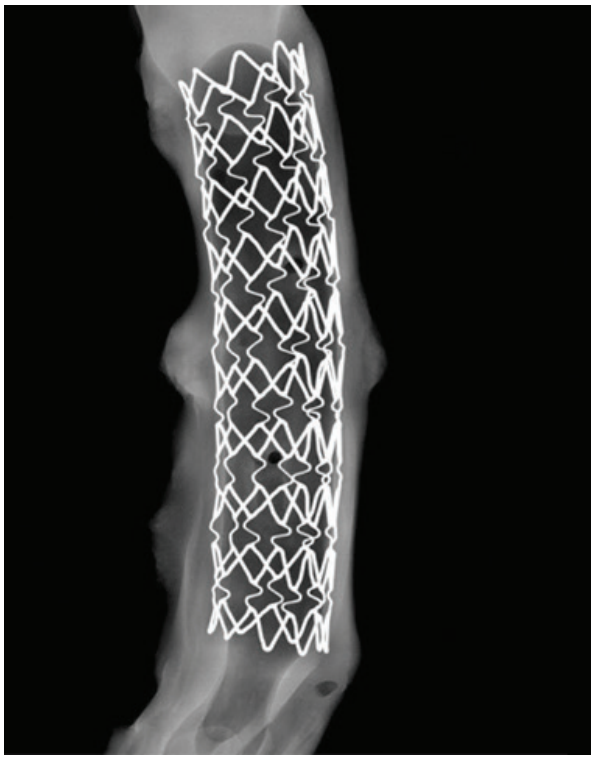
Arterial Tortuosity

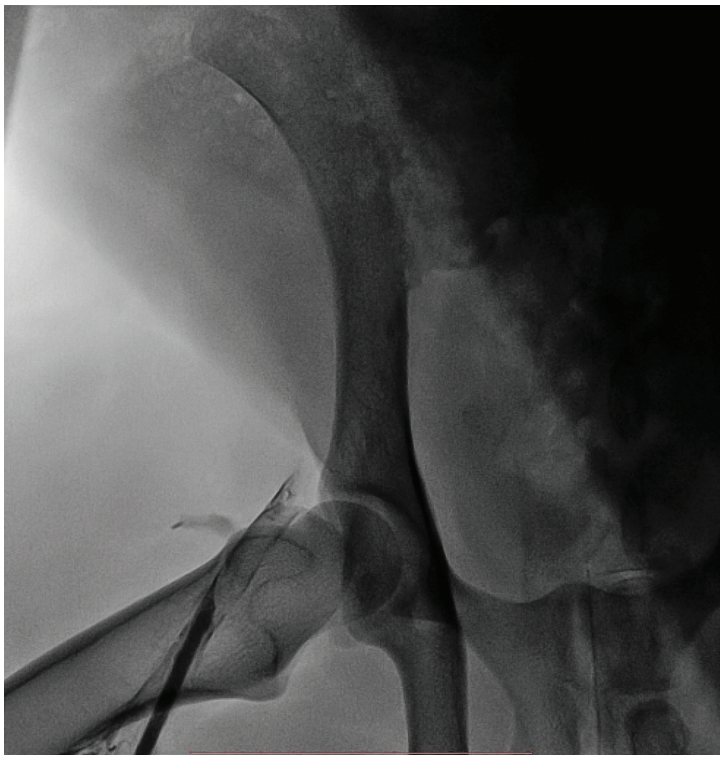
SOME OF OUR IN-HOUSE TECHNICAL CAPABILITIES



OUR PARTNERS HAVE INCLUDED THESE AND OTHER PROMINENT MARKET-LEADING COMPANIES:

AORTYX · Edwards Lifesciences · FIRE1 · LimFlow · Medtronic · MicroPort · Robocath · STENTYS · VETEX medical





PRECLINICAL RESEARCH

plays a pivotal role in the medical technology development process. Studies conducted in large models provide essential information about product design and performance at the scale of human anatomy, and they are invaluable in helping to ensure that human clinical trials with investigational devices can be performed safely, correctly and with compelling outcomes. To deliver this value, studies must be performed under appropriate supervision, according to established standards and in accredited facilities with requisite capabilities and experience. Our clients typically engage us early in their development process, taking advantage of our significant experience across all stages of product development:

PROOF OF CONCEPT STUDIES

Proof of Concept studies are intended to provide confidence to all stakeholders that a new medical innovation has a promising future. In this stage, new innovations will encounter the hostile conditions of the in vivo environment for the first time. At this point, studies can fail and the project can be shut down if the technology is not handled properly by a team with experience, expertise, and creativity to problem-solve in real time. **At this stage, IMMR interventionalists can help innovators work with rudimentary or incomplete prototypes to successfully collect the data and images they need to satisfy key stakeholders that the project holds promise, including the R&D team, the Board of Directors, and existing and prospective investors.**

FEASIBILITY AND R&D STUDIES

After Proof of Concept has been established, feasibility or R&D studies are conducted to identify and address all inadequacies in product design, manufacturing and delivery or implantation through the evaluation of successive prototype iterations. This further value-enhancing stage permits perfection of the device design until a version of the product is achieved that proves efficient and safe, allowing the design to be frozen. **IMMR provides consistency across the veterinary surgical and technical support teams, high procedure volume capacity, and our decades of experience to help innovators anticipate and correct flaws in a product's design, delivery system or placement procedure with respect to ease of use, navigability, risk of tissue trauma, thrombogenicity and other elements.**

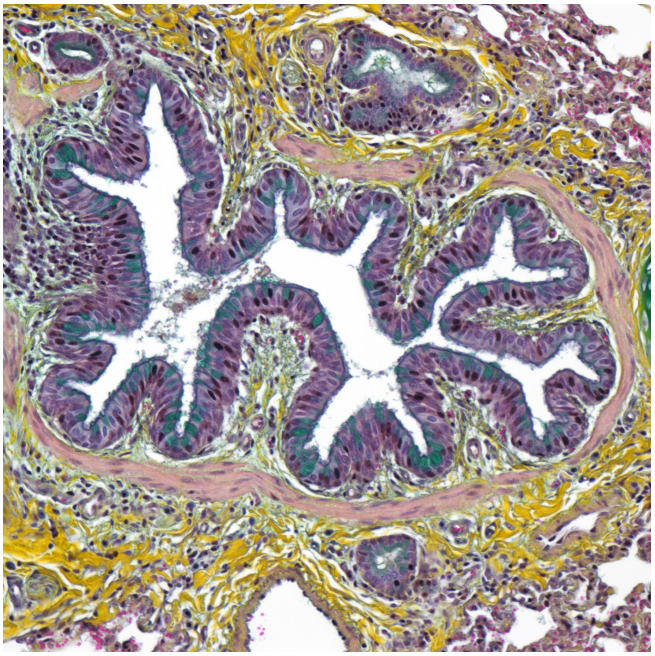
GLP-COMPLIANT STUDIES

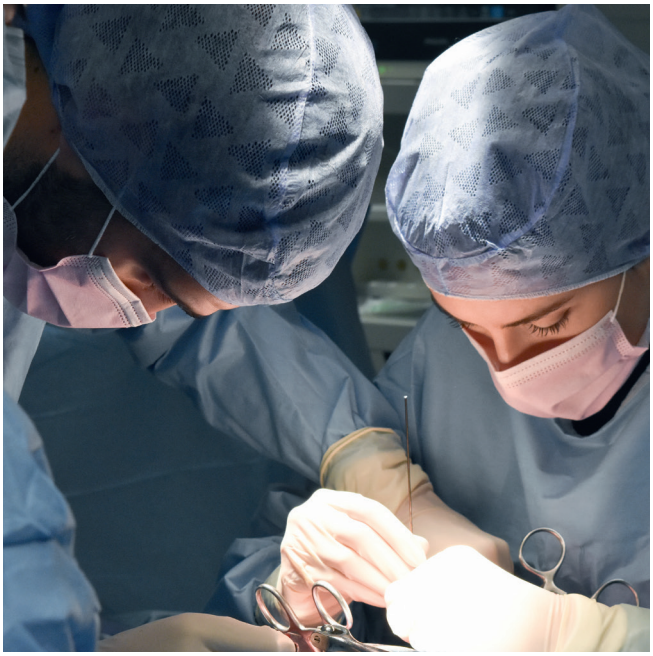
After design freeze, GLP studies are completed to generate data for submission to regulatory authorities to obtain approval for advancing to human clinical evaluation. Studies need to rigorously follow highly specific protocols with complete collection of prespecified data. **IMMR excels in GLP studies for the US FDA as well as regulatory authorities worldwide. IMMR's Scientific Directors can help advise on study designs to meet applicable regulatory requirements, including the use of appropriate study sizes and control groups, predicate comparator devices, thrombogenicity evaluation and possibly using pathological models. IMMR's interventionalists perform procedures meticulously and with consistency. Our Quality Assurance professionals oversee all activities to ensure their regulatory compliance. The result is a scientifically robust, compelling data set that is carefully documented in a detailed and meticulously illustrated study report.**

IMMR EXCELS IN GLP STUDIES FOR THE US FDA AS WELL AS REGULATORY AUTHORITIES WORLDWIDE.

FDA Inspected

PROUDLY, AN aaalac INTERNATIONAL ACCREDITED PROGRAM





PATHOLOGY EVALUATION

IMMR's Board-certified Veterinary Pathologists provide a comprehensive suite of pathology evaluation services. Their presence during all study phases (implant/placement, follow-up, termination, and explant) affords them critical context in which to evaluate gross and histopathology. With specialized embedding, sectioning and staining techniques, our Pathologists can work with a diversity of soft and hard tissues, biomaterials, and metallic elements. **Their reports are praised by clients and regulatory bodies for being clear, comprehensive, informative, and richly illustrated with annotated images.**

INVESTIGATOR TRAINING

The final yet equally crucial stage of the preclinical phase is the training of the medical team that will first use novel, innovative technology in the treatment of patients. Training cases serve as a full rehearsal of all elements of the placement and delivery procedure. Trainees should include not just the interventionalist or surgeon, but representatives of all team members including the imaging specialist and the scrub and circulating nurses who need to act in close coordination to ensure that new procedures can be performed correctly, safely, and efficiently. **IMMR's state-of-the-art facilities provide a familiar environment to investigators who will carry new technologies into the clinical arena.**

IMMRemote

If travel isn't an option, clients can still work with us virtually to complete their preclinical research and advance to human clinical trials as quickly as possible using **IMMRemote**, our secure and advanced telecommunications and data streaming platform. **IMMRemote** allows you to focus on what observations and data are important to you, and all sessions are recorded at high resolution. You can oversee your studies, provide direction, and make first-hand observations all in real time. Any or all of your team and your key stakeholders, no matter where in the world, can all interact with our team and each other, participate in and learn from your study together.

IMMR VASCULAR RESEARCH SENIOR SCIENTIFIC AND TECHNICAL DIRECTORS

LUC BEHR,
DVM, PhD
Co-Founder and Scientific and Technical Director

Dr. Behr completed his training in veterinary medicine, his surgical residency, and his MSc and PhD degrees in stem cell research at prestigious institutions in France, as well as an externship at The University of Missouri College of Veterinary Medicine. He joined IMM Recherche in 2001 and became a Co-Founder and Scientific Director of IMMR following its spin-out as an independent company in 2003. Dr. Behr is a recognized thought leader in preclinical science and the design of surgical and transcatheter medical devices, having helped hundreds of small and large companies to innovate sophisticated medical technologies and implant procedures, and to navigate the complex regulatory environment that governs preclinical research.

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NICOLAS BORENSTEIN,
DVM, PhD
Co-Founder and Scientific and Technical Director

Dr. Borenstein completed his veterinary medical and surgical training in Paris and in Fort Collins, CO in the US. He completed a Master of Science in Surgical Science with Professor Alain Carpentier in Broussais Hospital, and his PhD with IMM Recherche. In 2003, Dr. Borenstein led the spin-out of IMMR as an independent company as Co-Founder and Scientific Director. He has pioneered surgical and transcatheter preclinical science, is a widely published author of research articles and textbook chapters and has served as a reviewer for multiple peer-review journals.

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LAURENCE FIETTE,
DVM, PhD, DESAPV, HDR
Head of Pathology

Dr. Fiette completed her training in veterinary medicine, Board certification in Veterinary Pathology (DES) and PhD in virology at prestigious institutions in France. Prior to joining IMMR in 2016 as Head of the Pathology Division, she worked at the Institut Pasteur in Paris as an Experimental Pathologist in the field of animal models of human infectious diseases and cancer, and she also created a platform of Pathology for research at the Faculty of Medicine in Geneva. Dr. Fiette has authored and co-authored more than 50 research articles and book chapters. She is also active in teaching and organizing international scientific meetings in the fields of animal models and pathology.

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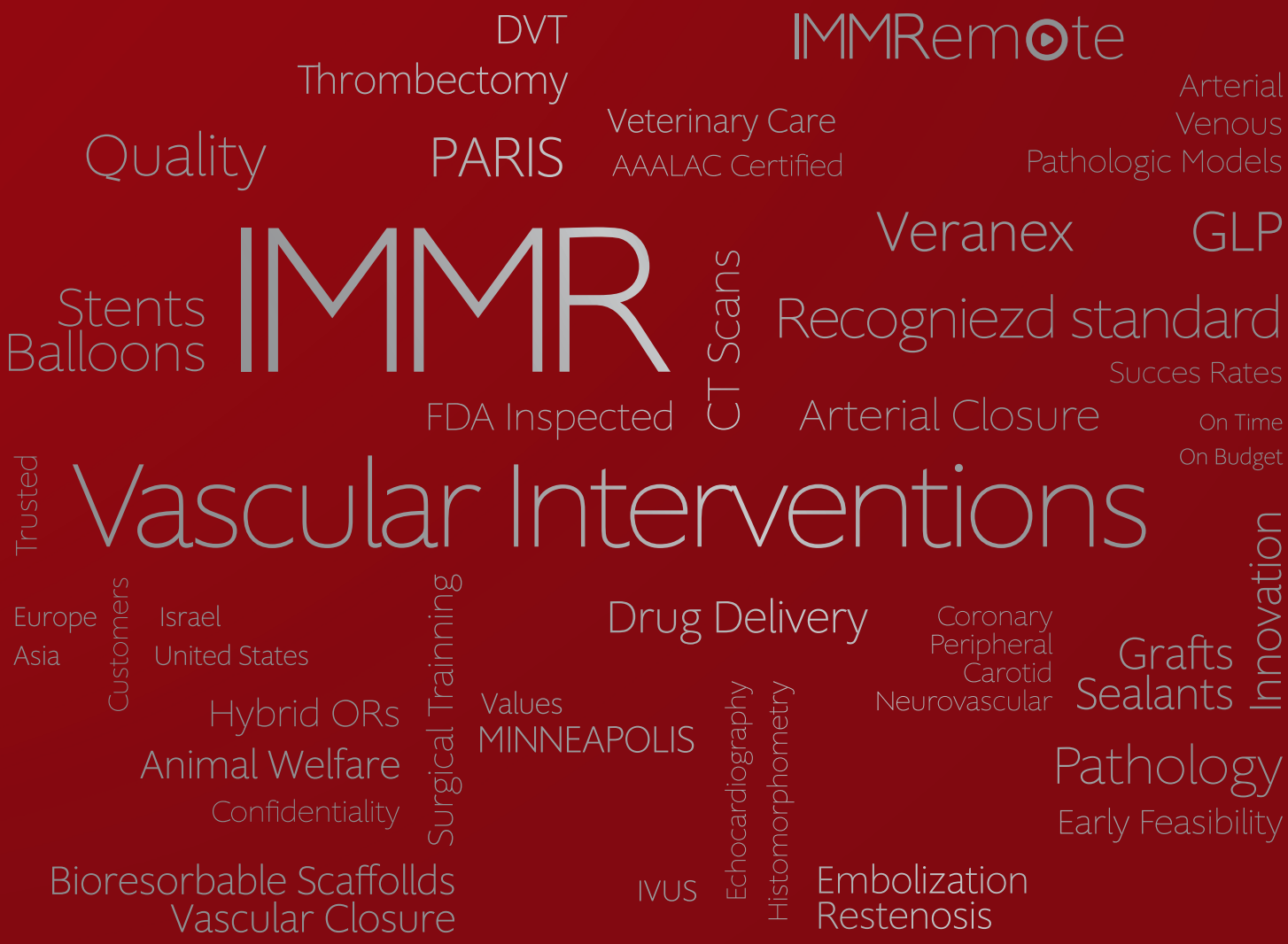

IMMR
Now a Part of Veranex

Editor: Nicolas Borenstein
Photos: © Nicolas Borenstein

Videos and previous newsletters on our services are available online here:
www.imm-recherche.com