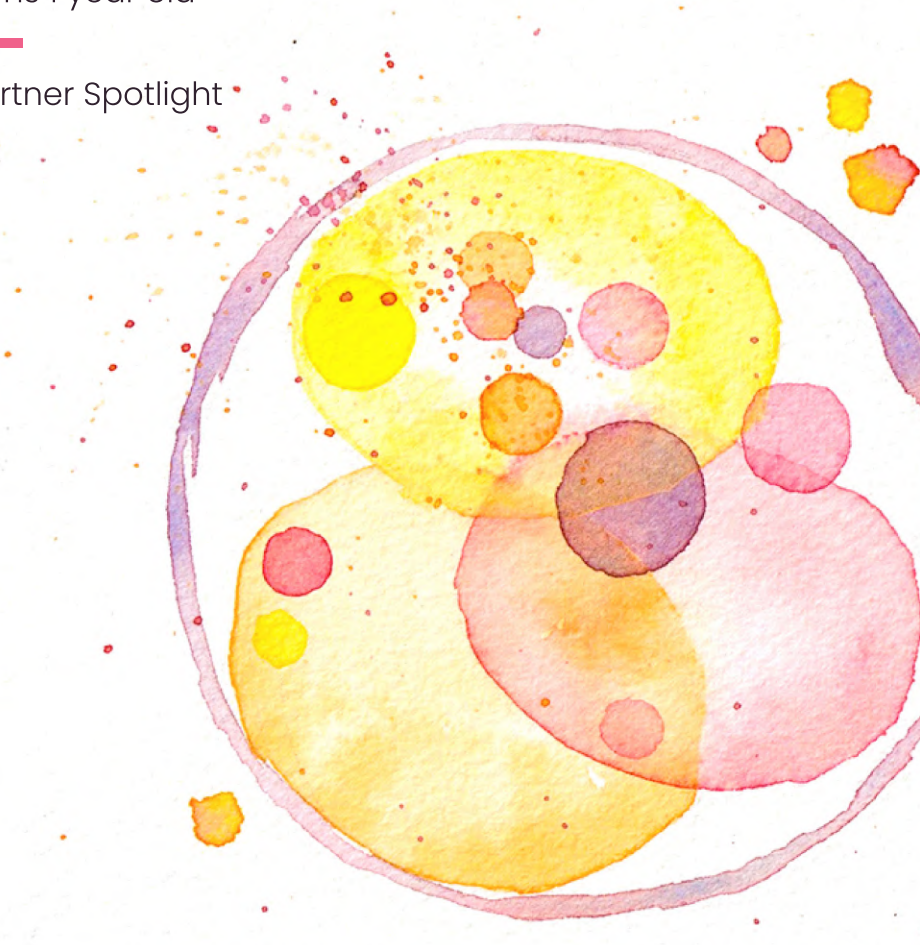
Second Issue / 2021 Q2

Genomic Prediction

GENOMIC

in this issue



Genomic Prediction Newsletter

Second Issue / 2021 Q2

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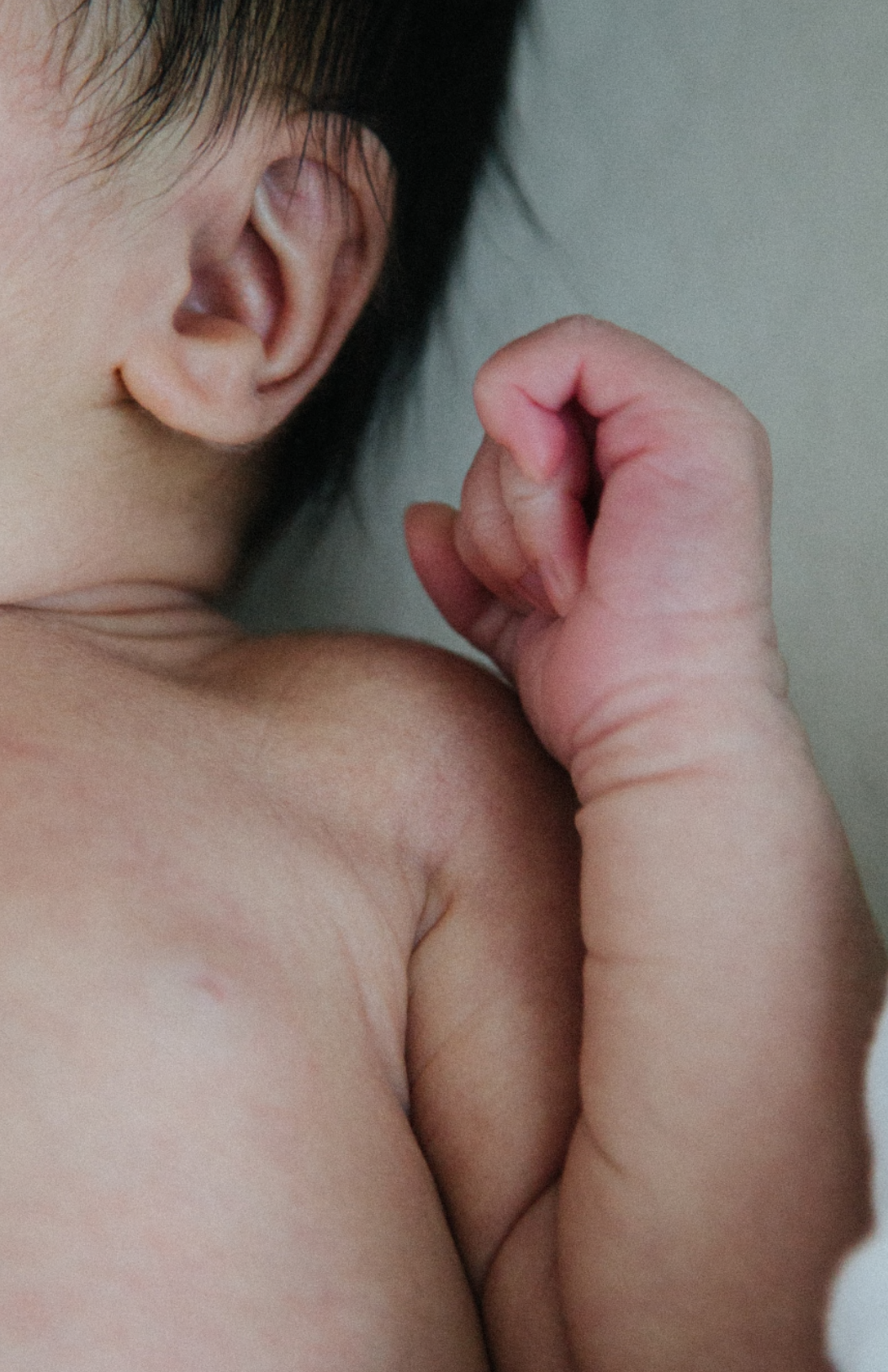
Editorial Board

Cover Art

Watercolor version of IVF baby Elizabeth Carr's embryo, as created by artist by Sara Puig Alier, www.sarapuigalier.com.



Editor's Corner

It's been a year since the first baby, Aurea Smigrodski, was born following embryo preimplantation genetic testing for polygenic disorders, known as PGT-P.

Theirs was the first of over a hundred couples doing PGT-P so far. We've worked from the start to ascertain that these new PGT-P results, now being routinely delivered to IVF couples for the first time, are balanced and helpful. To this end, we are gathering data for the Embryo Health Study, registered on clinical-trials.gov, centered around the investigation of the experience of couples using PGT-P. How these novel test results impact decision-making and psychological well-being is of the highest importance to our mission: helping couples to have healthy babies together.

We are pleased to announce that, despite a very competitive process, we will be presenting 5 scientific abstracts at the American Society for Reproductive Medicine (ASRM) Scientific Congress this October, in Baltimore. One of these papers has been selected for the Prize Papers session, and several more for oral presentation. The honored paper, in collaboration with Columbia University, is about use of the high density LifeView platform to provide a high-fidelity, deeply granular analyses of research embryos edited to remove whole chromosomes using CRISPR technology.

We are also proud to announce that ASRM's agenda will include an oral presentation by Dr. Klaus Wiemer of POMA Fertility, describing the first head-to-head performance comparison between several PGT platforms in IVF history. This study was performed within a single clinic, was demographically matched, and within the same time period. Our platform is one of several PGT platforms being compared head-to-head in this study. The results will include comparison of differences in miscarrirage rates, pregnancy rates, and aneuploidy rates between the platforms.

As we continue to advance the field of reproductive genetics, please know that our door is always open. We pride ourselves on being accessible. Should you be new to Genomic Prediction, or if you are among our current providers, please e-mail us to continue the process of providing patients the highest standard of care.

We wish you well in the coming months ahead and welcome you to Genomic Prediction and the future of IVF!

Laurent Tellier, CEO

Nathan Treff, CSO

Jia Xu, CTO

Elizabeth Carr

Genomic Prediction

First IVF baby in U.S. joins the team

Elizabeth Carr was born December 28, 1981. She is the first baby born via In-vitro fertilization in the United States.

In the media spotlight since 3 cells old, Elizabeth is a passionate advocate for those fighting for fertility rights. From battles over insurance coverage, to educating doctors on how to interact with patients going through infertility treatments, to advice for parents on how to talk to your child about assisted reproductive technologies, Elizabeth is proud to share her voice and story in order to fight for those who may not be able to fight for themselves.

Elizabeth has joined Genomic Prediction as a Patient Advocate, striving to educate, help, and empower patients based on her life experiences within the fertility world.

She has been helping patients and scientists speak the same language, giving presentations to audiences at the United Nations, ASRM, ESHRE, Midwest Reproductive Symposium, and the national infertility association, RESOLVE.

Elizabeth spent most of her career as a journalist covering health-related topics. Her work has been published in The New York Times, The Boston Globe, and a dozen magazines and books.

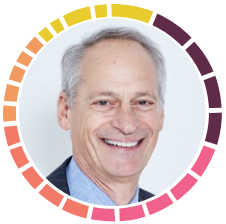
"Over the years, I have had the privilege and honor of hearing story after story about those experiencing infertility, I am so humbled and honored to join Genomic Prediction in their quest to help every IVF family to have a healthy baby,"
she said.

Meet our Scientific Advisory Board

Meet the members of Genomic Prediction's Scientific Advisory Board. Each member brings a unique perspective to our mission of bringing innovation to IVF from molecular genetics, to embryonic developmental physiology, to engaging and educating our patients in a meaningful way.

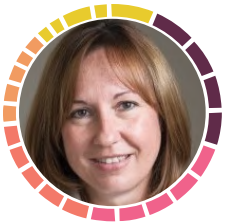
Jamie Metzel, PHD - New Addition

Jamie Metzl is a leading technology and healthcare futurist and Founder and Chair of OneShared.World. A faculty member of Singularity University Exponential Medicine, Senior Fellow of the Atlantic Council, and member of the World Health Organization expert advisory committee on human genome editing, Jamie is also prominent media commentator and science fiction novelist. He previously served in the U.S. National Security Council, State Department, and Senate Foreign Relations Committee and with the United Nations in Cambodia.



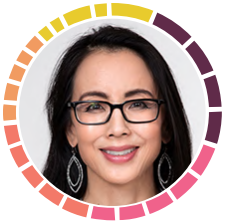
Professor Simon Fishel - Chair

Founder and President CARE Fertility Group and Professor at Liverpool John Moore's University. Physiologist, biochemist and pioneering IVF specialist, Professor Fishel was Deputy Scientific Director of the original "clinical team of four" which opened the world's first IVF unit in 1980, alongside Nobel Laureate Prof Sir Robert Edwards.



Dr. Kathleen Miller

Dr. Miller is Vice President of Laboratory Solutions at MedTech, and Embryology Laboratory Director at IVF Florida and Reproductive Medicine Associates of Connecticut and Michigan. Dr. Miller is well known for research advances in the field of blastocyst culture, and preimplantation genetics as well as a leading expert in laboratory management, quality improvement programs, and single embryo transfer.



Dr. Serena Chen

Dr. Chen serves as Director for the Division of Reproductive Medicine in the Department of Obstetrics and Gynecology at Saint Barnabas Medical Center, and the Institute for Reproductive Medicine and Science. Dr. Chen is widely recognized as a public advocate for education, reproductive rights, and access to reproductive care for all.

Partner Spotlight

Dr. Wiemer has an extensive clinical and scientific background and experience in embryo culture, cryopreservation of embryos, embryo morphology and assessment, co-culture, blastocyst development, IVF lab design, and laboratory supervision. He has extensive experience in all aspects of clinical embryology.

"We are very pleased to work with Dr.Treff and GPCL for numerous reasons: Dr. Treff has always been a leading innovator in our field."

Poma Fertility Laboratory
2021

He received his doctorate in Reproductive Physiology (Embryology) in 1989 from Louisiana State University, Baton Rouge, LA, USA. He trained extensively with Dr. Jacques Cohen at Cornell Medical University. Dr Wiemer has over 30 years of experience directing IVF Laboratories. He also has been an off-site director of several fertility clinics. He currently collaborates with IVF centers in Argentina and Peru.

Dr. Wiemer has published over 80 peer-reviewed articles and book chapters on a wide range of topics in the area of clinical embryology. He has received numerous awards for his research, including the Overall Grand Prize awarded by the American Society for Reproductive Medicine.

His main interests are in embryo culture systems, improving laboratory outcomes and studying the effects of follicular stimulations on subsequent oocyte and embryo quality. He is currently conducting research on developing an embryo morphology grading system that can be used to predict rate and quality of blastocyst development. He is also conducting research in the field of embryo metabolomics as well as the use of AI to predict blastocyst quality and ploidy status. Other projects include various aspects of oocyte as well as blastocyst vitrification systems.

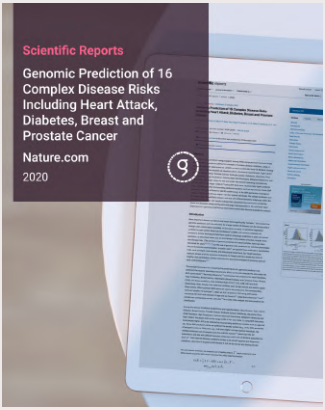
First baby born via PGT-P turns 1 year old

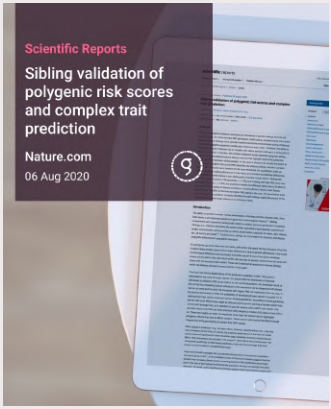
Aurea Smigrodzki was born in the USA last summer. She is a baby at the forefront of science. She is the first baby in history to be conceived with the help of polygenic testing. The test is called **PGT-P**, an abbreviation for "preimplantation genetic testing for polygenic disorders".

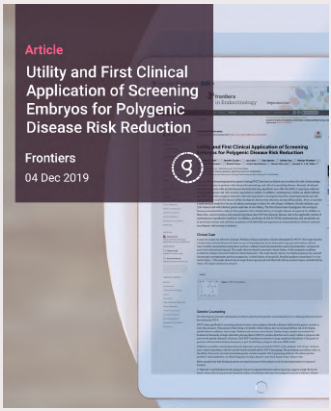
Aurea's father, **Dr. Rafal Smigrodzki**, is a physician. He has seen the impacts of especially heart disease first-hand, and understands the benefits of minimizing these challenges through embryo testing, before the transfer of the embryo.

He said: "I heard about LifeView sometime before Aurea was a glimmer in my eye, I'm always paying attention to research and science in general. I didn't realize that Aurea would be the first baby born using PGT-P. But you know, somebody has to be the first."

Publications







We are dedicated to innovative research and development as well as patient education. Here are some of our current publications. Future issues will highlight the importance of individual papers as we advance the science of reproductive genetics and medicine.

First baby in history to be conceived with the help of polygenic testing. **IVF Babble.** 20201
https://www.ivfbabble.com/on-the-40th-anniversary-of-the-first-ivf-in-the-usa-the-first-baby-elizabeth-jordan-carr-looks-at-how-science-today-has-produced-a-new-world-first-baby-aurea/

Zuccaro et al. Allele-specific chromosome removal after Cas9 cleavage in human embryos. **Cell**. 2020.
https://www.cell.com/cell/pdf/S0092-8674(20)31389-1.pdf

Paulson and Treff. Isn't it time to stop calling preimplantation embryos "mosaic"? **Fertility and Sterility Reports.** 2021
https://www.fertstertreports.org/article/S2666-3341(20)30096-9/pdf

Treff. Polygenic risk scoring in the human embryo: reproductive genetics, final frontier? **Fertility and Sterility Science** 2020
https://www.fertstertscience.org/action/showPdf?pii=S2666-335X%2820%2930013-6

Marin et al. Preimplantation genetic testing for aneuploidy: A review of published blastocyst reanalysis concordance. **Prenatal Diagnosis** 2020.
https://obgyn.onlinelibrary.wiley.com/doi/epdf/10.1002/pd.5828

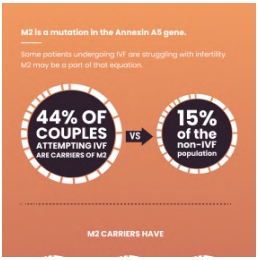
Treff et al. Preimplantation genetic testing for polygenic disease relative risk reduction: evaluation of genomic index performance in 11,883 adult sibling pairs. **Genes** 2020.
https://www.mdpi.com/2073-4425/11/6/648/htm

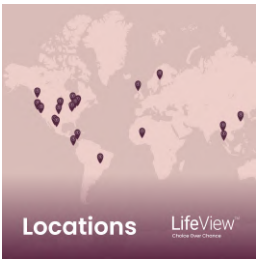
Treff et al. Preimplantation genetic testing for polygenic disease risk. **Reproduction** 2020.
https://rep.bioscientifica.com/view/journals/rep/160/5/REP-20-0071.xml

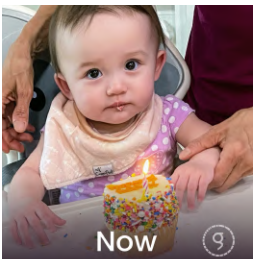
Treff et al. Utility and first clinical application of screening embryos for polygenic disease risk. **Frontiers in Endocrinology** 2019.
https://www.frontiersin.org/articles/10.3389/fendo.2019.00845/full

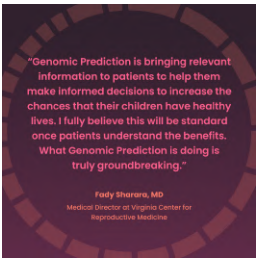
Treff et al. Validation of concurrent preimplantation genetic testing for polygenic and monogenic disorders, structural rearrangements, and whole and segmental chromosome aneuploidy with a single universal platform. **European Journal of Medical Genetics** 2019.
https://www.sciencedirect.com/science/article/pii/S1769721219301016?via%3Dihub

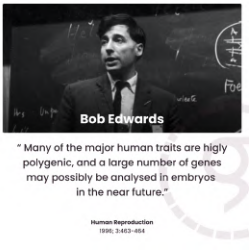
Lello et al. Genomic prediction of 16 complex disease risks including heart attack, diabetes, breast and prostate cancer. **Scientific Reports** 2019.
https://www.nature.com/articles/s41598-019-51258-x

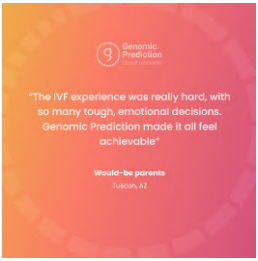












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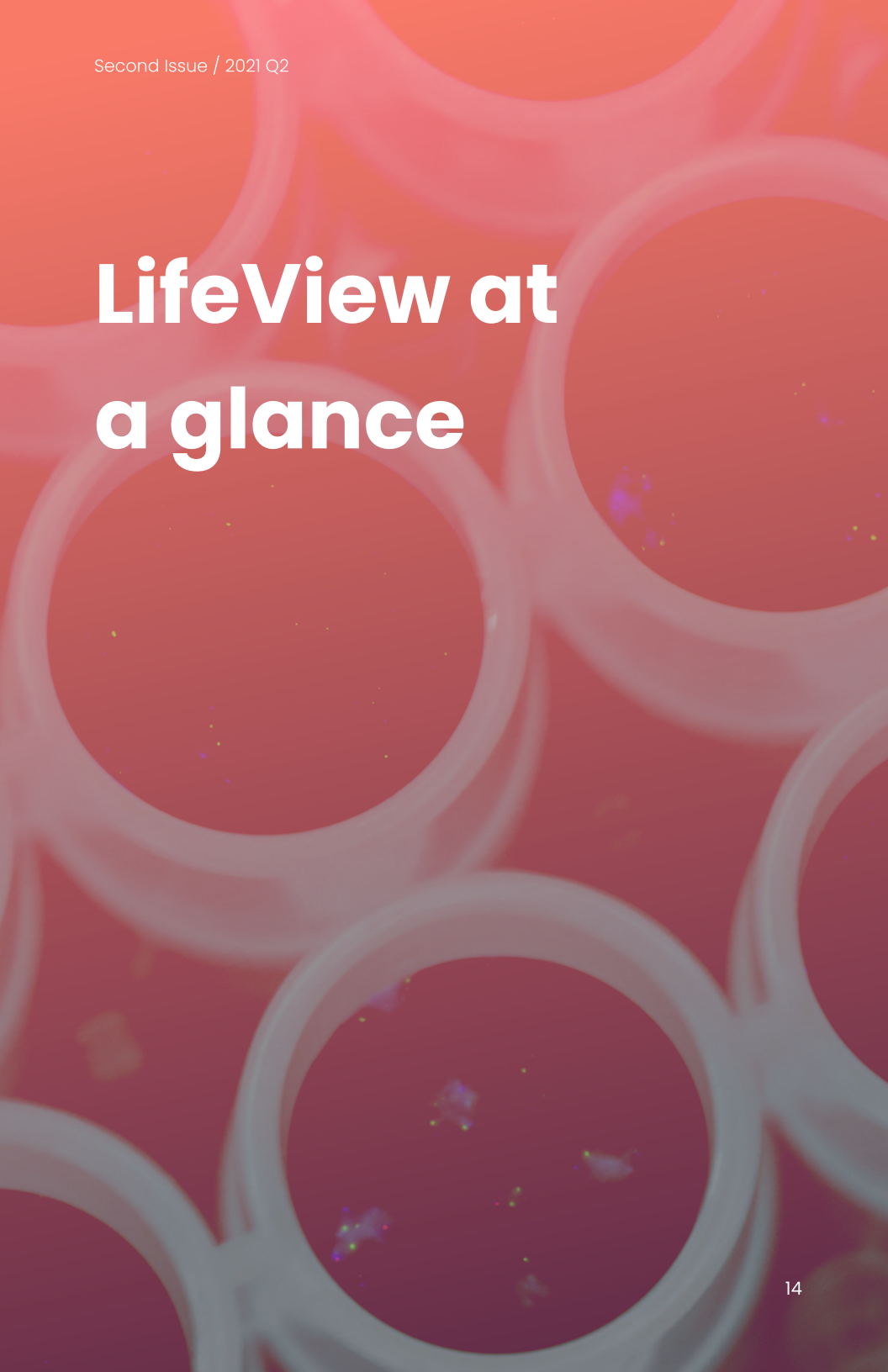
LifeView at a glance



309 Publications

241 LifeView Provider Clinics and Laboratories

26 Countries around the world

5 Registered, ongoing clinical trials

See More

With LifeView

Backed by rigorous preclinical validation and a unique interdisciplinary approach that combines years of experience in molecular genetics and computational biology, LifeView provides a one-of-a-kind machine learning based prediction of genetic abnormalities.

PGT-A

NGS uses copy number data thatcan lead to inaccurate diagnoses (particularly mosaicism) due to the inability to distinguish signal from noise. By **combining copy number and genotyping data**, LifeView provides the most accurate and highest resolution prediction of chromosomal abnormalities in the industry. Fewer false positives mean more embryos available for transfer.
www.lifeview.com/materials#pgta

PGT-SR

LifeView PGT-SR provides more than 5 times the resolution of NGS based testing and the ability to **distinguish between balanced translocation carrier and truly normal embryos**
www.lifeview.com/materials#pgtsr

PGT-M

Rapid workups and broader accommodation mean faster time to pregnancy for prospective patients. By combining linkage-based analysis of several hundred markers with direct testing of the mutation, LifeView PGT-M provides the most convenient, cost effective, and accurate method available.
www.lifeview.com/materials#pgtm

PGT-P

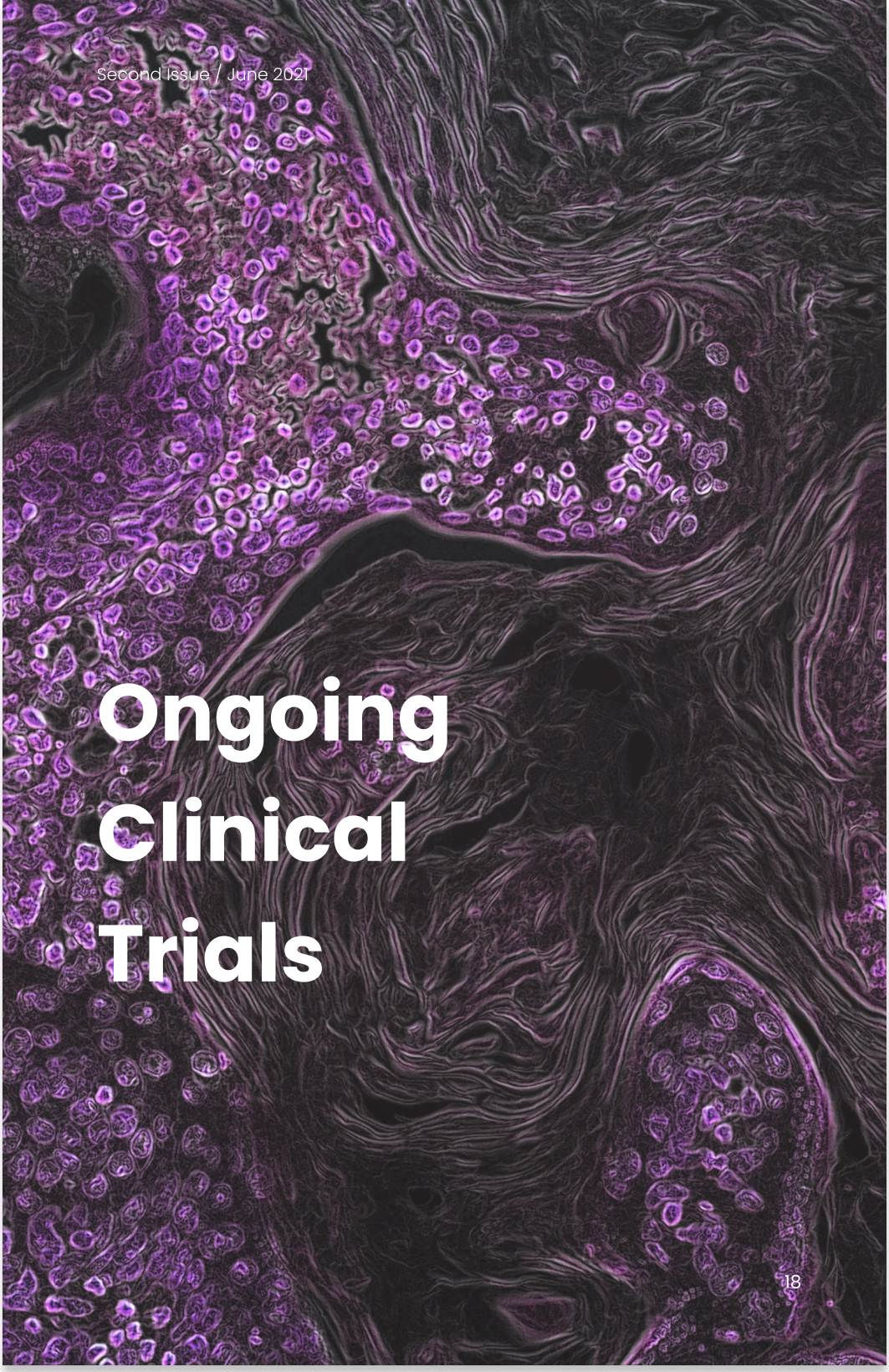
The Embryo Health Score provides a unique opportunity for patients to **rank euploid embryos to reduce the risk of several polygenic disorders.** Importantly, the benefit of relative risk reduction is apparent even when only 2 euploid embryos are available for selection from patients, regardless of family history.
www.lifeview.com/materials#pgtp

M2

Carriers of the M2 Haplotype can be identified using LifeView for M2. Carriers have a higher risk of several pregnancy complications and may benefit from low molecular heparin or LifeView PGT-M for M2 to **improve the chance of reaching term delivery**
www.lifeview.com/materials#m2

PGT-A+

A pioneering upgrade of PGT-A, which includes not only aneuploidy testing, but also the origin of discovered aneuploidies, determining whether they are maternal or paternal.
www.lifeview.com/materials#pgtaplus



Ongoing Clinical Trials

Our commitment to research extends beyond platform development. Contact us to find out how participation in clinical trials with Genomic Prediction Clinical Laboratory can help your patients succeed.

The Embryo Health Study

Patient perspectives on the prospect of reducing polygenic disease risk will be instrumental in future applications of LifeView PGT-P. This study will evaluate decisions made by patients using PGT-A, including the impact of known family history and the number of euploid embryos available for ranking with the Embryo Health Score. Eligible participants will receive free LifeView PGT-P.

The GETSET Study

This multicenter intention-to-treat double blinded randomized controlled trial will evaluate the utility of PGT-A to achieve sustained implantation after a single embryo transfer in women of advanced maternal age (35-40). Secondary objectives include development of non-invasive and cell division origin of aneuploidy analysis methods to better predict mosaicism. Eligible participants will receive free LifeView PGT-A.

The M2 Miscarriage Risk Study

Genomic Prediction has developed a test for would-be parents to identify carriers of the Annexin A5 M2 Haplotype. Carriers have an increased risk of several pregnancy complications. However, when informed with test results, carriers can opt for either low molecular informed with test results, carriers can opt for either low molecular weight heparin treatment or PGT-M for M2 to improve the chance of achieving term delivery. Eligible participants will receive free LifeView M2 testing.

Visit https://www.lifeview.net/studies for more information

Contact Us

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