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European Biotechnology

Life Sciences and Industry Magazine

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Interview

Pistoia Alliance data manager Ian Harrow on making life science data FAIR for the Age of AI.

FREE EXCERPT

COVID-19

The EU strikes back

Artificial Intelligence
How progress in AI and biology is transforming how we live

Antimicrobials
The pharma industry commits to launch a €1bn VC fund for AMR

Focus Corona
Who will provide the solutions for the pandemics of the future?

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SARS-CoV-2 vaccines will not cure COVID-19

As the race for a SARS-CoV-2 vaccine increases, many people neglect the simple fact that, even if it is found and shown to be safe, it will not cure patients suffering from COVID-19. Once the virus has invaded the respiratory system of a patient, a vaccination is of little help. Moreover, vaccine development is often a very long process, and the production needs to supply doses for several billion people worldwide. Realistically, it will take many years, and it will cost billions of dollars. Until we have vaccinated the world and eradicated the virus, hundreds of thousands of people will likely die from COVID-19. That is why we need antiviral drugs in addition to vaccines. And, we need them quickly to treat severe COVID-19 cases and save lives today.

DR THOMAS SCHIRRMANN is the CEO of YUMAB GmbH and CORAT Therapeutics GmbH in Braunschweig, Germany. He is a biochemist by training and completed his PhD in immunology. He worked as a scientist and research group leader for 20 years and published more than 70 scientific articles in the fields of immunology, immunotherapy, and antibody technologies. In 2012/13, he founded YUMAB, which is dedicated to antibody drug development. In May 2020, YUMAB spun out CORAT Therapeutics to bring a fast-track COVID-19 antibody program to clinical trials.

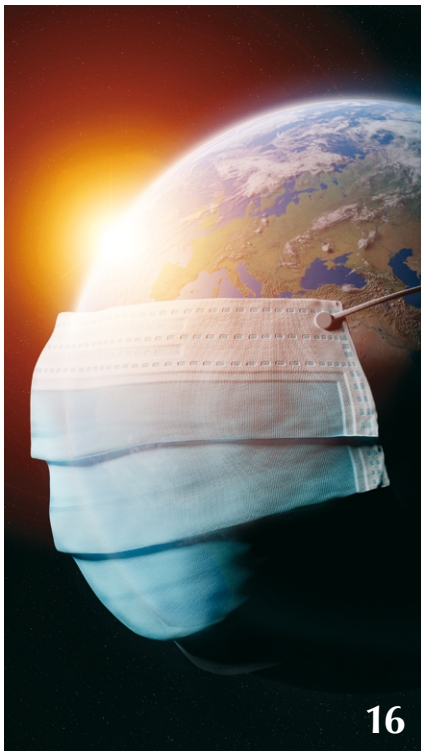
The development of novel drugs can take more than ten years from research to market. On short notice, the pharma industry tried to repurpose existing drugs, but many of them showed no significant benefits so far, with some even worsening the patient's condition. Some recent trials demonstrated moderate progress in ameliorating inflammation symptoms in later stages, or interfering with the virus replication to improve the prognosis for patients, but none have yet the ability to stop the virus from infecting host cells. The high financial risk of new drug development and the uncertainty of the COVID-19 "market" led many players to postpone decisions. However, there is another hope in the battle against COVID-19. When our immune system responds to the infection, it generates a valuable resource for an antiviral drug – our own antibodies that neutralise the virus. Serum from convalescent donors achieved some positive effects, but this is a quite limited and undefined resource. The better alternative would be a recombinant, fully human, virus-neutralising antibody. This type of molecule could even reach the clinics much quicker than other drug types. Fully human antibodies are typically safe and well-tolerated. Moreover, development pathways for antibody drugs are well established, and, significantly, a vast large-scale antibody manufacturing infrastructure is available. Unlike vaccines, neutralising antibodies act immediately without delay and are hoped to cure COVID-19 in later stages, as well. Due to the long halftime, antibodies can be even used as a "passive vaccine", to protect risk groups and health care workers for a few weeks.

So, what is the challenge? Normally, with the neutralising antibody candidate in hand, one needs two to three years to start the first clinical trials in humans. Luckily, due to the pandemics' pressure, it seems that all institutions are doing their best to significantly shorten this process. Thanks to a concerted effort, some antibody development programmes are already on their way, and they have been conceived and approved to take only a few months. For the benefit of the patients that will still populate our intensive care units for years to come, it is important to keep these programmes up and running and financially-supported, even if the first vaccine studies appear promising. ■

Picture: Verena Meier Fotografie

FREE EXCERPT

COVER STORY



COVID-19 therapies: The EU strikes back

More than six months after a novel coronavirus in China first hit headlines, we're staggering under the scope of the pandemic. How much energy and how many resources should we be pumping into vaccines, mass diagnostic testing or new therapeutics? Europe is making plans to bring production of some medicines back from Asia. Just one step in a strategy that could prove perfect or pointless, in a world that is continuing to batten down the hatches. We look at some of the many measures that could make a difference.

INSIGHT EUROPE

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ARTIFICIAL INTELLIGENCE

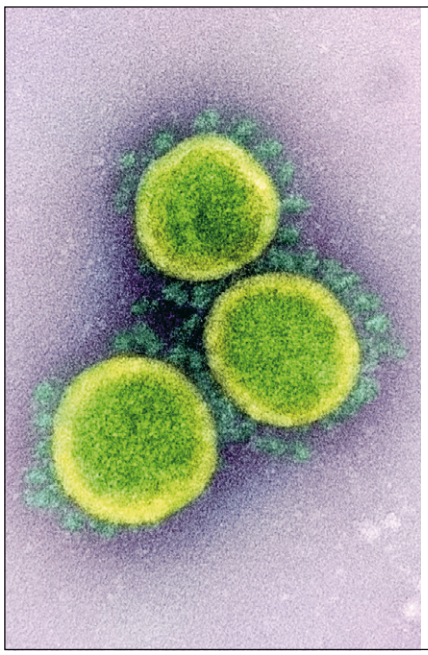
Medicine – a new age

Self-learning algorithms are growing common not only in oncology, and a flood of new publications suggests they already outperform trained experts in many areas of diagnosis. Pharma giants have cracked open the door to machines choosing drug candidates. AI is set to have a huge impact in the coming years on both health systems and patients.

DATA MANAGEMENT

Collecting FAIR data

A survey conducted by the Pistoia Alliance found that AI in the life sciences is still being held back by data issues and skills shortages. We spoke with Ian Harrow, a Consultant at the Alliance, about how to improve data management in the field with help from a new toolkit that makes data Findable, Accessible, Interoperable and Reusable – in brief: FAIR.



FOCUS

COVID-19

EDITORIAL

Positive perception

Will the COVID-19 crisis prove to be a turning point for the acceptance of biotech in Europe? Until recently, a majority of EU citizens only had negative associations with biotechnology – GMOs are a case in point (see p. 6). The novel coronavirus, however, is changing this mass perception dramatically (see p. 26). With the world desperate to put lockdowns behind as quickly as possible, biotech fields are the only ones to offer hope through possible solutions – whether in diagnostics, therapies or vaccines (see COVID-19 Special pp. 16–35).

And when biotech is no longer viewed as a threat, its platform technologies will bear economic fruit more quickly, and much more of it. At least, that's according to a new McKinsey study entitled "The Bio Revolution" (see p. 50). It predicts biotech could have €10 trillion in growth potential by 2040 – but only if it gains wider acceptance. Only then will sustainable methods in areas such as agriculture, AI-supported diagnostics and enzyme synthesis prevail, the study says. With biotech's help, will politicians be able to seize this opportunity to make Europe the most sustainable place on the planet? Or will governments prioritise preserving vested interests – a choice that will be paid for by our children's children? We'll only know when the pandemic has passed. But until then, there's plenty we can personally do to keep the vision alive.

Thomas Gabrielczyk
Editor-in-Chief

Pictures: NIAID (below), pinkeyes/stock.adobe.com (upper left), Pistoia Alliance (middle), BIOCOM AG (right)

Digitally colored scanning electron micrograph of apoptotic cells (burgundy) heavily infected with SARS-CoV-2 virus particles (green), isolated from a patient sample. Image captured at the NIAID Integrated Research Facility (IRF) in Fort Detrick, Maryland (US).

FREE EXCERPT

COVID-19 therapy – the EU strikes back

CORONA CRISIS No one can yet predict with any certainty what strategies will prove most effective against COVID-19. Along with upping production capacities for vaccines and diagnostics, European Union leaders are discussing plans to expand production of the first effective therapeutics. Under the German EU presidency, some production could be brought back from Asia.

For Andrea Ammon, Director of the European Centre for Disease Control (ECDC), the decline in the number of infections with the new SARS-CoV-2 coronavirus in most European countries is only a stage, not a victory. "I don't want to draw a doomsday picture, but I think we have to be realistic. The virus seems to be very well adapted to humans. Now is not the time to completely relax," she said – just before a second wave of infection hit Israel.

Three-pronged strategy

Experts like former FDA head Scott Gottlieb are predicting that a second wave could descend on Europe and the US this autumn, roughly two years before the European Medicines Agency (EMA) estimates a protective vaccine will be available for the broader population. While heavily funded vaccine coalitions have advanced the clinical development of potential jabs, and are busy ramping up capacities for potential mass production (see p. 18), there are a lot of open questions. For example, it's unclear whether any of the current vaccine candidates in clinical testing will be able to prevent virus entry where it's needed – at the mucous membranes in the upper respiratory tract.

According to HIV pioneer and Aicuris GmbH founder Helga Rübsamen-Schaeff "there's no guarantee" that there will even be a COVID-19 vaccine, and no real idea how long development could take. Then there's the question of how long it will protect recipients.

At a virtual expert briefing of the German biotech industry association BIO Deutschland, she suggested establishing a monitoring system by September that includes making diagnostics available in every doctor's practice in the country, in order to to quickly identify infected people who have to be quarantined. She also recommended making therapies available that demonstrably alleviate the course of the two disease phases of COVID-19 – viremia and host immune response.

DR. PETER LLEWELLYN-DAVIS
CEO, Apeiron Biologics AG, Vienna, Austria

? Why is APN01 more specific for the treatment of COVID-19 than other therapies?

! *APN01 is specific to treat COVID-19. It's not a repurposed drug. SARS and SARS-CoV-2 use the same receptor to enter cells. An imitator of the ACE2 molecule, APN01 binds specifically to the virus, inhibits infection, and protects the lung."*

"Realistically, vaccine development will take many years, and will cost billions of dollars," says Thomas Schirrmann. The CEO of antibody developer Yumab and CORAT Therapeutics GmbH told European Biotechnology that "until we have vaccinated the world and eradicated the virus, hundreds of thousands of people will likely die from COVID-19. That's why we need antiviral drugs in addition to vaccines."

Results from the UK's RECOVERY trial demonstrate that approved drugs like dexamethasone could provide a quick lifeline. The cheap anti-rheumatic corticosteroid (US$15/10-day course of treatment) saved the life of one in eight ventilated COVID-19 patients compared to the standard-of-care. On the other hand, the antiviral HIV treatment lopinavir-ritonavir and malaria medicine hydroxychloroquine failed. The first clinical results from IL-6 blockers like Sanofi-Regeneron's saralimumab or Roche's tocilizumab – which might help control late-stage cytokine storms – showed mixed results […]

›› Read the full story in the printed issue.

Pictures: NIAID, NIH (left); ECDC (right)

Patient data grows more readable for machines by the day. Has the Biohacking Era dawned with the advent of Big Medicine? There's no longer a way to get around machine analysis of personal medical information, because it has the potential to significantly improve diagnosis, therapy and healthcare decisions. Under the FAIR guidelines, the biopharma industry is taking an approach to data acessibility in AI-driven research that seeks to strike a balance with protecting patient data.

FREE EXCERPT

My robot doctor – a new age in medicine

DEEP LEARNING The machines take over – it's the backdrop for countless science fiction novels. Will it happen first in medicine? Self-learning algorithms are already helping oncologists analyse Big Data, and a flood of new publications suggest they already outperform trained experts in image-, sequencing- and clinical data-based diagnosis. Pharma giants have cracked open the door to machines choosing drug candidates, and are using them to analyse deficient signaling pathways that lead to cancer and other health threats. So what impact will AI have on health systems – and patients?

In tandem with accelerating developments in computing, data processing, and artificial intelligence (AI)-driven analytics, advances in the biological sciences are fueling a new wave of innovation that could have a significant impact in a wide range of sectors – from healthcare and agriculture to consumer goods and energy. That's the outlook that sets the tone for the new McKinsey Global Institute report "The Bio Revolution". According to senior partner Matthias Evers and his co-authors, transformative "new methodologies, including automation, machine learning, and proliferating biological data are enhancing discovery, throughput and productivity in R&D." Self-learning algorithms that allow both automatic interpretation and comparison of next-generation sequencing (NGS) as well as diagnostic imaging data – and which additionally integrate the current knowledge on coronaviruses – are not just being used to find drugs and targets that could help arrest the current COVID-19 pandemic (see interview pp. 60-61). They also have the potential to improve productivity across the entire diagnostic and therapeutic pipeline.

And some applications go far beyond that. According to the report, in human health alone, at least 45% of the global disease burden could be addressed if existing scientific data were findable, accessible, interoperational and reusable (FAIR) by machines, particularly in an automated manner. Depending on how quickly the technologies are adopted, the authors estimate economic potential among all biologic applications in the next 10 to 20 years of US$2tn-$4tn annually (see Fig. 1, p. 52).

PROF. DR. HARTMUT JUHL
Founder and CEO Indivumed Group, Hamburg, Germany

? How important do you think self-learning algorithms will be to cancer diagnosis in the future?

! *Deciphering the biological complexity of cancer is the future of precision oncology. AI-based algorithms are essential for achieving this goal, because they enable highly efficient drug development and patient diagnostics for personalised medicine.*

Stripping disease to its basics

Just as with human intelligence, there's no single accepted definition for AI. In simple terms, however, it includes all attempts to transfer human learning and thinking to a computer system so it can solve problems independently. Normal, rule-based systems written by programmers are not AI, because they are for example unable to recognise an image of the same person in fog, rain, backlight, with a beard or clean-shaven, etc. AI algorithms, on the other hand, can learn to distinguish people from existing images or data. And they can do the same for tumours or tissues. By applying the rules they learn to billions of new images, they can recognise patterns in Big Data sets. The same applies to other analytical data from the life sciences laboratory. The combination of machine-readable Big Data and its analysis via AI therefore offers hitherto unimaginable possibilities for the life sciences. In the analysis of both structured and unstructured data, self-learning algorithms are far superior to rule-based software […]

›› **Read the full story in the printed issue.**

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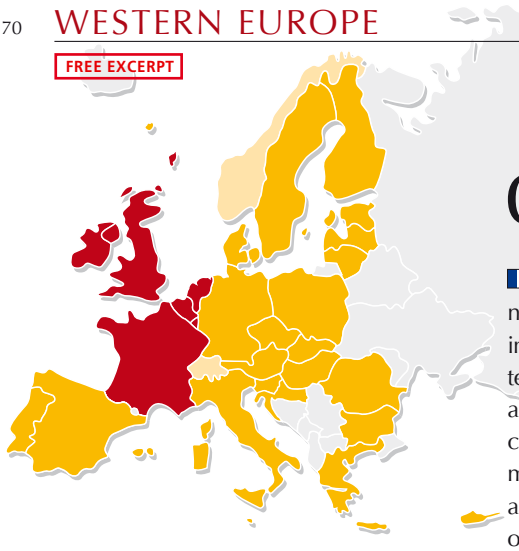


Beam me up

COVID-19 After the chimpanzee adenoviral COVID-19 vaccine ChAdOx1 nCoV-19 – developed at the University of Oxford by Sarah Gilbert and Andrew Pollard and produced by Halix BV – successfully passed Phase I safety testing, AstraZeneca plc acquired the worldwide marketing rights. In Phase II/III trials, which started enrolment of up to 10,260 volunteers at the end of May, the immunogenicity and *in vitro* virus neutralisation capability of the jab, renamed AZD-1222, and the MenACWY 'control' vaccine is now to be compared.

In June, Lyon-based vaccine and gene therapy vector CDMO Novasep SA announced that it will contribute to the production for up to 300 million doses of AZ1222 ordered by the Inclusive Alliance for Vaccines (IAV), consisting of France, Germany, Italy and the Netherlands. But the Alliance will also make AZD-1222 available for other countries in Europe starting from autumn.

In its Seneffe (Belgium) facilities, the CDMO will produce the active substance of the vaccine, while Emergent Biosolution Inc will be AstraZeneca's manufacturing partner in the US. There, AZ-1222 was selected for a €1.2bn funding within US President Donald Trump's COVID vaccine accelerator "Operation Warp Speed" that is aimed to provide 400 million doses until September 2020. Through an EU emergency fund of €2.3bn, the European Commission has the mandate to purchase up to six different COVID-19 vaccines for all member states. ■

Citizens alone at home

ANTIBODY TESTING An international research consortium has found initial evidence that SARS-CoV-2 antibody tests are only useful for population-based analyses. This is no good message for policymakers willing to relax social distancing measures based on immunity passports or antibody titers against the spike- and nucleocapsid proteins of SARS-CoV-2: In SCIENCE IMMUNOLOGY, Juliet Bryant from Fondation Mérieux in Lyon, France, and colleagues highlight the potential power of population-level serological, or antibody testing to provide snapshots of infection history and immunity in populations as the COVID-19 pandemic progresses. In contrast, they emphasise the risks of using current serological tests to assess individual immunity to the SARS-CoV-2 virus.

While the World Health Organization WHO recommends restricting such antibody testing to research use only, scientists here argue that these tests – even with moderate sensitivity and specificity levels – could provide highly valuable information to address critical public health questions, such as when to relax stay-at-home orders or school closures.

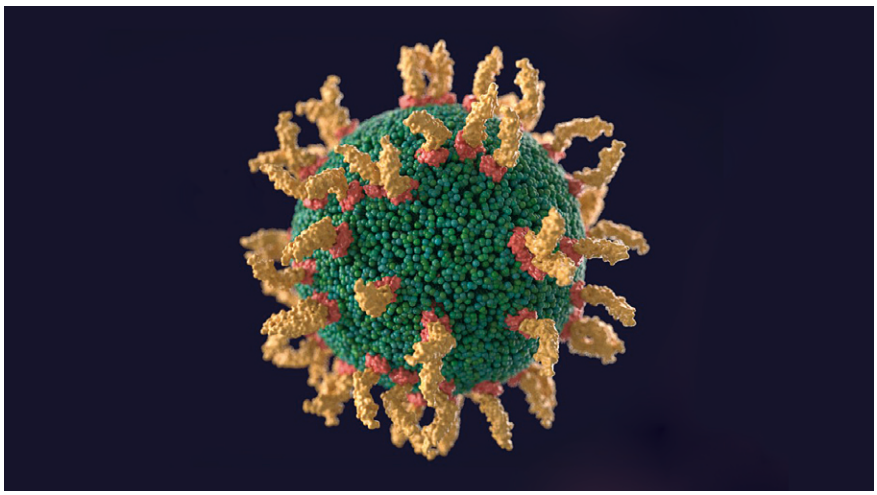
In theory, antibody tests can examine whether or not a person has ever been exposed to a certain virus. However, what SARS-CoV-2 antibody test results mean for protection and immunity is still poorly understood. Thus, as tools to issue "immune passports" that certify an individual's immunity, current serological tests were insufficient and even harmful, the authors write; the tests would, in fact, need near-perfect specificity to provide a reliable gauge of immune protection. By contrast, as tools to ascertain population-level epidemiological trends, and in conjunction with PCR testing, serological surveys could help officials estimate the risk of future waves of disease, measure the impact of interventions, and may provide a less biased picture of infection fatality rate than PCR testing of viral RNA. ■

Picture: SeraNova BV

Struggling for market shares

ONCOLOGY Dutch formulation specialist SeraNovo BV has extended the existing licence contract with US kinase blocker expert Carna Biosciences, Inc. Under a new contract, the companies will co-develop an oral GRAS excipient-based formulation to increase the oral bioavailability of a preclinical pipeline product of Carna BioSciences. ■

New vesicular vehicle



Picture: Evox Therapeutics Ltd

DRUG DELIVERY Evox Therapeutics Ltd has licenced its exosome-based RNAi/antisense RNA delivery technology to Eli Lilly to target selected brain/CNS disorders. Lilly paid US$20m upfront and US$10m per convertible bond. Additionally, Evox Therapeutics is eligible to receive up to US$1.2bn in development, regulatory and commercial milestone payments. Under the contract, Eli Lilly will provide antisense oligonucleotides directed against five, not specified yet, neurological drug targets. Evox Therapeutics will functionalise exosomes in order to achieve brain/CNS targeting, drug loading and analytics and some in vitro assay development, as well as material supply for initial in vivo studies. Lilly will have the right to opt in after preclinical proof of concept and will receive the exclusive right to commercialise all licenced drug candidates. Evox will receive tiered royalties on net sales if a product makes it to the market. ■

Money for CBD developers

FINANCE In June Óskare Capital SAS launched the first European fund particularly dedicated to EU companies in the medical cannabinoid industry: Óskare Fund I targets next-generation cannabinoid therapies and related industry infrastructure, leveraging the expertise and track record of the founding team in medicine, engineering, chemistry, venture capital, and intellectual property.

"I am convinced that Europe has the optimal regulatory and research environment to build the future key players in the global medical cannabinoid industry," said Bruce Linton, co-founder and non-executive Chairman of Óskare Capital SAS and former CEO and founder at Canopy Growth. The fund will invest in a diversified portfolio of companies with disruptive technology and strong barriers to entry. The team is supported by a highly experienced senior advisory board that provides critical expertise and expands its network. Medical grade cannabinoid-based products are already approved and used in Europe to treat conditions such as epilepsy, multiple sclerosis and chronic pain. Now the science and the medical community are driving opportunities in human as well as animal health and wellness. The fund will invest in the entire value chain as well as look to valorise hemp and cannabis biomass for new sustainable material applications. A first investment has been made in Denmark's Octarine Bio. ■

NEWS

Bone growth

Belgian Bone Therapeutics SA has secured €11m to foster the development of its late-stage pipeline candidates. The company said it will use the proceeds to advance two key assets of its allogeneic cell therapy platform, ALLOB and JTA-004, which have both completed Phase IIa tests. The financing operation consists of a €4.75m bridge loan, €1.26m in equity private placement by existing shareholders and, on an as-needed basis, a €4.99m private placement of convertible bonds. Subject to the completion of the current financing operation, supporting the company's further development and strengthen its balance sheet, Bone Therapeutics expects to have a runway into Q1/2021.

Adding compounds

For years, French Carbios SAS has worked to set up a process that effectively depolymerises polyethylenterephtalate (PET) waste, which makes one-fifth of the 359 million tons of mostly non-degradable plastics produced annually. In April, details of the process were published. While mechanical properties are lost during the physico-mechanical approaches applied today to degrade PET, Carbios' optimised bacterial hydrolase/depolymerase leads to over 90% of PET recovery by a process that lasts 10 hours and is to be scaled up by 2021. The company's process provides recycled PET that exhibits the same properties as petrochemical PET and can be produced from enzymatically depolymerized PET waste, thereby contributing towards the concept of a circular PET economy.

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TOPIC CALENDAR

June
› Topic: Green. Circular. Sustainable

July
› Topic: Food, Feed & Nutrition

August
› Topic: Fashion & Textiles

September
› Topic: Financing & Investing
› **Topic: Materials & Packaging**

October
› Topic: Bioprocesses & Technologies

› **Digital EFIB 2020 week: All topics + 1:1 Partnering Meetings**

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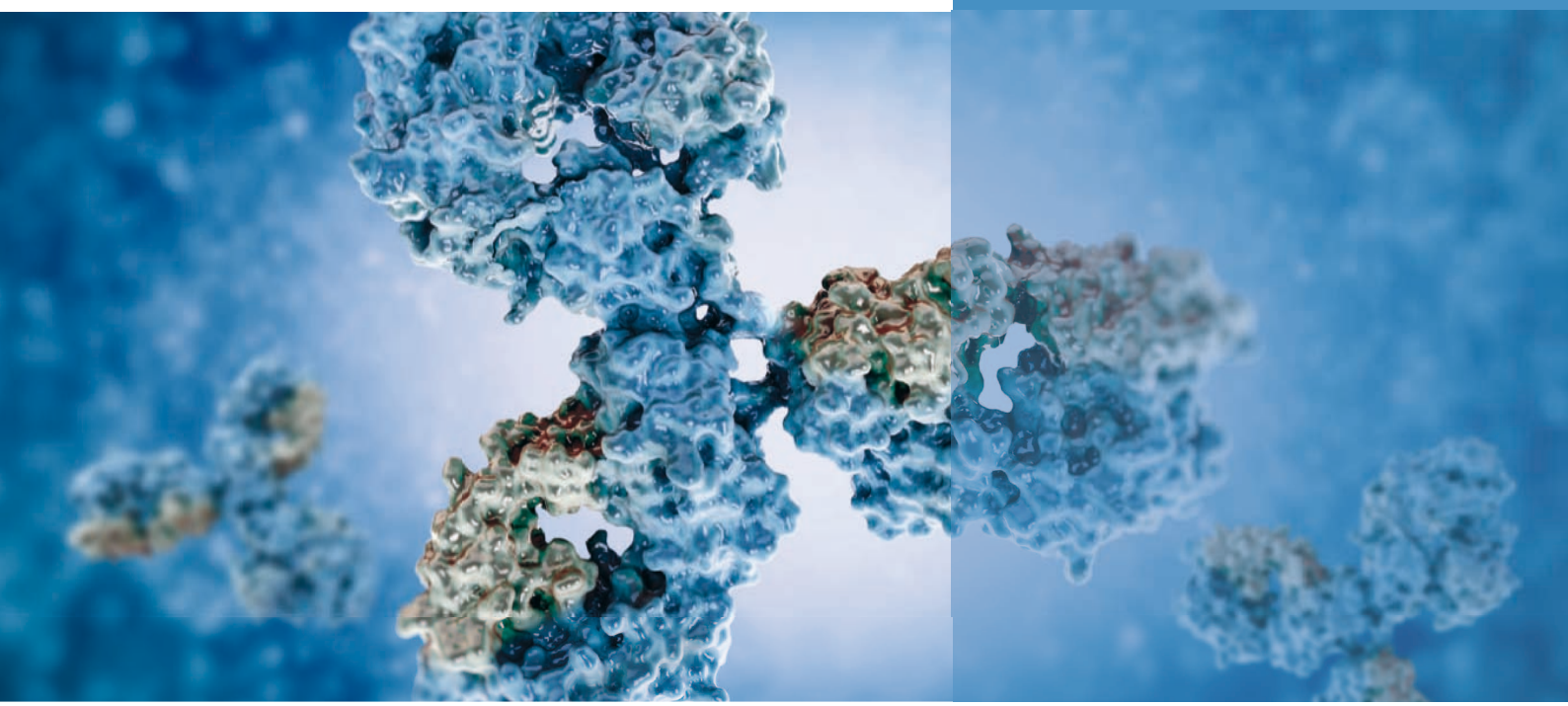

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