octapharma

Annual Report 2020

Remaining strong, resilient and agile

Family owned since being established in 1983, Octapharma is a global healthcare company reaching hundreds of thousands of patients every year.

Our passion drives us to provide new health solutions advancing human life. The importance of this was ever more evident in 2020 with the advent of the global COVID-19 pandemic. We continue our mission to help even more people in need through the strength and resilience of all our employees.

06

"These are unprecedented times. Patients with a lifelong bleeding disorder such as VWD cannot put their treatment on 'hold'. They rely on their medicines."

Contents

42

"The PANS diagnosis was missed by infectious disease specialists and neurologists. In fact, several of the neurologists didn't believe in PANS or PANDAS."

16

"Honestly, I'm afraid of COVID-19, so infusing from home is much safer for me. I don't want to die lying in an intensive care unit on a ventilator."

Chairman and CEO's introduction

"What a remarkable year 2020 has been. The COVID-19 global pandemic has re-shaped much of our lives, but I am proud to report that Octapharma has not only risen to every challenge but continued to evolve and grow.

In this year's report, we speak to some of those patients whose lives are being impacted by our products. The stories of Kerri, Ingrid and young Avery and her mother Carrie remind us of the impact that our products have every day on our patients all around the world. We also explore some of the measures we took in response to the pandemic."

Wolfgang Marguerre
Chairman and CEO, Octapharma Group

From left to right:

Frederic Marguerre
Shareholders' Representative,
President Octapharma Plasma, Inc., USA

Wolfgang Marguerre
Chairman and CEO, Octapharma Group

Tobias Marguerre
Managing Director, Octapharma Nordic AB

As governments and health authorities acted to slow the spread of the virus, we established an operations task force to monitor and respond to the quickly evolving situation. As a result, we implemented enhanced safety protocols in our offices, production sites and plasma collection centres, so that we could keep our employees and donors safe while continuing to provide life-giving medications to our patients.

Early in the pandemic, we recognised that due to its immune-modulating properties intravenous immunoglobulin (IVIg) had the potential to improve treatment outcomes and reduce mortality in severely ill COVID-19 patients. Based on encouraging data obtained from initial studies, we launched a phase III clinical trial to assess the efficacy and safety of octagam® 10% in COVID-19 patients with severe disease progression. This study was approved by the USA Food and Drug Administration (FDA) in May under an Investigational New Drug (IND) application and is due to be completed in the first quarter of 2021.

Apart from this important initiative in COVID-19, we also made good progress with several other clinical trials in 2020.

We commenced the PRO-SID (Primary Infection Prophylaxis with panzyga® in Secondary Immunodeficiency in Chronic Lymphocytic Leukaemia) study to systematically evaluate the efficacy and safety of IVIg for primary prophylaxis for infection control in patients with chronic lymphocytic leukaemia (CLL). In addition, we launched a phase III, multi-centre superiority study to compare the effectiveness of panzyga® 10% versus placebo in patients with paediatric acute-onset neuropsychiatric syndrome (PANS).

The FDA also approved updated prescribing information (PI) for Nuwiq®, our human cell line-derived recombinant factor VIII (FVIII). The updated PI includes immunogenicity data from the NuProtect study, the largest prospective study of a single FVIII concentrate in previously untreated patients with haemophilia A.

9,067 employees
(2019: 9,307)

€2.4bn revenue
(2019: €2.2bn)

€451m operating income
(2019: €424m)

Since its foundation 38 years ago, Octapharma has grown into a truly global company. In all major countries and regions, we are a significant supplier of our life-saving products and a trusted partner of the national healthcare systems.

We continued to invest in our plasma collection capacities to be able to increase the future supplies of our life-saving products for patients. We now operate more than 160 plasma donation centres across our fleet in Germany and the USA.

Despite the significant challenges posed by the pandemic to all aspects of our business, we managed to achieve revenues of €2.4 billion, representing a growth of around 8% over 2019. As I look forward to 2021 and beyond, I believe that Octapharma is well placed to continue to grow in the future.

Wolfgang Marguerre
Chairman and CEO, Octapharma Group

“As I look forward to 2021 and beyond, I believe that Octapharma is well placed to continue to grow in the future.”

Facing VWD during COVID-19 as both a nurse and patient

When Kerri first heard about COVID-19, she did not immediately grasp the severity of the disease or how big an impact it would have on all our daily lives. "Initially, I thought that precautions we take for the flu would be sufficient, but I quickly realised that those would not be enough," explains the 28-year-old nurse at Lucile Packard Children's Hospital in Palo Alto, California, USA.

Kerri – who was diagnosed with the genetic rare bleeding disorder type 3 von Willebrand disease (VWD) when she was just six months old – remembers that "once businesses, schools, workplaces and events started getting shut down or cancelled, I realised COVID-19 was here to stay and probably for a long time". She quickly realised the possible implications for patients like herself.

Bleeding disorders do not stop for COVID-19

While so much of the world has stopped for COVID-19, bleeding disorders have not. In fact, the pandemic has just made them much harder to treat. The additional pressure on resources has meant that healthcare systems and workers have often had to focus elsewhere. Supply chains have been disrupted and the need for social distancing has created its own obstacles. Travel restrictions and health risks posed by the virus have also made it more difficult for many patients with bleeding disorders to get the care they need.

These challenges have made it more important than ever that Octapharma continues to produce and supply medicines for the many patients we serve around the world.

"These are unprecedented times. Patients with a lifelong bleeding disorder such as VWD cannot put their treatment on 'hold'. They rely on their medicines," explains Kerri, who infuses VWF concentrate, wilate®, once a week to prevent bleeding.

"These are unprecedented times. Patients with a lifelong bleeding disorder such as VWD cannot put their treatment on 'hold'."

Facing the challenge

VWD is the most common inherited bleeding disorder, affecting about 1% of the population. It is caused by a genetic mutation that results in the absence or defective production of a critical blood-clotting protein, von Willebrand factor (VWF). VWF plays two key roles in the blood: when a bleed starts it immediately binds platelets together to form the start of a clot, and it also carries factor VIII (FVIII) around the body. Treatment for VWD needs to correct the dual defect of low FVIII and low/abnormal VWF, which can be resolved by intravenous infusions of wilate®.

For Kerri, growing up with VWD was not easy. When she was a teenager her greatest challenge, as it still is, was her heavy ongoing menstrual and breakthrough bleeding. "This was the hardest thing to initially treat and manage, and also the hardest to talk about and explain to other people," she remembers vividly.

Patients with type 3 VWD, the most serious form of the disease, can have severe bleeding symptoms, such as frequent nosebleeds. Women often experience heavy menstrual bleeding that lasts longer than average. They are also at particularly high risk of bleeding during pregnancy and childbirth, with some studies showing a ten-fold increase in the maternal mortality rate for mothers with VWD[1].

Left Friendly and easy-going, Kerri continues to manage everything with her characteristic optimism.

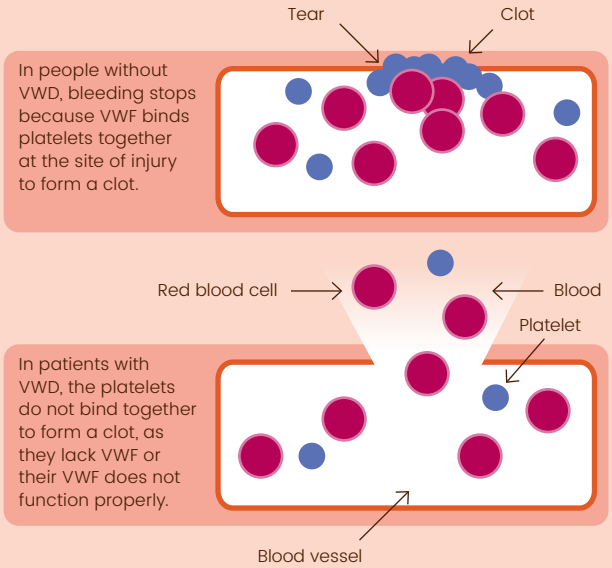
1 Kouides (2016). Present day management of inherited bleeding disorders in pregnancy. Expert Review of Hematology, 9(10): 987-995

Von Willebrand Disease — the scale of the challenge

What is von Willebrand disease?[1]

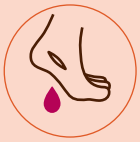
Von Willebrand disease (VWD) is an inherited genetic disorder in which the blood does not clot properly.

Patients with VWD experience excessive or prolonged bleeding due to either low levels of von Willebrand factor (VWF) or VWF that does not work as it should. There are three main types of VWD (types 1, 2 and 3), with 3 being the most serious. Although both males and females can be affected by VWD, women are more likely to be diagnosed than men as they are disproportionately impacted with bleeding challenges due to menstruation and childbirth.

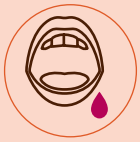


The symptoms of VWD are:


Easy bruising


Prolonged bleeding even from minor wounds


Frequent or heavy nosebleeds


Bleeding from the gums

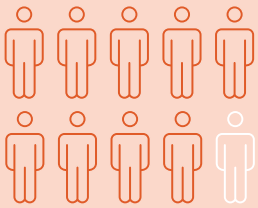

Heavy menstrual bleeding (menorrhagia)


Prolonged or excessive bleeding after childbirth, surgery, tooth extraction or trauma[2]

Challenges faced for diagnosis[3]

1%

of the world population is estimated to be affected, but only a small number of patients are aware they have the condition. It is estimated that 9 out of 10 people with VWD have not yet been diagnosed.



Diagnosis is difficult for several reasons:

- Lack of awareness
- Mild or no symptoms
- Lack of a definitive test result
- Large variation in severity of the disease
- Lack of specialists and resources to diagnose

Treating VWD[4]

Treatment choice is based on VWD type, the nature and severity of the bleeding, and its site.


Desmopressin stimulates the release of stored clotting factors and can be used to treat some type 1 and type 2 patients. However, it is not suitable for all VWD patients.


VWF-containing concentrates are used when desmopressin is ineffective or not indicated.


Antifibrinolytic medications such as tranexamic acid and aminocaproic acid slow the breakdown of blood clots.


Fibrin glue can be used to seal a bleeding site and can be useful after a tooth extraction.


For women with menorrhagia, contraception such as an intrauterine device or hormone medication can sometimes reduce menstrual bleeding.

1 Adapted from https://vwdtest.com/about-vwd/
2 Adapted from https://vwdtest.com/vwd-symptoms-diagnosis/
3 https://www.wfh.org/en/our-work-global/vwd-initiative-program
4 Adapted from https://vwdtest.com/vwd-treatments/

Above Kerri admits there are some limitations but she has learned to adapt.

Determined to make an impact

Kerri is fully committed to the bleeding disorder community. Besides her job as a nurse in the antepartum and maternity departments, she is an Octapharma patient educator, working with us to encourage others living with the disease to become their own advocate, to find their voice and to speak up. "Don't be afraid to say what you need. There are going to be days where you're going to feel awful, or you're going to be moody or angry. Don't be afraid to say what you're feeling," she says.

In more normal times, Kerri would be travelling across the USA to speak at community events hosted by Octapharma, meeting directly with patients. Today, affected by COVID-19 restrictions like the rest of us, her current work location is her living room. "The bleeding disorder community has adapted really well to online events and conferences, and meeting online could be the way we continue to connect even after the pandemic, as it brings people together, no matter their location."

"Of course, I've had my moments of anxiety, fear and despair but I have a great support system – my family, friends and boyfriend – who have all lifted me up."

This too shall pass

Friendly and easy-going, Kerri continues to manage everything with her characteristic optimism. "I try to keep doing the things that make me happy and keep me sane," she explains, before adding: "Of course, I've had my moments of anxiety, fear and despair but I have a great support system – my family, friends and boyfriend – who have all lifted me up."

More than ever, Kerri knows that if it had not been for her loving parents and sisters, things could have been even harder. As she remembers, "Growing up with sisters – Bridget and Molly – was the best. I always had someone around and feel grateful to have them in my life.

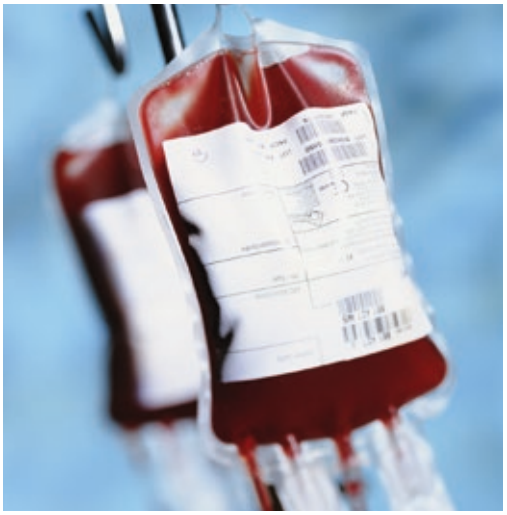
"My grandmother taught me that 'this too shall pass', meaning whatever the situation is that's happening right now, it will end, and you can move on. I've thought about that a lot with regard to COVID-19 and I know it will be true. It may take some time, but I'll be ready when it does."

Patient Blood Management – A new standard of care

Each year, over one million cardiac surgical procedures take place around the world. Like other major surgeries, a significant number of cardiac surgeries require the transfusion of blood components such as plasma, red blood cells and platelet concentrates – something which, by itself, is not without significant risk to patients.

"Although transfusion can be life-saving in many critical situations," says Professor Thorsten Haas, Head of the Patient Blood Management (PBM) programme at the Children's Hospital in Zurich, Switzerland, "it also carries inherent risks, such as infections, respiratory complications and immunomodulation, which can increase patient morbidity and mortality."

Approaches to reduce the number of unnecessary transfusions, such as a PBM programme, are therefore of great interest in improving patient safety. Although a relatively new and evolving concept, increased adoption of PBM around the world is expected given the benefits it offers for both patients and hospitals. These include shorter stays in intensive care units and in hospital, and overall reduced healthcare costs including a reduction in the cost (and volume) of blood products used during procedures.



> **"Although transfusion can be life-saving in many critical situations, it also carries inherent risks, such as infections, respiratory complications and immunomodulation, which can increase patient morbidity and mortality."**
>
> **Professor Thorsten Haas**
> Head of the Patient Blood Management programme at the Children's Hospital in Zürich

What is PBM?

PBM is a multidisciplinary, evidence-based approach to individualising patient care which is now recommended by many medical societies. "The objectives of PBM are primarily patient-centred," says Professor Haas. "Our goal is to use point-of-care diagnostics and targeted bleeding management in order to minimise the use of blood products and improve patient outcomes."

Professor Haas and his team use viscoelastic testing as a preferred option to guide their bleeding management. "PBM is an interdisciplinary approach, which tries to optimise patients' care in terms of blood transfusion. So, our basic goal is to reduce the amount of transfused blood products by lowering the intra-operative blood loss," he explains – in other words, finding the optimal intervention for each individual patient and each surgery. Avoiding blood transfusion can be very straightforward. "In some cases, simply supplementing iron in a preoperative patient suffering from iron deficiency anaemia can remove the need for transfusion," remarks Professor Haas.

Professor Keyvan Karkouti MD, FRCPC, MSc (who is Chief of the Department of Anaesthesia and Pain Management for the University Health Network/Sinai Health System/Women's College Hospital in Toronto, Canada) shares a similar view: "PBM aims to improve patient outcomes and safety by reducing the need for red blood cell and other blood product transfusions and/or by supporting patients' own reserves."

Patient Blood Management

What is Patient Blood Management?

Patient Blood Management (PBM) is an interdisciplinary approach that aims to optimise the utilisation of blood components and consequently improve patient care.

Goal

The goal of PBM is to reduce the amount of transfused blood products by lowering the intra-operative blood loss.

Three pillars of PBM[3]

A multidisciplinary team determines the best approach to:

1. optimise the patient's own blood volume
2. minimise blood loss
3. optimise the patient's physiological tolerance of anaemia

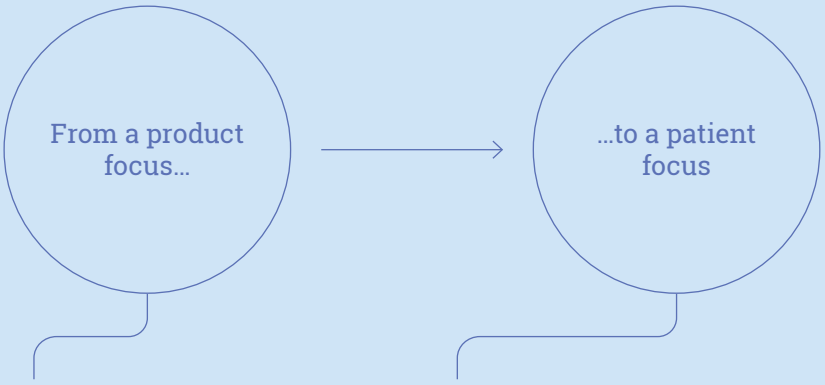
Each pillar involves various practices which can be initiated in the pre-, intra- or post-operative stages of surgery.

2005[1]

The term "Patient Blood Management" was coined by an Australian haematologist, Professor James Isbister, in 2005. He realised that the focus of transfusion medicine should be changed from blood products to the **patients themselves**.

Multidisciplinary[2]

As well as transfusion medicine specialists, PBM involves anaesthesia and intensive care unit professionals, surgeons involved in planned operations, and any other specialists who have a role in diagnostic and therapeutic care.



Blood transfusion aims to replace blood that is lost through surgery or injury. The patient might be given four types of blood product through blood transfusion: whole blood, red blood cells, platelets and plasma.

- ⊕ conventional standard
- ⊖ time consuming
- ⊖ can create waste
- ⊖ associated with potential transfusion reactions

In a targeted point-of-care guided bleeding management setting, only those factors that are needed are supplemented.

- ⊕ Avoids risk of transfusion-triggered adverse reactions
- ⊕ Decreases hospital and ICU stay lengths
- ⊕ Lowers costs

A highly purified fibrinogen concentrate

Fibrinogen is the first factor to become deficient during perioperative bleeding and is often the only deficiency that needs to be treated.

fibryga® is a sterile, virally inactivated, freeze-dried preparation of highly purified fibrinogen concentrate prepared from human plasma. It is indicated for the treatment of uncontrolled severe haemorrhages in acquired fibrinogen deficiency.

1 Franchini, Massimo, et al. (2019), Patient Blood Management: a revolutionary approach to transfusion medicine. Blood Transfusion, 17(3): 191–195
2 Franchini, Massimo and Manuel Muñoz (2017). Towards the implementation of patient blood management across Europe. Blood Transfusion, 15(4): 292–293
3 Adapted from https://www.blood.gov.au/patient-blood-management-pbm#whatispbm

> **"Octapharma is committed to raising awareness of PBM within the medical community, particularly among those anaesthesiologists and intensivists who participate in the different education events supported by the company worldwide."**

Dr Oliver Hegener
VP Head of IBU Critical Care

Targeted point-of-care bleeding management

An emerging area of study is in the use of fibrinogen, also known as factor I, in lieu of whole blood to facilitate clotting. Fibrinogen is a glycoprotein that occurs naturally in plasma and is essential in binding blood platelets to form blood clots. This is critical for stopping excessive bleeding resulting from various traumatic injuries, or during surgery.

Fibrinogen is the first factor to become deficient during perioperative bleeding or trauma and is often the only deficiency that needs to be treated. "Fibrinogen concentrate allows the administration of a precise dose to reach your desired target level. It is immediately available, and it has a really excellent safety profile," confirms Professor Haas. "In bleeding patients with hypofibrinogenaemia, administration of fibrinogen concentrate is always our first choice."

Unlike with rare congenital fibrinogen deficiency, acquired fibrinogen deficiency arises when excessive blood loss and consequent clotting caused by trauma or major surgery uses up fibrinogen reserves in the blood. "If you follow a targeted, point-of-care bleeding management strategy, you can supplement those factors that are actually needed," explains Professor Karkouti, continuing: "Fibrinogen is chief among those that need to be addressed."

"When running a viscoelastic test such as a thromboelastometry, in many cases we can identify that acquired fibrinogen deficiency is the main and only underlying problem, and therefore reduce transfusions," remarks Professor Haas.

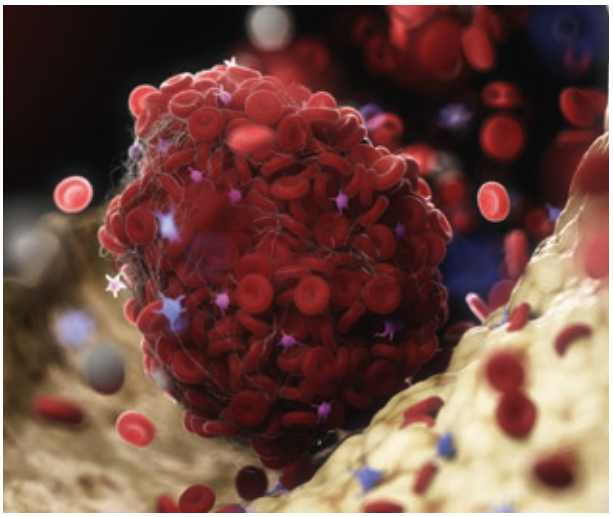
Fibryga® – a high-purity human fibrinogen concentrate

Octapharma has conducted several studies investigating replacement of fibrinogen by its fibrinogen concentrate fibryga® as an effective alternative to cryoprecipitate, a fraction of plasma. Cryoprecipitate is less pure, contains several coagulation factors and carries the risk of pathogen transmission, while fibryga® is a virally inactivated, highly purified fibrinogen concentrate with standardised content that allows precise dosing.

In November 2019, fibryga® received approval for its use in treatment of acquired fibrinogen deficiency (AFD) in 15 European countries, before receiving further approval for use in an additional 13 EU countries in 2020. Dr Olaf Walter, Board Member at Octapharma, notes that "This approval greatly expanded the potential for using fibrinogen replacement in the management of bleeding, particularly in a surgical setting."

Octapharma also provides educational programmes to raise awareness of PBM and supports the implementation. As Dr Oliver Hegener, VP Head of IBU Critical Care, describes: "Octapharma is committed to raising awareness of PBM within the medical community, particularly among those anaesthesiologists and intensivists who want to go the next steps towards individualised treatment solutions for improved outcome and safety."

Below 3D illustration of a blood clot.



Cancer was not part of the plan

Ingrid has always enjoyed life. "I laugh a lot. I have fun," she says. "I'm content. Most of the time I'm calm and relaxed. This disease, this cancer, was not part of the plan I had for my life – but there it is."

In March 2003, Ingrid, who lives with her husband in a small town in Hesse, Germany, was diagnosed with chronic lymphocytic leukaemia – just nine years after her sister died of acute leukaemia. "What was meant to be a reassuring check-up with my doctor turned my life upside down," she remembers.

Ingrid had a small lump in her groin and was given a precautionary blood test which revealed an increased number of leucocytes – white blood cells – the first sign that she had CLL. The first weeks after her diagnosis are still very clear in her mind. "Honestly, it was awful. I thought of my sister, of course, and was sure I was soon going to die," she says, candidly.

Fortunately, Ingrid's initial fears did not come true and, immediately after her diagnosis, at the age of 51, she began to "watch and wait" – a common approach to CLL in which patient and doctor monitor the condition without treatment. Eventually, however, after five years of active surveillance, in 2008 a change in Ingrid's blood values persuaded her doctor to initiate a therapy.

CLL is a cancer of the immune system. It starts in the body's infection-fighting white blood cells, called B cells. As it progresses, it produces abnormal white blood cells in the bone marrow and blood that cannot fight infection. Because CLL is a slow-growing cancer, some people do not need to start treatment for many years – as was the case for Ingrid.

Ingrid's doctor laid out a couple of options which would hopefully kick the CLL into remission for an indefinite period. However, when her symptoms eventually reappeared a few years after the first therapy, Ingrid went through further treatment cycles in 2013 and 2019.

"What was meant to be a reassuring check-up with my doctor turned my life upside down."

Above On top of everything else, Ingrid was also diagnosed with SID.

The domino effect

On top of everything else, Ingrid was also diagnosed with secondary antibody deficiency, a type of secondary immunodeficiency (SID). With SID, the immune system is weakened and patients become more susceptible to infections, increasing their morbidity and mortality. SID is a common complication in patients with haematological malignancies such as CLL, with up to 85% of CLL patients developing antibody deficiency during the course of the disease, either due to the underlying disease or as a side effect of their treatment.

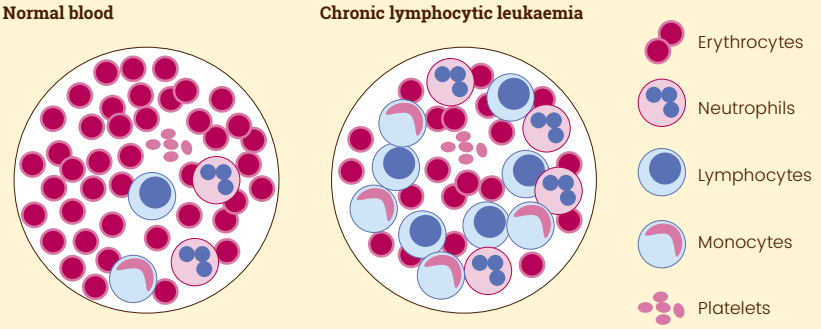
Patients like Ingrid are given immunoglobulins (either intravenously in a clinic or subcutaneously by self-administering at home) to boost their low levels of antibodies to help to protect them against infections. Ingrid started her treatment with immunoglobulins in November 2015, initially with intravenous infusions (IVIg), but recently switched to cutaquig®, a subcutaneous immunoglobulin treatment (SCIg), to keep her antibodies more in balance. "With immunoglobulin therapy, I am less afraid of developing infections," says Ingrid.

"Compared with IVIg, I now have more stable immunoglobulin G (IgG) levels with SCIg, which seems to be more effective," she continues, adding: "During the COVID-19 pandemic, it is even better to use SCIg as I don't need to go to hospital." Ingrid infuses at home by injecting purified immunoglobulin into the fatty tissue just underneath the skin. "Honestly, I'm afraid of COVID-19, so infusing from home is much safer for me. I don't want to die lying in an intensive care unit on a ventilator."

Chronic lymphocytic leukaemia (CLL)[1]

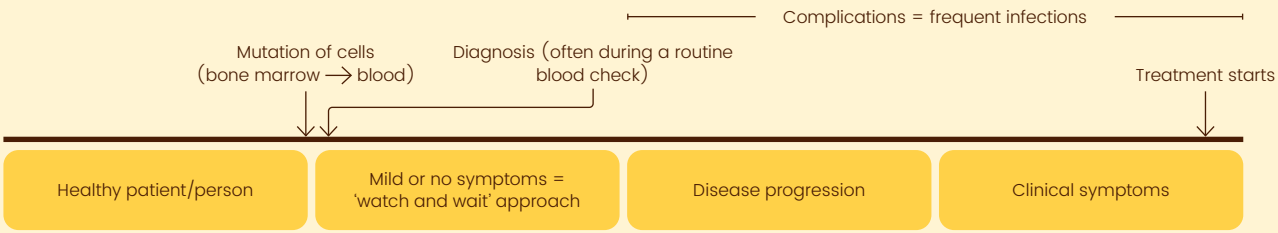
CLL is a type of blood cancer that starts in the bone marrow and affects the lymphocytes, which are a type of white blood cell. The cancerous CLL cells grow slowly, displace the healthy blood cells, then propagate in the bone marrow and bloodstream.

In patients with CLL, the immune system does not function normally, and one of the most common complications is frequent infections.



The "watch and wait" approach

CLL is a slow-growing cancer and carefully monitoring the evolution of the disease without treatment is a common approach. Patients remain under active surveillance but often do not start treatment right after the diagnosis.



The domino effect – secondary immune deficiency (SID)[2]

CLL patients are susceptible to infections due to inherent immune defects related to their primary disease (CLL itself), or as a side effect of their treatment.

>80%[3]
of CLL patients develop secondary antibody deficiency (a type of SID) and are more likely to develop infections

20%[4]
of CLL patients develop major infections

>60%[4]
of CLL-related deaths are causesd by infectious complications

The PRO-SID study

Intravenous immunoglobulin (IVIg) is commonly used to reduce the rate and severity of infections in patients with haematological malignancies suffering from frequent infections.

Octapharma recently launched a phase III clinical trial in patients with CLL and SID. The PRO-SID trial is the first randomised, placebo-controlled study to systematically evaluate the efficacy and safety of IVIg for primary prophylaxis for infection control in patients with CLL.

For more information on SID and haematological malignancies, you can visit the website: secondaryimmunodeficiency.com

Treatment

Standard treatments include:

1 Adapted from https://www.cancer.gov/types/leukemia/patient/cll-treatment-pdq
2 Adapted from https://www.secondaryimmunodeficiency.com/
3 Adapted from Tadmor, T. et al. (2018). Expert Review of Hematology, 11(1): 57–70
4 Adapted from Hensel, M. et al. (2003). British Journal of Haematology, 122(4): 600–606

Sailing through uncharted waters
Over the years since her diagnosis and during her treatments, she has sometimes been numb, or beyond sad, and at other times has felt optimistic. But what has always kept her fighting is her family, her children and grandchildren, whom she is most proud of in life.

She acknowledges that the love of her entire family, friends and even her dear dog has, over the years, been central to making everything more bearable. "I am so lucky to have found myself surrounded by such support, to have felt so loved and cared for by so many people," says Ingrid. "All of them have really helped me in their own way when I needed it, allowing me to stay as focused as I can on trying to figure out what the next step should be, as I sail through these uncharted waters."

Weeks, even days, can still be full of highs and lows, but as she puts it: "It's okay to be anxious and scared about this. But remember that you won't have those feelings 24 hours every day and that there are many great things to do in life. Just focus on that, stay positive and try to stay calm despite your disease."

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"All of them have really helped me in their own way when I needed it, allowing me to stay as focused as I can on trying to figure out what the next step should be, as I sail through these uncharted waters."

Octapharma working to support CLL patient care
Octapharma recently launched a phase III clinical trial in patients with CLL and SID. The PRO-SID trial is the first randomised, placebo-controlled study to systematically evaluate the efficacy and safety of IVIg for primary prophylaxis for infection control in patients with CLL.

"Despite and even because of improved B-cell targeting therapy options in CLL patients, infections are still one of the major causes of morbidity and mortality," says Wei Ding, MBBS, PhD, Mayo Foundation for Medical Education and Research, who sits on the steering committee of the PRO-SID study. "Primary prophylaxis with IVIg before severe infection occurs has the potential to reduce infection rates and the burden on patients and the healthcare system."

Dr Olaf Walter, Board Member at Octapharma, adds: "There remains a significant need to reduce the burden of the disease in managing patients with haematological malignancies and secondary immunodeficiency. Initiation of the PRO-SID study represents a key milestone in Octapharma's efforts to improve the care of patients with CLL."

“It’s okay to be anxious and scared about this. But remember that you won’t have those feelings 24 hours every day and that there are many great things to do in life. Just focus on that, stay positive and try to stay calm despite your disease.”

We are Octapharma

Our vision

Our passion drives us to provide new health solutions advancing human life

Our mission

For the safe and optimal use of human proteins

■ **Octapharma Global HQ**
Lachen, Switzerland

▲ **Octapharma Plasma, Inc.**
North Carolina, USA

● **Manufacturing sites**
1. Dessau-Rosslau, Germany
2. Lingolsheim, France
3. Mexico City, Mexico
4. Springe, Germany
5. Stockholm, Sweden
6. Vienna, Austria

● **R&D sites**
1. Berlin, Germany
2. Frankfurt, Germany
3. Heidelberg, Germany
4. Lachen, Switzerland
5. New Jersey, USA
6. Paris, France
7. Vienna, Austria

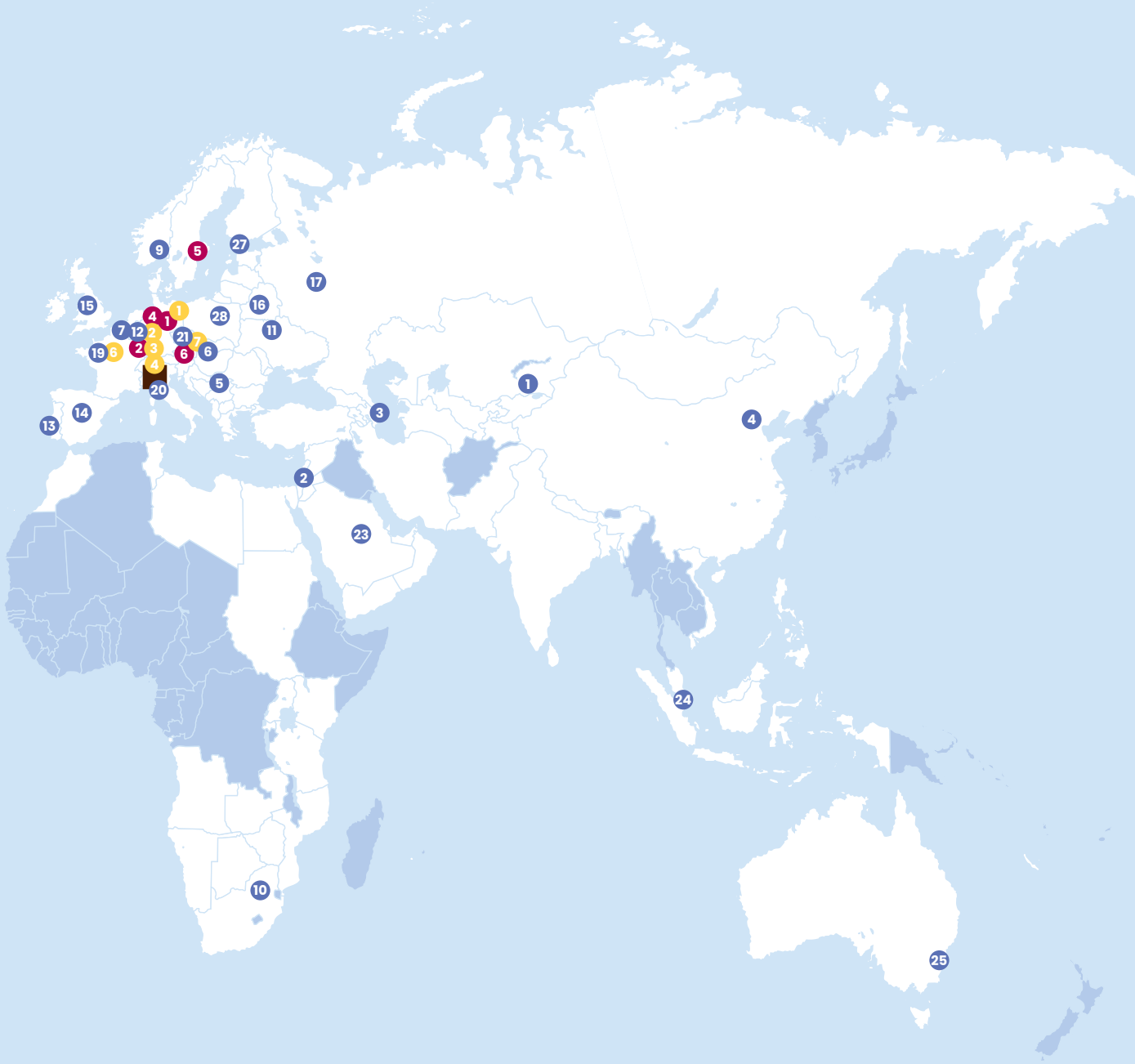
Countries where patients are treated with our products

● **Octapharma locations**
1. Almaty, Kazakhstan
2. Amman, Jordan
3. Baku, Azerbaijan
4. Beijing, China
5. Belgrade, Serbia
6. Bratislava, Slovakia
7. Brussels, Belgium
8. Florida, USA
9. Jessheim, Norway
10. Johannesburg, South Africa
11. Kiev, Ukraine
12. Langenfeld, Germany
13. Lisbon, Portugal
14. Madrid, Spain
15. Manchester, UK
16. Minsk, Belarus
17. Moscow, Russia
18. New Jersey, USA
19. Paris, France
20. Pisa, Italy
21. Prague, Czech Republic
22. Rio de Janeiro, Brazil
23. Riyadh, Saudi Arabia
24. Singapore
25. Sydney, Australia
26. Toronto, Canada
27. Vantaa, Finland
28. Warsaw, Poland

>160
plasma donation centres

>7m
litres of plasma processed annually

9,067
employees



Committed to the fight against COVID-19

As COVID-19 began to evolve into a global pandemic in 2020, Octapharma moved rapidly to find new ways in which to protect patients and employees. In the space of just a few weeks in March, the company created a special project team to confront the disease, joined a coalition with other leaders in the industry to develop a hyperimmune immunoglobulin therapy, and launched multiple initiatives involving our currently approved and marketed products.

Through these various projects, partnerships and alliances, Octapharma is committed to helping to accelerate the end of the pandemic worldwide.

IVIg to treat critically ill COVID-19 patients

Octapharma supported an investigator-initiated study (IIS) focused on treating the most critical patients – namely those experiencing hypoxaemia, being at the highest risk of requiring mechanical ventilation. The research was led by Dr George Sakoulas, MD, at Sharp Memorial Hospital, San Diego, California.

Since its first usage, IVIg has been found to have broad therapeutic applications for the treatment of a variety of inflammatory, infectious, autoimmune and viral diseases. Administration of IVIg solutions not only replaces missing antibodies but also modulates the immune response via multiple mechanisms including blocking a wide array of proinflammatory cytokines that potentially lead to severe inflammatory responses, as well as inhibiting Fc-gamma receptor binding of activated macrophages.

> **"Most of the morbidity and mortality in COVID-19 patients, as well as the burden on healthcare resources, follows the need for mechanical ventilation. If you can prevent the need for ventilation, the disease becomes much easier to manage at many levels."**
>
> **Dr George Sakoulas, MD**
> Sharp Memorial Hospital,
> San Diego, California

This IIS was the first study to evaluate prospectively the addition of IVIg to otherwise standard of care (SOC) treatment for adults with moderate to severe hypoxaemia secondary to COVID-19. In this open label, randomised, controlled trial, 33 patients were enrolled – 17 patients were randomised to SOC alone and 16 received SOC plus 0.5g/kg IVIg (octagam® 10%) per day for three days.

One patient who was part of the trial is 37-year-old father of six Eli Centeno who spent 58 days in Sharp Memorial Hospital, including five weeks sedated on a breathing machine. Eli was randomised to not receive IVIg as part of the trial but, with his condition not significantly improving after 36 days on a ventilator, his family approached Dr Sakoulas to prescribe octagam®. After receiving octagam® 10% therapy, his oxygen levels slowly improved. "It cut his oxygen requirement down quite a bit and then, next thing you know, he's getting extubated," recalls Dr Sakoulas.[1]

This pilot study showed that IVIg significantly improved hypoxaemia and reduced both intensive care unit (ICU) and hospital length of stay as well as the rate of progression of respiratory failure requiring mechanical ventilation.

"Most of the morbidity and mortality in COVID-19 patients, as well as the burden on healthcare resources, follows the need for mechanical ventilation," said Dr Sakoulas. "If you can prevent the need for ventilation, the disease becomes much easier to manage at many levels."

This research has been recently published in the journal "Critical Care Explorations" and was presented at major conferences including the European Society for Immunodeficiencies, the Immunoglobulin National Society and the American Society of Hematology.

1 https://www.sandiegouniontribune.com/news/health/story/2020-07-03/after-five-weeks-on-a-ventilator-young-father-asks-public-to-celebrate-the-fourth-at-home-this-year

Left Octapharma is committed to helping to accelerate the end of the pandemic worldwide.

> **"We are happy to see the results of our data leading to further prospective randomised multi-centre trials in severely ill COVID-19 patients, and we are really very excited to see the results."**

Prof Dr Figen Esen
Head of the Intensive Care Department, Istanbul University Hospital, Istanbul

Turkey: Istanbul University Hospital study

Octapharma also conducted a retrospective data analysis of a COVID-19 patient cohort in Turkey. The objectives were to compare clinical outcomes and biomarkers in patients with severe COVID-19 treated with SOC alone or in combination with IVIg (octagam® 5%). This study was conducted under the lead of Prof Dr Figen Esen, Head of the Intensive Care Department, Istanbul University Hospital, Istanbul.

The data from this retrospective study of 93 critically ill COVID-19 patients shows that IVIg treatment reduces inflammation, which is associated with poor clinical outcomes and death, and points to an increase in both overall survival and a longer survival time. Overall survival was 61% in the IVIg group compared with 38% in the control group. There was also a significantly longer median survival time of 68 days in the IVIg group compared with 18 days in the control group. IVIg significantly reduced levels of C-reactive protein, which is a marker of inflammation.

Prof Dr Esen noted: "We are happy to see the results of our data leading to further prospective randomised multi-centre trials in severely ill COVID-19 patients, and we are really very excited to see the results."

FDA approves phase III clinical trial

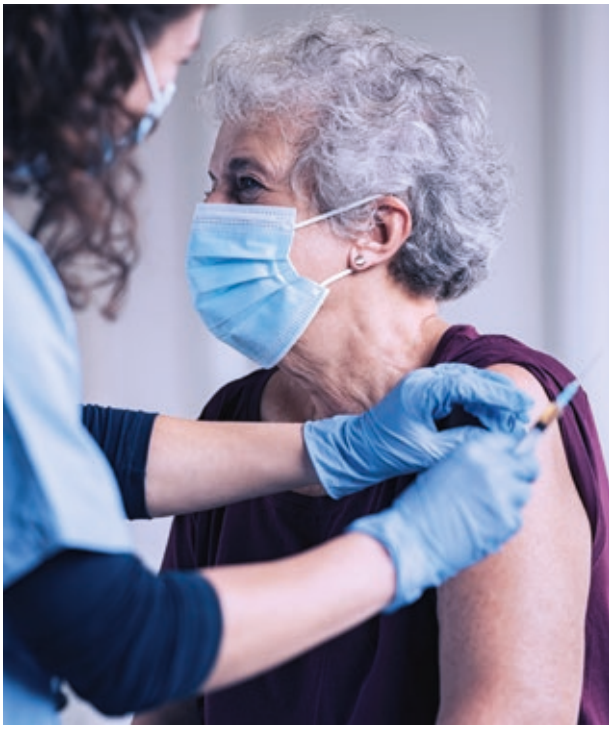
In addition to the above study, Octapharma also immediately set up a phase III clinical trial. This large multi-centre, randomised, double-blind, placebo-controlled study was approved by the USA Food and Drug Administration (FDA) under an Investigational New Drug (IND) application in May 2020.

The primary objective of this study is to determine if high-dose IVIg (octagam® 10%) therapy will slow or stop respiratory deterioration in patients with severe COVID-19. The secondary objectives are to measure the effects of high-dose octagam® 10% on slowing or stopping the clinical deterioration of COVID-19 by improving pulmonary function, quality of life and correlated impacts on metabolic factors.

The study was launched in the USA with enrolling adult patients diagnosed with COVID-19 requiring oxygen supplementation. Total enrolment for the full study is 208 patients; 14 sites in the USA have been initiated, with the recent addition of 8 more study sites in Ukraine and Russia. The overall enrolment requirement has been achieved and it is expected that the main study results will be submitted to the FDA in the first quarter of 2021.

Wolfgang Frenzel, MD, Head of Research & Development at Octapharma, noted: "Several case reports of utilising IVIg treatment for COVID-19 patients have shown positive results. We are, therefore, hopeful that we will observe improved clinical status in patients receiving octagam® 10%."

Below Octapharma also conducted a retrospective data analysis of a COVID-19 patient cohort in Turkey.

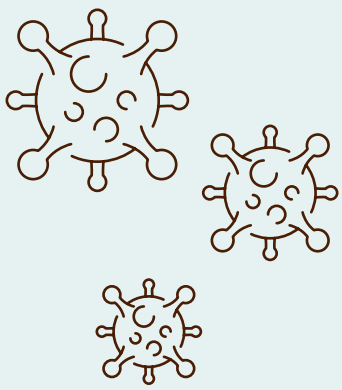


Octapharma acts to accelerate development of COVID-19 plasma therapies

COVID-19

In the space of just a few weeks in March 2020, as COVID-19 began to evolve into a global pandemic, Octapharma:

- Created a special project team to confront the disease
- Joined a coalition with other leaders in the industry to develop hyperimmune immunoglobulin (IVIg) therapy
- Launched multiple initiatives involving our currently approved and marketed products



82,416,557
Number of COVID-19 cases worldwide in 2020[1]

1,801,638
Number of COVID-related deaths worldwide in 2020[1]

$28 trillion
The amount the International Monetary Fund estimates the pandemic will cost the world economy in lost output over the next five years[2]

Why IVIg?

IVIg has broad therapeutic applications for the treatment of a variety of inflammatory, infectious, autoimmune and viral diseases.

Administration of IVIg solutions:

- Replaces missing antibodies
- Modulates the immune response via multiple mechanisms

Supporting research to fight COVID-19

Retrospective study comparing clinical outcomes and biomarkers in patients with severe COVID-19 treated with standard of care treatment (SOC) alone or in combination with IVIg

"The data from our retrospective study shows that IVIg treatment significantly reduces inflammation, which is associated with poor clinical outcomes and death, and points to an increase in both overall survival and a longer survival time."

Prof Dr Figen Esen
Head of the Intensive Care Department, Istanbul University Hospital, Istanbul

Investigator-initiated study to evaluate addition of IVIg to SOC treatment to treat critically ill COVID-19 patients

"Most of the morbidity and mortality in COVID-19 patients, as well as the burden on healthcare resources, follows the need for mechanical ventilation. If you can prevent the need for ventilation, the disease becomes much easier to manage at many levels."

Dr George Sakoulas, MD
Sharp Memorial Hospital, San Diego, California

Phase III clinical trial to determine whether high-dose IVIg therapy will slow or stop respiratory deterioration in patients with severe COVID-19

"Several case reports of utilising IVIg treatment for COVID-19 patients have shown positive results. We are, therefore, hopeful that we will observe improved clinical status in patients receiving octagam® 10%."

Wolfgang Frenzel, MD
Head of Research & Development, Octapharma

1 https://covid19.who.int (accessed 21 February 2021)
2 https://www.imf.org/en/Publications/WEO/Issues/2020/09/30/world-economic-outlook-october-2020

Beyond our core values – ownership, integrity, leadership, sustainability and entrepreneurship – we aspire to create a culture in which our employees feel inspired. Here are five snapshots of how our culture is taking shape.

Louis DiCriscio
Senior Vice President, Finance & Operations,
Octapharma USA, Inc.

"When there are market supply disruptions, we at Octapharma have always been very transparent with our partners to protect them and their patients."

Integrity is not something that you can just claim, but rather something that takes years to build through consistent action and honesty with those who depend on our products throughout their lives. It is the backbone to developing sustainable business and patient relationships that can last many years. Underlying this notion are both transparency and honesty, without which no relationship can last long. When there are market supply disruptions, we at Octapharma have always been very transparent with our partners to protect them and their patients. It is this openness, this integrity, and the trust that comes with it, which makes us able to work with our distributor and end-user accounts in creative ways to ensure that patients still receive their therapies during times of supply disruption.

Snehal Udavat
Study Manager, Immunology & ICE,
Octapharma USA, Inc.

"Working in clinical trials forces you to be creative under time pressure."

Working in clinical trials forces you to be creative under time pressure. We must embrace our **entrepreneurship** from the very beginning when we start building a protocol, through seeking interested and qualified physicians to join our study, and through managing the various challenging scenarios that arise as we collect data. A good example would be GAM10-08, a pivotal clinical trial into the use of octagam® 10% in dermatomyositis, for which I was the Clinical Study Manager. In that trial, we developed creative and entrepreneurial processes to overcome traditional approaches and succeeded in connecting study patients with this rare disease to our important trial in a very short time period. One way we did this was through the use of remote start-up and remote verification of data. At first, this was seen as a novel approach, but now, with COVID-19, remote visits are the norm. Overall, this change in strategic tactics helped us accelerate study enrolment from 0 patients to 27 patients, making the USA the country with the highest number of patients enrolled overall, and helping to ensure the trial met its timelines.

Huub Kreuwel
Vice President, Scientific & Medical Affairs,
Octapharma USA, Inc.

Octapharma took the lead and organised an advisory board with key opinion leaders to better understand the paediatric acute-onset neuropsychiatric syndrome/ paediatric autoimmune neuropsychiatric disorders associated with streptococcal infections (PANS/PANDAS) disease and to develop a new study for it. Octapharma was the first to bring together different specialities, such as immunologists, psychiatrists, neurologists and paediatricians, to discuss this disease and the evidence for IVIg treatment. Following several discussions, the members of the advisory board unanimously recommended pursuing a study in paediatric acute-onset neuropsychiatric syndrome/paediatric autoimmune neuropsychiatric disorders (PANS/PANDAS). Before jumping into a full phase III study, Octapharma again showed **leadership** and funded another study by three immunologists to verify some of the findings in the literature – something no other company had done. Later, Octapharma took the lead yet again to work with top physicians to fund additional research.

Our company, and our managers at all levels, take leadership seriously. We are curious – curious to experiment, curious to continuously learn new skills and curious to explore new or better ways to re-imagine medicine together. And we are always eager to take a step forward, ahead of the crowd. It is highly energising to be part of such a team.

"Our company, and our managers at all levels, take leadership seriously. We are curious – curious to experiment, curious to continuously learn new skills and curious to explore new or better ways to re-imagine medicine together."

Andrea Buchacher
Head of Quality Unit, Octapharma Austria

One important project in which I was heavily involved was the replacement of in vivo pyrogen assays in rabbits with far more **sustainable** in vitro endotoxin assays on microtiter plates.

The absence of pyrogenic substances is a prerequisite for all parenterals (sterile preparations prepared to be injected, infused or implanted into the body). The European Pharmacopoeia originally required in vivo pyrogen assays to verify this, but the requirement was later changed to allow in vitro endotoxin tests. Clearly, extensive validation studies were required to show that the new tests were equivalent to in vivo assays. As part of the process, hygienic conditions throughout the production process were monitored over several years, accompanied by the preparation of a careful definition of risk mitigation measures and an evaluation of adverse side effects in patients.

Ultimately, all Octapharma products lay in the scope of this project and nearly all corporate and quality control (QC) departments from our sites were involved. My part was to motivate, support and coordinate all stakeholders, as well as contributing to documents and proofreading them.

Today, as a result of the success of our efforts, all our main products are now exclusively tested by in vitro assays, saving both valuable resources and the lives of tens of thousands of rabbits every year. This is what it means to be sustainable.

Clare Worden
General Manager, Octapharma UK

In 2020, our company value of **ownership** had great importance to me personally. Watching the global pandemic unfold in the UK, it was clear to see the impact the situation was having on our people and patients. With so many issues requiring attention and clarity of thought, I truly felt the responsibility to make the right decisions, some of which were difficult. The priority was to ensure our life-saving medicines reached patients and that each team member remained safe, well and able to perform their roles effectively. The only way in which we could do this and stay focused on our objectives was to work together with each employee and provide support regarding wellbeing, working as a team to find solutions where necessary. As always, our people responded brilliantly and showed their commitment throughout the crisis. I am proud to say our business is strong, and our team is performing productively with a shared sense of ownership of both the challenges and successes we are experiencing together.

Donating plasma and saving lives

Left "None of us can change the world on our own, but we can all do our bit – and that bit, donating your plasma, could give someone a new lease of life," says Dean.

“I didn’t think about donating until somebody else’s donation saved my wife’s life,” says Dean, a retired army officer. “Danica, my wife, was diagnosed with cancer and needed plasma-derived medicine for her cancer treatment. It was only then that I realised how much and how easily I could help to heal and save other people’s lives.”

Plasma collection is the foundation of Octapharma’s business. We rely on our plasma donors to ensure we can continue to produce our life-saving medications for our patients around the world. Donors give many different reasons for donating and their motivations vary. Some see it as a social obligation, while others think of it as a humanitarian act. For many, like Dean, it is the realisation that other donors helped a loved one to recover from an illness. “My first donation was back in January 1998 and it felt good to give back,” recalls Dean, adding: “Now I donate twice a week and I would definitely recommend it to anyone.”

William, another donor who first donated two years ago after getting the idea from his brother-in-law, also now gives plasma twice a week. “I donate because my mother has anaemia,” he says, adding: “There are so many others who are in desperate need – and a simple donation can help them have a better life.”

“Danica, my wife, was diagnosed with cancer and needed plasma-derived medicine for her cancer treatment. It was only then that I realised how much and how easily I could help to heal and save other people’s lives.”

Dean
Plasma donor

Left William, who first donated two years ago after getting the idea from his brother-in-law, now gives plasma twice a week.

Donating during COVID-19

More than 70% of the world's supply of human plasma comes from donors in the USA, who give plasma at donation centres across the country. As a result, social distancing requirements due to COVID-19 and fears over the disease have weighed heavily on donations in 2020.

The situation could have been far worse, however, had donation centres in many countries not been exempted from COVID-19 lockdown measures. Employees at Octapharma Plasma, Inc. (OPI), which manages our centres in the USA, rose to the challenge, working seven days a week to ensure our donation centres continued to operate effectively while doing everything in their power to ensure that donors felt safe.

Octapharma centres introduced stringent new safety measures, including the wearing of masks, increased sanitation and social distancing, to protect both staff and donors, and to allow them all to continue their important work.

"OPI introduced several safety changes to give us donors confidence about hygiene and social distancing," says Dean, who has continued to donate during the pandemic, adding: "It is just 45 minutes of my time and I really have no issues about it. It all works fine and feels safe." Like Dean, William has also continued to donate during the pandemic and shares a similar outlook. As he puts it: "As long as you're following the recommendations of each donor centre, you are safe."

Doing good feels good

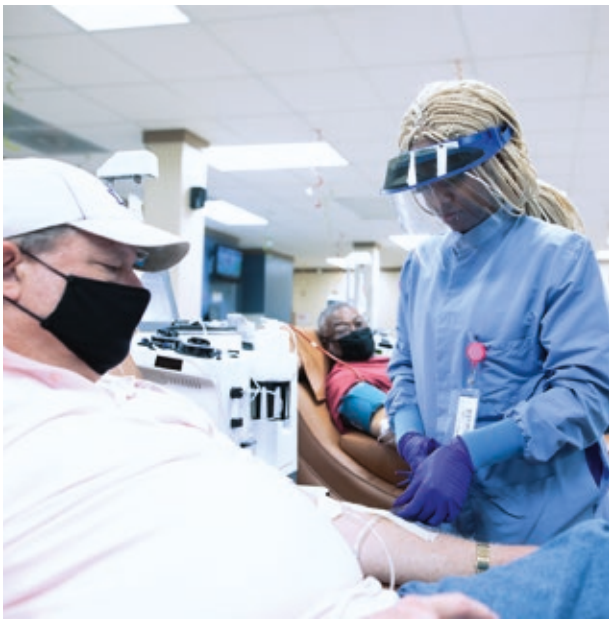
Now donating for over 20 years, Dean likes to cook and enjoy the outdoors during his free time. A grandfather to four grandchildren, he is a full-time volunteer, working at local animal and homeless shelters when he is not donating plasma. As he puts it: "Doing good feels good."

Each of our donors is registered on our Donor Management System where their full name, address, allergies, distinguishing characteristics, medical history and other relevant information are recorded. To become qualified, a donor must donate two times and have acceptable test results for each donation. All donors undergo a screening before each donation to ensure they meet safety requirements defined by the USA Food and Drug Administration (FDA) and other regulatory agencies.

"Without a doubt, I would recommend being a donor," says William, who loves to spend his free time with family and enjoys preparing tasty barbecues. "I don't know anyone personally who needs the medicines my blood helps to produce, but I do know that, by donating, I'm doing the right thing." Dean could not agree more: "It's such an easy thing to do and it costs nothing but time," he explains, adding: "None of us can change the world on our own, but we can all do our bit – and that bit, donating your plasma, could give someone a new lease of life. To the world you may be one person, but to one person you could be the world."

"Without a doubt, I would recommend being a donor. I don't know anyone personally who needs the medicines my blood helps to produce, but I do know that, by donating, I'm doing the right thing."

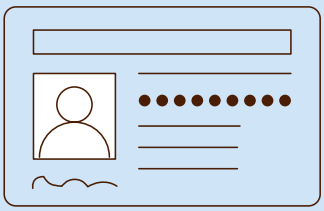
William
Plasma donor



Right Plasma collection is the foundation of Octapharma's business.

Plasma donation

Donor's profile



18 – 67 years old
Donors must be aged between 18 and 67

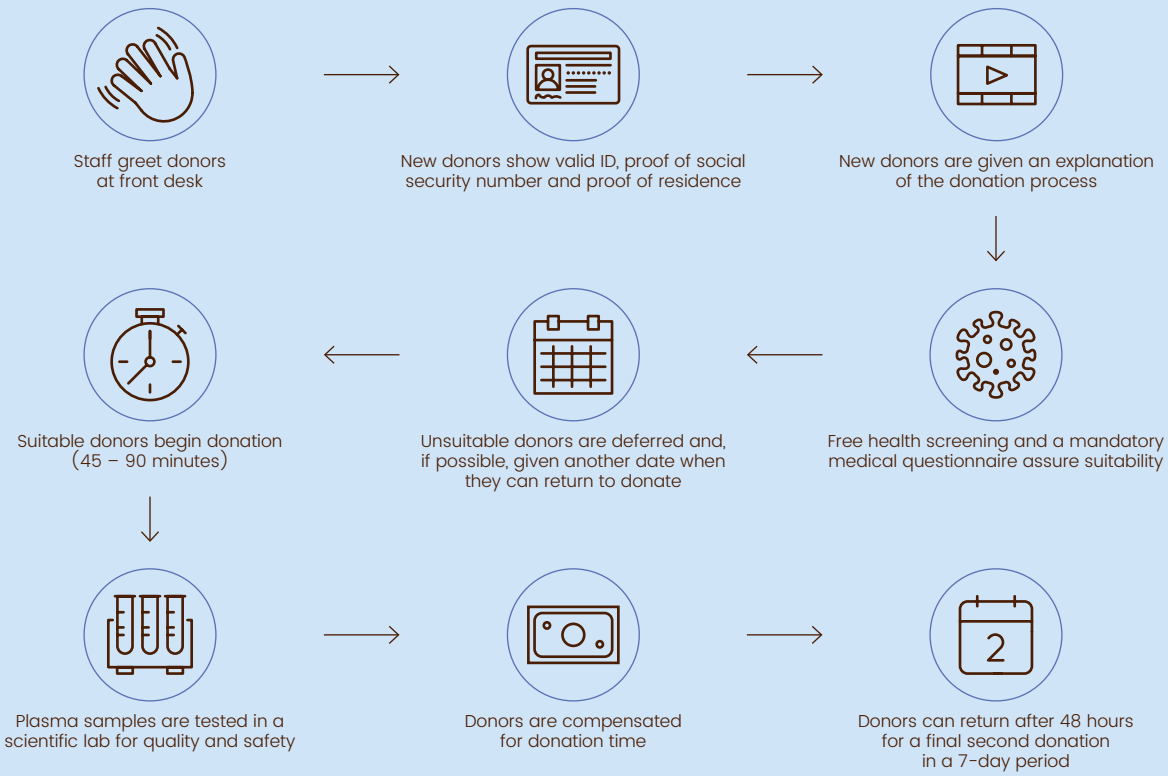
50+ kg/110+ lbs
Donors must weigh more than 50 kg/110 lbs

Health information
Donors are given a free health screening and must provide a suitable medical and social history, including details of any medication and travel

130,000
About 130,000 donors donate plasma at our Octaplasma, Inc. (OPI) donation centres each month

1.5 million square feet
OPI's donation centres in the USA cover over 1.5 million square feet, equating to almost 140,000 square metres – or 20 football fields

Plasma donation process



OctaPass

OctaPass is OPI's new web application. It allows returning plasma donors to complete their health history questionnaire online. It also promotes COVID-19 physical distancing recommendations, helping donors feel safer. It reduces waiting time at self-serve kiosks and eliminates donor contact with high-touch surfaces.

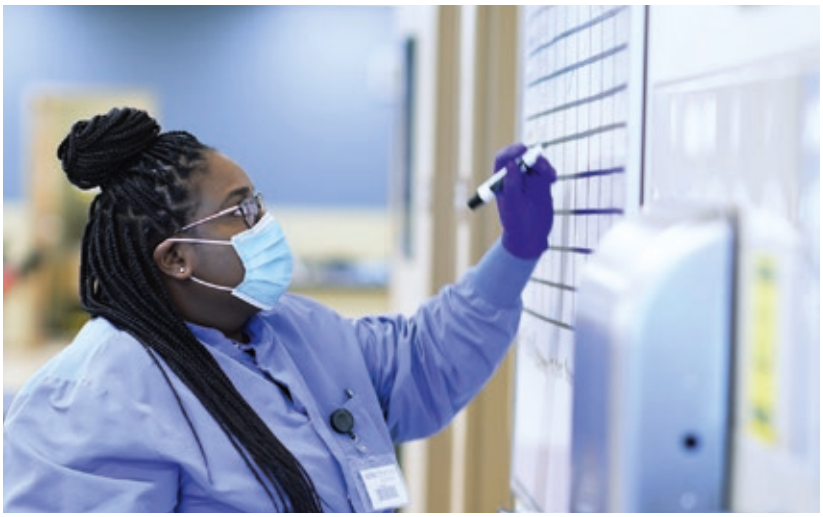
Donor Management System

Each donor is registered on our Donor Management System with

- Full name
- Address
- Social security number
- Allergies
- Distinguishing characteristics
- Medical history
- Other relevant information

Protecting our patients: ensuring plasma supplies during COVID-19

Below More than 80% of the plasma used to manufacture Octapharma products is sourced from company-owned donation centres.



Left Ashleigh Kline and her team had to fundamentally change the way they worked in response to COVID-19.

As COVID-19 began to spread across the USA, it became clear to Ashleigh Kline, Donor Centre Director in Raleigh, North Carolina, that she and her team would have to fundamentally change the way in which they worked to ensure the safety of their donors, colleagues and the surrounding community.

"I quickly realised that the pandemic would affect every aspect of our business. Accepting our 'new normal' – including delivery and staffing challenges as well as masks, increased sanitation and social distancing – helped me and my team to respond effectively," explains Ashleigh.

Her story is one of many in which Octapharma employees went the extra mile to secure a safe supply of plasma to ensure that we could continue to deliver our life-saving products to patients around the world.

Operating through the crisis

More than 80% of the plasma used to manufacture Octapharma products is sourced from company-owned donation centres.

The effects of the pandemic – national lockdowns, business shutdowns, ruptured supplies, and travel and shipping restrictions around the globe – posed significant challenges to our plasma donation centres and made it harder than ever for donors to continue donating plasma.

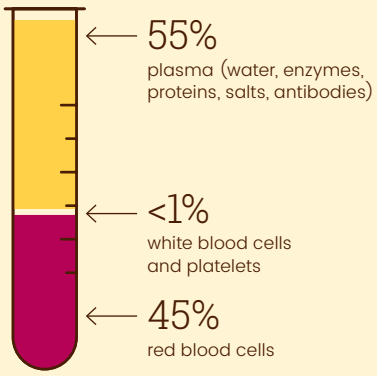
"I quickly realised that the pandemic would affect every aspect of our business. Accepting our 'new normal' – including delivery and staffing challenges as well as masks, increased sanitation and social distancing – helped me and my team to respond effectively."

Ashleigh Kline
Donor Centre Director in Raleigh, North Carolina

Crucial plasma collection continues in our donation centres, even during the pandemic

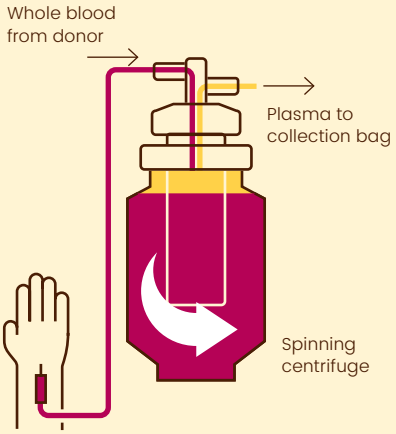
What is plasma?

Plasma is the liquid part of the blood carrying cells and proteins throughout the body. Plasma makes up 55% of human blood.



Plasma collection

Plasma can either be sourced from donors through plasmapheresis or recovered from whole blood donations.



Plasma donation at a glance

45 – 90 minutes
A donation session takes between 45 and 90 minutes

300 – 880ml
Between 300 and 880ml of plasma is taken for each donation

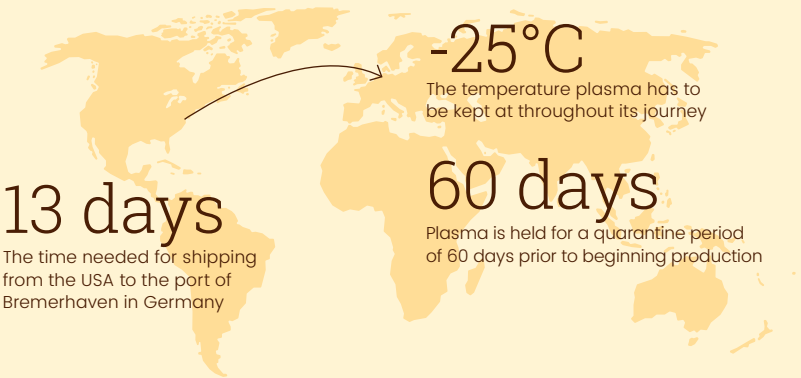
48 hours
A donor can return after 48 hours for a second (and final) donation in any 7-day period

Virus check
The plasma is tested for viruses like hepatitis, HIV and parvo B19

1,200
On average, 1,200 plasma donations are needed for prophylactic treatment of a severe haemophilia A adult patient for one year

130,000
About 130,000 donors donate plasma at our OPI donation centres each month

The plasma journey



-25°C
The temperature plasma has to be kept at throughout its journey

13 days
The time needed for shipping from the USA to the port of Bremerhaven in Germany

60 days
Plasma is held for a quarantine period of 60 days prior to beginning production

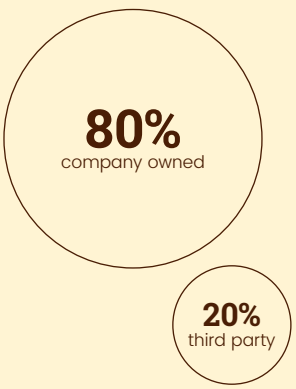
"I think this pandemic has increased everyone's awareness of what is important – life and those who share it with you."

Ashleigh Kline
Donor Centre Director

"We all had to be prepared to adapt in real time while making the most prudent decisions to help us meet deadlines. Multiple departments within OPI continue to work cohesively to achieve this while remaining organised and focused on all our goals."

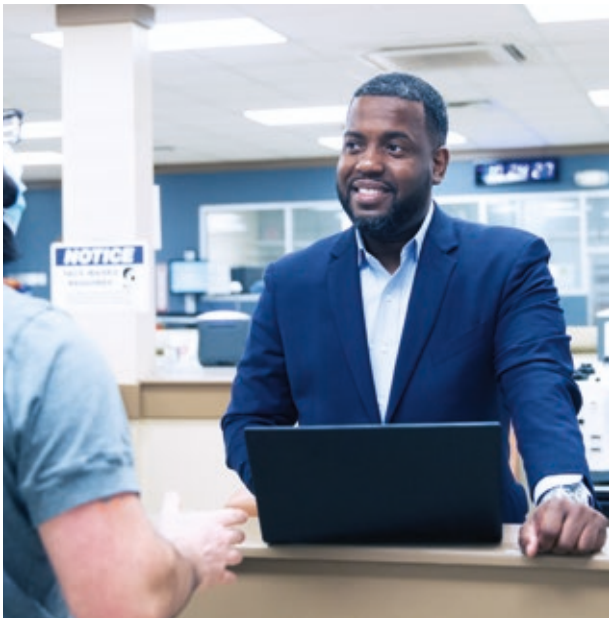
John Randolph
OPI Regional Director Operations

Supplies coming from company-owned donation centres



"Having all departments working together with clear objectives, laser focus, effective collaboration, consistent communication and frequent follow-up helped us achieve our goals."

Brian Robinson
Divisional Director at OPI, Texas, USA



Left "Clear objectives, effective collaboration and consistent communication helped us achieve our goals," says Brian.

Responding to the challenge and going the extra mile

Faced with these challenges Ashleigh, her team and the wider OPI family, rallied together to ensure the safety of donors and each other, and to continue collecting as much plasma as possible. Many employees took on additional responsibilities and some even changed roles to meet the needs of the business. Together, they not only recruited new donors to ensure a continuous supply of plasma but were also able to open new donor centres.

The goal, from the start, was to forecast as many obstacles as possible in order to minimise the impact on our business, while being prepared for anything. As Brian Robinson, Divisional Director at OPI, notes, it was an "all hands on deck" approach: "Having all departments working together with clear objectives, laser focus, effective collaboration, consistent communication and frequent follow-up helped us achieve our goals."

Left Opening several new centres was an impressive achievement.

John Randolph, OPI Regional Director Operations, shares a similar view: "We all had to be prepared to adapt in real time while making the most prudent decisions to help us meet deadlines. Multiple departments within OPI continue to work cohesively to achieve this while remaining organised and focused on all our goals."

In the face of local, state and federal restrictions, challenges in material supply and disruptions to worldwide logistics and consequent construction delays, opening several new centres was an impressive achievement. "There were times when it felt like an uphill struggle", remembers John, "but we achieved it by working together with clear objectives, and by sharing our knowledge and skills across teams."

Elle Wall, Assistant Manager, New Centre Development team, shares a similar view on teamwork: "We work with a great team of colleagues who are goal oriented, who work efficiently and effectively with others, and who do everything they can to meet our goals."

Above "We work with a great team of colleagues," says Elle (right).

"We work with a great team of colleagues who are goal oriented, who work efficiently and effectively with others, and who do everything they can to meet our goals."

Elle Wall
Assistant Manager, New Centre Development Team

Building new teams despite the challenges
For Brian, recruitment and selection were the biggest hurdle to opening the new centres. The pandemic created an aggressive job market in which Octapharma was in competition for top talent with other plasma donation centres, pharmaceutical companies and hospitals affected by COVID-19. Brian says that leadership and teamwork were crucial in these challenging times. "We had existing centres that took on additional responsibilities supporting new centres in recruitment, hiring and training," says Brian, adding: "This was a perfect example of excellence, going above and beyond to support the wider company."

As an example, the Raleigh Centre assisted the New Centre Development team in the opening of the Rocky Mount Centre. "By taking ownership of the tasks assigned to us – as if they were for our own centre – we were able to hire and complete training with a portion of the new Rocky Mount staff," recalls Ashleigh.

Stronger together
Looking back on the year, Ashleigh is sure that some things have clearly changed. "I think this pandemic has increased everyone's awareness of what is important – life and those who share it with you," she says, before adding: "Facing the problems raised by COVID-19 sometimes feels like a never-ending journey. But when it's over, I'm sure we'll all be proud, and remember how much easier and better it has been to share the journey with good colleagues and friends. And that's a good lesson to learn."

"There were times when it felt like an uphill struggle, but we achieved it by working together with clear objectives, and by sharing our knowledge and skills across teams."

John Randolph
OPI Regional Director Operations

Reaching a community in need: helping patients with PANS

Above Avery was treated with antibiotics for approximately eight months as well as given multiple supplements to help boost her immune system.

It is estimated that up to one in 200 children have paediatric acute-onset neuropsychiatric syndrome (PANS), characterised by sudden onset of obsessive-compulsive disorder (OCD) symptoms and/or severe eating restrictions, along with at least two other cognitive, behavioural or neurological symptoms. The medical options to treat this rare disease remain limited but immunomodulation with intravenous immunoglobulin (IVIg) seems to offer a real breakthrough.

"Before this all started, our daughter was a happy and energetic toddler. In fact, she was the easiest of our three children as a baby – we had no hint of any of the problems to come," recalls Avery's mother Carrie. Then suddenly, at the age of three, Avery started exhibiting extreme obsessive-compulsive symptoms, separation anxiety and severe sensory sensitivities.

"During the initial onset, Avery's symptoms were so severe that we could not touch her clothing," remembers Carrie, adding: "If we did, she would rub them and panic about them 'bunching', and often we just had to allow her to change her clothes, over and over. This could mean 20 or more changes a day. It was a terrifying experience because we had no idea what was wrong, and it was very obvious that she was also extremely scared."

"The search for safe and effective therapies for PANS has been difficult, but there is strong evidence that immunomodulation can mitigate or cure this disease. Intravenous immunoglobulin has been used in prior studies and shown significant efficacy."

Dr Roger H. Kobayashi
Westgate Professional Centre
Omaha, Nebraska, USA

Below At the age of six, Avery was hospitalised for four days due to an extreme flare-up in her symptoms.

> **"The PANS diagnosis was missed by infectious disease specialists and neurologists. In fact, several of the neurologists didn't believe in PANS or PANDAS."**
>
> **Carrie**
> Avery's mother

A very challenging disease to treat

PANS appears to occur when a trigger – such as an infection or a toxin – initiates a misdirected immune response resulting in inflammation of a child's brain. This can lead to symptoms such as OCD, severe restrictive eating, anxiety, tics, personality changes, decline in mathematical and handwriting abilities, and sensory sensitivities.

At the age of six, Avery was hospitalised for four days due to an extreme flare-up in her symptoms following multiple viral and bacterial infections whilst in her first year of elementary school. During this flare-up, she experienced extreme OCD symptoms, severe separation anxiety, and sensory sensitivity related to touch, clothing and sound. Her food restriction was so severe that she literally lived on homemade fruit smoothies and one or two other items. Avery missed three months of school and was unable to leave home for two months following her hospitalisation. It was a distressing time for the whole family as they watched the illness take over Avery's body and mind.

"The PANS diagnosis was missed by infectious disease specialists and neurologists. In fact, several of the neurologists didn't believe in PANS or PANDAS," recalls Carrie. Avery wasn't officially diagnosed until April 2019, when she was seen by a paediatrician with knowledge of PANS and the related paediatric autoimmune neuropsychiatric disorders associated with streptococcal infections (PANDAS). Lab results showed evidence of past and active infection with mycoplasma, a known PANS trigger. To further support the diagnosis, she also underwent a Cunningham Panel blood test which showed elevations in four out of the five categories. "Up until that time, doctors had failed to identify the condition because her strep titres were not elevated, and other potential triggers were unknown to her regular paediatrician."

Avery was treated with antibiotics for approximately eight months as well as given multiple supplements to help boost her immune system. Her worst symptoms did improve with antibiotics; however, she continues to have flare-ups when exposed to infections. Carrie explains: "We are still seeing doctors specialising in PANS/PANDAS to determine the best treatment for Avery, and we pray that one day she will be fully healed."

Dr Roger H. Kobayashi, from the Westgate Professional Centre, Ohama, Nebraska, explains: "The search for safe and effective therapies for PANS has been difficult, but there is strong evidence that immunomodulation can mitigate or cure this disease. Intravenous immunoglobulin (IVIg) has been used in prior studies and shown significant efficacy."

Right Avery (centre) with her older sister (left) and mother, Carrie (right).

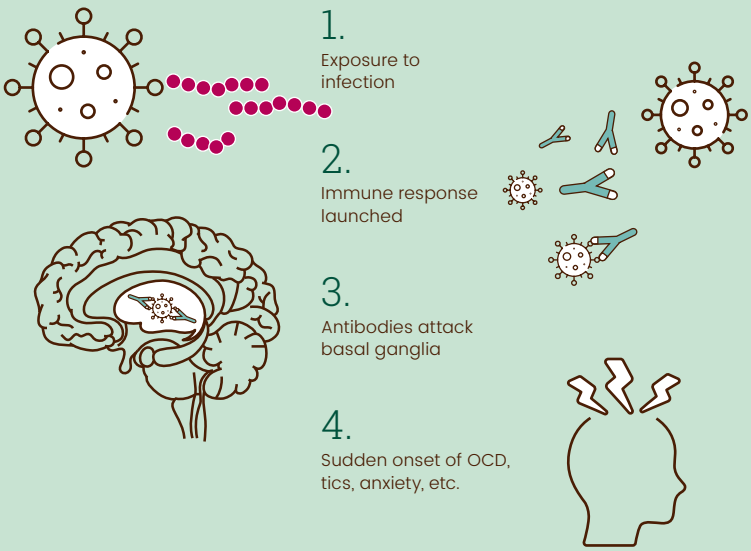
PANS/PANDAS[1]

Paediatric acute-onset neuropsychiatric syndrome (PANS) is a neuroinflammatory encephalitis affecting children which can have various triggers.

The triggers initiate a misdirected immune response resulting in the brain's inflammation.

Paediatric autoimmune neuropsychiatric disorders associated with streptococcal infections (PANDAS) is a subset of PANS, specifically triggered by a streptococcal infection.

81% of the infections are associated with streptococcus, while 19% are from other sources.



1. Exposure to infection
2. Immune response launched
3. Antibodies attack basal ganglia
4. Sudden onset of OCD, tics, anxiety, etc.

Symptoms[3]

Symptoms are:

Sudden onset of obsessive compulsive disorders (OCD) and/or tic disorders

Severe eating restrictions

Additionally, at least two comorbid symptoms are present:

Anxiety, emotional liability or depression

Irritability

Aggression or severely oppositional behaviours

Deterioration in school performance

Sensory or motor abnormalities

Somatic signs and symptoms – e.g. sleep disturbances, enuresis

1 in 200[2]

The number of children that may have PANS/PANDAS in the USA

4 – 9 years old[2]

The age range when the majority of children with PANS/PANDAS are diagnosed

Family medical history[2]

A family history of autoimmune illness and strep-related severity illness is a risk factor for developing PANS/PANDAS

Prevalence in boys[2]

Boys are two to four times more likely to get the disease than girls, with a ratio of 2.6:1 in general and 4.7:1 under the age of 8

Treating PANS/PANDAS with IVIg

Immunomodulation is thought to mitigate or cure the disease. Octapharma is supporting studies into the role of IVIg as an immunomodulatory drug for the management of PANS

2019

In 2019, Octapharma funded an investigator sponsored study to explore the effect of sequential infusions of octagam® 5% on PANS

2020

In 2020, Octapharma launched a clinical study investigating the efficacy of panzyga® in reducing functional impairment associated with PANS

"Octapharma is proud to sponsor this important research and we are hopeful that our medicines can make a difference in the lives of children and adolescents impacted by the syndrome."

Huub Kreuwel
Vice President, Scientific & Medical Affairs, Octapharma USA, Inc.

1 Adapted from https://www.nimh.nih.gov/health/publications/pandas/index.shtml and http://pandasnetwork.org/
2 http://pandasnetwork.org/
3 Thienemann, Margo, et al. (2017). Clinical management of pediatric acute-onset neuropsychiatric syndrome: part I—psychiatric and behavioral interventions. Journal of Child and Adolescent Psychopharmacology, 27(7): 566–573

Finding a way forward for patients

While IVIg is not a new therapy for PANS, there is a lack of adequate data to validate its safety and effectiveness to regulators such as the FDA. Consequently, it is not covered by most insurance companies and is financially out of reach for many families. To help solve this, Octapharma is supporting studies into the role of IVIg as an immunomodulatory drug for the management of PANS.

In an investigator-initiated trial in 2019 led by Dr Isaac Melamed, Dr Roger H. Kobayashi and Dr Maeve E. O'Connor funded by Octapharma, the research team tested the hypothesis that PANS is related to an immune dysfunction, representing a new form of post-infectious autoimmunity. Based on this, a multi-site, open-label study was designed to explore the efficacy of a novel IVIg treatment regimen.

The results of the trial were promising. As Dr Melamed put it: "In PANS, which may be associated with an underlying immune dysregulation, sequential infusions of IVIg, octagam® 5%, successfully ameliorated psychological symptoms and dysfunction, with sustained benefits for at least eight weeks and up to 46 weeks in a subset of subjects. In addition, baseline immune and autoimmune profiles demonstrated significant elevations in a majority of subjects, which requires further evaluation, characterisation and study to clarify the potential immune dysfunction by which PANS manifests and progresses."

Above The subject was asked to draw "self and others". Left-hand drawing: Subject's drawing prior to IVIg treatment. Right-hand drawing: Subject's drawing following IVIg treatment.

An ongoing battle

In September 2020, Octapharma launched a phase III, multi-centre superiority study of a trial to evaluate whether panzyga® is superior to a placebo (0.9% w/v sodium chloride) for reducing the severity of symptoms associated with PANS. The study further aims to determine the sustainability of the reduction of the severity of symptoms in children treated with panzyga® and to assess the efficacy of panzyga® in reducing functional impairment associated with PANS.

Researchers aim to enrol 92 patients with a confirmed diagnosis of moderate to severe PANS. Approximately 30 study sites are planned for this prospective, randomised, double-blind, placebo-controlled superiority study. "Octapharma is proud to sponsor this important research and we are hopeful that our medicines can make a difference in the lives of children and adolescents impacted by the syndrome," concludes Huub Kreuwel, Vice President, Scientific & Medical Affairs, Octapharma USA, Inc.

News of this research and emerging studies in the field is a source of cautious optimism for parents like Carrie. "The studies we're hearing about and the treatments being offered are potentially life-changing for families like ours. This trial offers hope that we may eventually have firm evidence of the safety and effectiveness of IVIg for treating this condition that has, in many ways, stolen our daughter's childhood."

"This trial offers hope that we may eventually have firm evidence of the safety and effectiveness of IVIg for treating this condition that has, in many ways, stolen our daughter's childhood."

Carrie
Avery's mother

Strength and resilience to continue to advance human life






Top row,
from left to right:

Wolfgang Marguerre
Chairman and CEO,
Octapharma Group

Frederic Marguerre
Shareholders'
Representative,
President
Octapharma Plasma,
Inc., USA

Tobias Marguerre
Managing Director,
Octapharma
Nordic AB

Roger Mächler
Chief Financial
Officer

Middle row,
from left to right:

Wolfgang Frenzel
Research and
Development

Norbert Müller
Board Member

Flemming Nielsen
President,
Octapharma USA, Inc.

Matt Riordan
Board Member

Bottom row,
from left to right:

Olaf Walter
Board Member

Josef Weinberger
Corporate Quality and
Compliance Officer

Gerold Rempeters
Corporate Production
Officer

"The Octapharma Group delivered yet another excellent performance in 2020, with strong sales growth and robust profitability despite the many challenges of COVID-19. Sales increased by 8.1% to €2.4 billion, compared to the prior year, and the company generated an operating income of €451 million."

Roger Mächler
Chief Financial Officer

The COVID-19 pandemic affected every part of our business, from plasma collection, to our supply chain, production and engagement with key stakeholders. Our employees across the business rallied to mitigate the worst effects of the crisis and, through close collaboration and thousands of individual actions, continued to produce and deliver life-saving medications on behalf of tens of thousands of patients who rely on them, while successfully executing our strategy for profitable organic growth.

As a result of this collective effort, we once again recorded strong year-on-year growth in our Immunotherapy product portfolio, as well as in sales of Albumin, Nuwiq®, fibryga® and atenativ®. Overall, we strengthened our position in key markets in North America, China and Europe and our presence in growth markets in Latin America and Asia.

Gross profit in 2020 was €840 million, up 7.4% from the prior year, while gross margin declined by just 0.3 percentage points to 35.1% and this largely due to higher costs associated with COVID-19. Total operating expenses for the year were €390 million, up from €359 million in 2019.

Operating income was €451 million and profit before taxes €386 million. The Group's effective tax rate was significantly reduced by a deferred tax asset recognised in 2020, a result of the corporate tax reform in Switzerland. This is reflected in net income for 2020 of €376 million.

Net cash from operating activities was €600 million. Our capital position remains extremely strong, with an equity ratio of 80%.

€451m operating income
(2019: €424m)

€2.4bn revenue
(2019: €2.2bn)

8% increase in revenue
(2019: 23%)

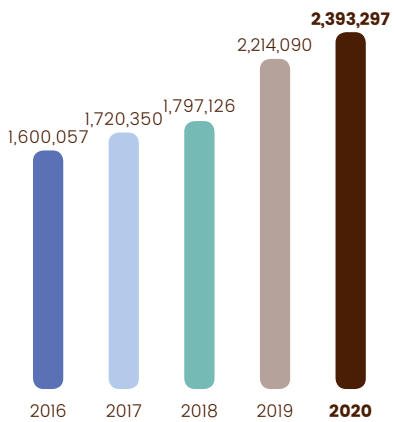
Significant investments were made in new donor centres, improved production capacity, operational efficiency and into R&D to expand our product portfolio and capabilities. This has positioned the Group well for further growth in 2021 and beyond, while enhancing our resilience to external shocks.

While COVID-19 continues to have a detrimental effect on our operations, Octapharma is well positioned to not only weather current challenges but come out stronger in the longer term.

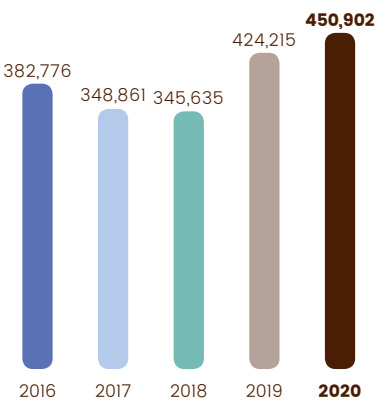
During 2021, the Group will invest further in talent, infrastructure and capabilities as we seek to continue the strong sales momentum which has delivered annualised revenue growth of 11% since 2016, build our position in our chosen markets, expand our product portfolio and continue to serve the needs of healthcare professionals and patients around the world.

Roger Mächler
Chief Financial Officer

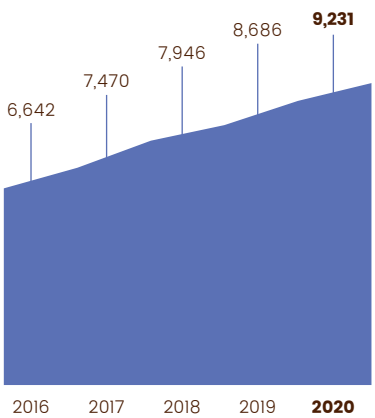
Revenue in 1,000 EUR



Operating income in 1,000 EUR



Average headcount



“Significant investments were made in new donor centres, improved production capacity, operational efficiency and into R&D to expand our product portfolio and capabilities.”

Key figures of the Octapharma Group

(Monetary figures are in 1,000 EUR)	2020	2019	2018	2017	2016
Operating income	**450,902**	424,215	345,635	348,861	382,776
Operating profit margin*	**18.8%**	19.2%	19.2%	20.3%	23.9%
Net profit of the year	**375,693**	403,445	303,480	252,116	345,450
Year-end headcount	**9,067**	9,307	8,314	7,674	7,094
Return on investment*	**11.1%**	13.5%	11.5%	10.2%	15.3%
Profit from operations per employee*	**49**	49	43	47	58
Cash ratio	**193%**	120%	174%	187%	180%
Days of sales in receivables*	**117**	141	126	126	137
Days of inventory range*	**225**	239	250	217	218
Cash flow from operations	**600,496**	257,180	261,393	350,837	287,966
Expenditures to ensure future prosperity	**306,310**	307,804	240,183	287,197	249,611
Research and development	**79,471**	75,748	87,291	86,508	83,500
Capital expenditures and investments in activities	**226,839**	232,056	152,892	200,689	166,111

* Key figures are determined as follows:
Operating profit margin: Operating income/revenue
Return on investment: (Net profit of the year + interest expense)/average total assets
Profit from operations per employee: Operating income/average headcount
Days of sales in receivables: Trade receivables/revenue * 365
Days of inventory range: Average inventories/material – and production cost (part of cost of sales) * 365

Financial statements of the Octapharma Group*

Consolidated income statement of the Octapharma Group

(All figures in 1,000 EUR)	2020	2019
Revenue	**2,393,297**	2,214,090
Cost of sales	**-1,552,814**	-1,431,275
Gross profit	**840,483**	782,815
Research and development	**-79,471**	-75,748
Selling and marketing	**-217,808**	-202,357
Regulatory affairs	**-22,535**	-19,494
General and administration	**-79,587**	-63,812
Other income	**11,967**	3,840
Other expenses	**-2,147**	-1,029
Total operating expenses	**-389,581**	-358,600
Operating income	**450,902**	424,215
Non-operating income and expenses	**-64,710**	3,727
Profit before taxes	**386,192**	427,942
Income tax	**-10,499**	-24,497
Net profit of the year	**375,693**	403,445

* The following summary financial statements are derived from the consolidated financial statements of Octapharma Nordic AB, Stockholm and comprise the summary income statement for the period from 1 January to 31 December 2020, the summary balance sheet and the summary cash flow statement for the year then ended, aggregating non-material financial statement captions.

Consolidated statement of financial position of the Octapharma Group

(All figures in 1,000 EUR)	2020	2019
Assets		
Cash and cash equivalents	**682,783**	434,845
Trade receivables	**766,010**	854,992
Other receivables and current assets	**77,540**	67,590
Loans granted	**191**	96
Derivative financial instruments	**9,548**	1,129
Inventories	**869,335**	923,342
Total current assets	**2,405,407**	2,281,994
Financial investments	**1,172**	1,411
Deferred tax assets	**131,673**	103,798
Loans granted	**676**	738
Property, plant and equipment	**1,084,777**	973,890
Intangible assets	**4,009**	7,197
Total non-current assets	**1,222,307**	1,087,034
Total assets	**3,627,714**	3,369,028

(All figures in 1,000 EUR)	2020	2019
Liabilities and equity		
Trade payables and other payables	**104,905**	119,602
Derivative financial instruments	**192**	0
Income tax payables	**33,586**	44,236
Short-term lease liabilities	**14,011**	11,614
Accruals	**142,830**	151,049
Current provisions	**57,626**	36,279
Total current liabilities	**353,150**	362,780
Deferred income	**1,864**	2,008
Non-current provisions	**99,048**	111,437
Long-term lease liabilities	**216,497**	177,787
Deferred tax liabilities	**45,713**	45,492
Other non-current liabilities	**3,670**	378
Total non-current liabilities	**366,792**	337,102
Total liabilities	**719,942**	699,882
Share capital	**100**	100
Retained earnings	**2,939,284**	2,665,738
Currency translation adjustments	**-31,612**	3,308
Total equity	**2,907,772**	2,669,146
Total liabilities and equity	**3,627,714**	3,369,028

Consolidated statement of cash flows of the Octapharma Group

(All figures in 1,000 EUR)	2020	2019
Net profit for the year	**375,693**	403,445
Depreciation of property, plant and equipment and intangibles	**159,899**	140,697
Impairment of fixed assets	**64**	3,233
Change in fair value of non-current assets	**-8,061**	-55
(Profit) loss on sale of property, plant and equipment and equity investments	**1,877**	367
Changes in long-term liabilities and provisions	**21,276**	13,684
Finance cost	**12,663**	9,520
Tax expense	**12,585**	24,497
Unrealised foreign currency (gain) loss	**18,538**	-3,279
Cash flow before changes in working capital	**594,534**	592,109
(Increase) decrease of working capital	**5,962**	-334,929
Net cash from operating activities	**600,496**	257,180
Acquisition of property, plant and equipment	**-226,839**	-213,629
Acquisition of subsidiary, net of cash acquired	**0**	-18,427
Change of financial and equity investments	**307**	415
Proceeds from sales of property, plant and equipment	**78**	1,035
Interest received	**2,727**	1,012
Net cash used in investing activities	**-223,727**	-229,594
Financing activities	**-97,596**	-78,450
Payments of lease liabilities	**-26,163**	-17,665
Net cash used in financing activities	**-123,759**	-96,115
Net change in cash and cash equivalents	**253,010**	-68,529
Cash and cash equivalents beginning of period	**434,845**	502,153
Effect of exchange rate fluctuation on cash held	**-5,072**	1,221
Cash and cash equivalents end of period	**682,783**	434,845

Report of the Independent Auditor on the summary financial statements

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REPORT OF THE INDEPENDENT AUDITOR ON THE SUMMARY FINANCIAL STATEMENTS

Octapharma Nordic AB, Stockholm

Opinion

The accompanying summary financial statements on pages 55 to 58, which comprise the summary balance sheet as at December 31, 2020, the summary income statement and summary cash flow statement for the year then ended, and related notes, are derived from the audited financial statements of Octapharma Nordic AB, Stockholm, for the year ended December 31, 2020.

In our opinion, the accompanying summary financial statements are a fair summary of the audited financial statements, on the basis described on page 55 of the annual report 2020.

Summary Financial Statements

The summary financial statements do not contain all the disclosures required by International Financial Reporting Standards (IFRS). Reading the summary financial statements and the auditor`s report thereon, therefore, is not a substitute for reading the audited financial statements and the auditor`s report thereon.

The Audited Financial Statements and Our Report Thereon

We expressed an unmodified audit opinion on the audited financial statements in our report dated February 15, 2021.

Management`s Responsibility for the Summary Financial Statements

Management is responsible for the preparation of the summary financial statements on the basis described on page 55 of the annual report 2020.

Auditor's Responsibility

Our responsibility is to express an opinion on whether the summary financial statements are a fair summary of the audited financial statements based on our procedures, which were conducted in accordance with International Standard on Auditing (ISA) 810 (Revised), *Engagements to Report on Summary Financial Statements*.

KPMG AG

Toni Wattenhofer

Anna Pohle

Zurich, 15 February 2021

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