Understanding Grifols

Grifols is dedicated to enhancing the health and well-being of people around the world. Since 1909, we have strived to promote innovation and advance plasma science and diagnostic solutions to make a positive social impact. Guided by our longstanding solid values and ethical principles, we integrate responsible and sustainable business practices in all of our operations.

WE ARE GRIFOLS

- A **global company** that works every day to improve people's health.
- A **world leader in plasma therapies** and transfusion medicine.
- We act as a **bridge between donors and patients.** Our essential medicines create value.
- **More than 115 years of history** and the legacy of 4 generations serving society.
- **We promote science, innovation, and sustainability** to improve people's life.

BUSINESS UNITS

Plasma Procurement and Biopharma
Plasma procurement, production and commercialization of plasma and non-plasma solutions.
85% over revenues

Diagnostic
Leading-edge diagnostic solutions for blood and plasma analyses.
10% over revenues

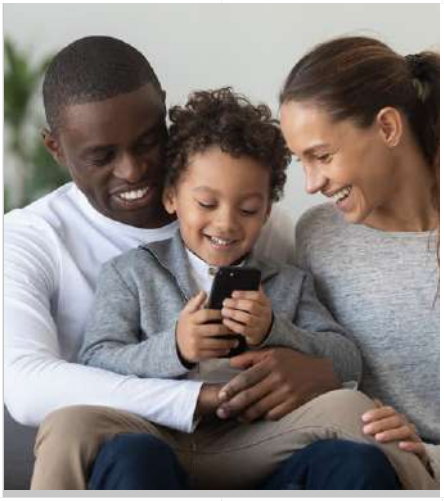
Bio Supplies
High-quality biological products for non-therapeutic use.
2% over revenues

Others
Specialty pharmaceuticals and hospital management solutions.
3% over revenues

AMONG THE WORLD'S MOST SUSTAINABLE COMPANIES

We address the needs of thousands of patients

Grifols strives to generate long-term sustainable value for all of its stakeholder groups, with a clear emphasis on patients and donors, whose generosity makes our plasma-derived therapies possible.



Therapeutic areas

6

Treatments
Plasma and non-plasma therapies

Diagnostic solutions
Transfusional and Clinical

Immunology and Neurology

Immunodeficiencies and autoimmune disorders

Flebogamma® DIF Human Normal Immunoglobulin (IVIg) 50 mg/ml 100 mg/ml
Hypermunes®
gamunex-c
Xembify® immune globulin subcutaneous human-klhw) 20%
Tavlesse® Film-coated tablets fostamatinib
HyperRAB®

Pulmonology

Alpha-1 antitrypsin deficiency

READY-TO-INFUSE PROLASTIN® C LIQUID alpha1-proteinase inhibitor (human)
AlphaID™
PROLASTIN®

Hematology

Hemophilia and other bleeding and clotting disorders

Thrombate III® antithrombin III (human)
Alphanate® Human coagulation FVIII/VWF complex
Koāte®-DVI Antihemophilic Factor (Human)
Fanhdi® Human coagulation FVIII/VWF complex
ProfilNine® Factor IX Complex
AlphaNine® Human coagulation Factor IX
VistaSeal™/MC
VeraSeal®

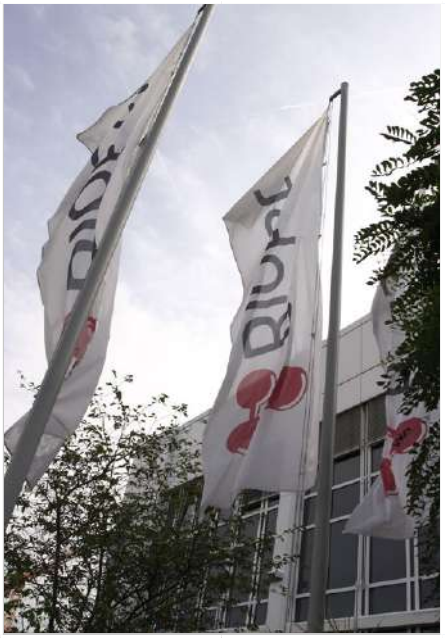
Hepatology / Intensive Care

Hypovolemia and hypoalbuminemia in liver diseases, cardiac surgery, severe infection and other conditions.

Albutein® Human Albumin
Albutein® Human Albumin FlexBag
Human Albumin Grifols®
Plasbumin® Albumin (Human), USP

Joining forces with Biotest

Since Grifols closed its Biotest investment in April 2022, both companies have closely collaborated to increase the availability of plasma therapies for the benefit of patients



Workforce

2,300+

Donor plasma centers

33+

Immunology and Neurology

Hematology

Hepatology / Intensive Care

Innovation

Strategic projects advanced: 2

Fibrinogen
IgM (Trimodulin)

Our global footprint

- Corporate Headquarters
- Industrial Facilities
- R&D Centers
- Biopharma Centers
- Diagnostic Centers
- Bio Supplies Centers
- Others Centers
- Plasma Donor Centers

North America

Clayton
Denver
Emeryville
Los Angeles
San Diego
Memphis
Montreal

North Carolina Hub
Research Triangle Park

California Hub
San Carlos
South San Francisco
Los Angeles
San Diego
Emeryville

U.S. **286**
Canada **2**

Clayton
Los Angeles
Montreal
Raleigh-Durham

Emeryville
Raleigh-Durham
San Diego

Memphis

Denver

RoW

Melbourne	China
Melbourne	Egypt **9** China **(SRAAS)**

Europe

Barcelona	Germany **58** Hungary **19** Czech Republic **14** Austria **3**	Barcelona Bilbao Dublín Düdingen Dreieich Leipzig Murcia San Sebastian	**European Hub** Dublin Andorra Barcelona Bilbao Zaragoza Düdingen Dreieich
Barcelona Dublin Dreieich	Barcelona Bilbao Düdingen	Leipzig	Barcelona Murcia San Sebastian

Our business model creates value

WE ARE GUIDED BY CLEAR OBJECTIVES

GOAL
Enhancing global health helping people live longer and better lives.

AMBITION
Increase our positive impact to strengthen our sustainable business model.

AND CORE VALUES

VALUES
- Honesty
- Transparency
- Integrity
- Independence
- Safety & Quality
- Ethics
- Compliance
- Human rights
- Sustainability

SUSTAINABILITY PLAN STRATEGIC PILLARS
Commitment to patients and donors
Employee pool
Social impact
Environmental responsibility

WITH A STRATEGIC VISION AND THREE ESSENTIAL AREAS OF EMPHASIS

INNOVATION

ETHICAL COMMITMENT

FINANCIAL PERFORMANCE

OUR ACTIVITY HAS A POSITIVE IMPACT

VALUE CHAIN

Donors Production Distribution Patient

Input

Donors

920,000+ donors
390+ plasma centers

Innovation

Robust ecosystem
6 therapeutic areas

Employees

23,741 employees
58% women
92 nationalities

Governance

New leadership
36% women board members

Resources

382 M€ net R&D investment*
210 M€ CAPEX*

Planet

32.8 M€ environmental investment
3.6 Mm³ water consumption
928 M kWh energy consumption
34.27% renewable electricity

Value creation

Patients

800,000+ treated
27,370 M$ value creation (SROI**)
6x quality of life improvement***
8.3 M€ product donations
7.7 M€ patient programs and organizations

Employees

5,582,576 training hours
852 employees with disabilities*
99% permanent contracts
69% training hours delivered to women

Resources

6,592 M€ revenue*
1,251 M€ EBITDA*
695 M€ total tax contributions
23.5 M€ social contribution

Planet

83% recovered ethanol
50% recovered waste
33% GHG Emissions reductions in relation to sales (Scope 1, 2 & 3)

* Including Grifols and Biotest.
** Calculated with Social Return of Investment methodology, described in appendix.
***In relation to the cost of treatment. Improvement in quality of life calculated using SROI methodology.

Sustainability and human rights

"Corporate sustainability is key. Companies will either be sustainable or they won't be. It is time to practice a new way of doing business. Sustainability transforms companies by making it easier to find business opportunities linked to sustainable development."

António Guterres, Secretary-General of the United Nations

BOLD FORWARD STEPS

- **A bridge between donors and patients**
  More treatments thanks to the generosity of our donors
- **Transformation underway**
  We have clear priorities
- **Sustainable business model**
  We add value to the economy, society and the environment
- **Commitment to the UN Global Compact**
  We do our bit to contribute to a sustainable transformation
- **Robust governance**
  We have strengthened our leadership team
- **Roadmap for Grifols 2030 Agenda**
  30 goals structured around six SDG-aligned pillars

OUR SUSTAINABILITY EFFORTS ARE GLOBALLY RECOGNIZED

A HOLISTIC VIEW OF SUSTAINABILITY

Grifols' commitment to sustainability is driven from its topmost echelons and firmly embedded into its corporate governance system. The company's strategic roadmap includes six core pillars to help address the world's most critical challenges: Commitment to Donors and Patients, Environmental Responsibility, Social Impact, Ethical Commitment, Innovation, and Our People.
Around the world, Grifols' employees all share the firm's staunch dedication to sustainability, working together to build a solid business model that creates value for all stakeholders.

Sustainability as a roadmap

Grifols has made major strides in recent years to integrate sustainability into its business model and elevate the positive impact and value generated by its operations.

This objective is reflected in Grifols' Sustainability Policy and 2021-2023 Sustainability Master Plan, which is included in its Strategic Plan and aligned with the United Nations Sustainable Development Goals (SDGs).

Numerous policies, programs and formal commitments support Grifols' Sustainability Policy to promote the material aspects of its activity from an ESG perspective.

Grounded on a thorough analysis of Grifols' relevant or material aspects, the Sustainability Master Plan outlines the 30 corporate objectives included in Grifols 2030 Agenda.

We align our activities with the Sustainable Development Goals.

Our Sustainability Master Plan is grounded on 6 Pillars

MAIN PILLARS

CARING ABOUT OUR PEOPLE

Our Aim: employees feel they are part of a company that promotes diversity, continuous development, equal opportunities, gender equality and that strives to improve well-being at the workplace

COMMITTING TO SOCIETY

Our Aim: healthier and wealthier society, by positively contributing to social progress, supporting organizations and actively participating in local communities

FOSTERING HEALTH

Our Aim: solid community where every donor feels valued for its commitment and understands its impact beyond compensation, and every patient receives the treatment it requires

EMBRACING NATURE

Our Aim: advance towards the common good of having healthy places to live, work and play, by raising awareness on the need to protect the planet

TRANSVERSAL PILLARS

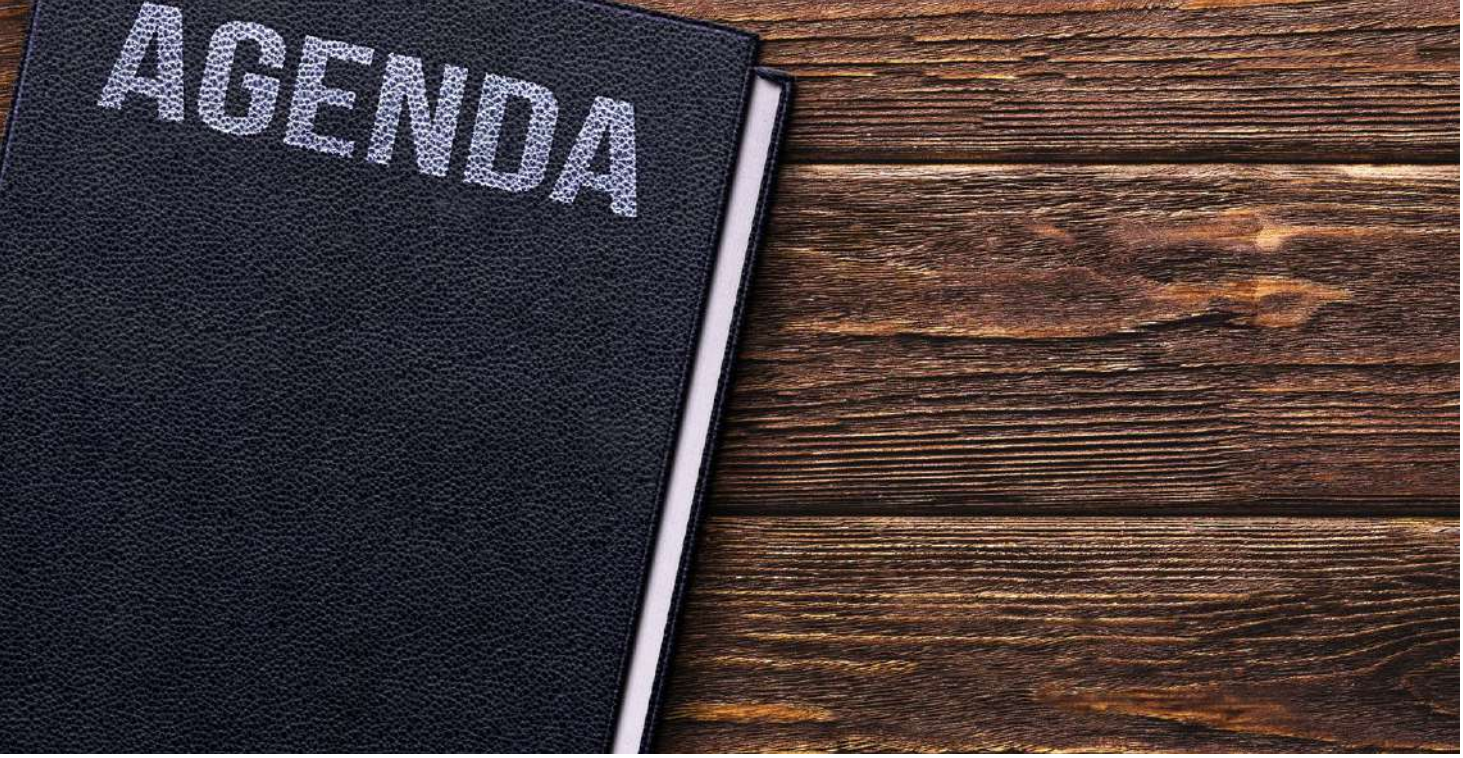
ENCOURAGING ETHICAL PRACTICES

Our Aim: placing human rights at the core of our practices and having the highest ethical standards integrated throughout the supply chain

FOSTERING INNOVATION

Our Aim: scientific progress addressing the needs of our patients, lead by our pioneering spirit and protecting the rights, safety and well-being of clinical trial participants

Access to:
Grifols' Sustainability Policy
Sustainability Master Plan
2030 Agenda
Overview of all Grifols policies: "Corporate Governance"



Materiality

Grifols conducts an annual materiality analysis to identify the most relevant issues related to its economic, social and corporate governance (ESG) performance. The study's findings and the contents of the Integrated Annual Report are approved by Grifols' Board of Directors.

In 2023, the materiality analysis followed a methodological approach grounded on universal GRI 3 standards: Material Topics 2021 and the ESRS 1 (EU Sustainability Reporting Standards) methodology, developed by the EFRAG (European Financial Reporting Advisory Group). This two-pronged materiality approach facilitated the analysis of Grifols' activity, products and value chain on the environment, as well as the environmental impacts and opportunities that could influence its financial performance.

The methodology comprised three blocks: (1) defining the material issues to report; (2) identifying impacts, risks and opportunities; and (3) assessing and prioritizing material issues according to the identified impacts, risks and opportunities

"We follow a double materiality approach by addressing how our business impacts its surroundings and how external factors impact our financial performance.

Define material aspects to report: context assessment

1.

This first step entails an internal and external analysis to gather the requisite qualitative and quantitative baseline information. Through this context assessment, Grifols is able to identify potentially material issues for its main stakeholders from an ESG standpoint. Grifols' business activities and relationships and their associated sustainability context were evaluated taking into account its main stakeholders and business partners.

As a starting point, the identification of material matters in 2023 began with those detailed in the 2022 double materiality analysis, with updates to reflect the current methodology, company context, business climate and information analyzed through the contextual assessment. Also examined were data from industry studies, national and international media outlets, and a benchmark of the industry's core companies.

Material matters identified in the 2023 double materiality analysis

Topic	Related aspects	Link to Grifols' strategy	Priority SDG
Water	• Water consumption management • Wastewater management • Local constraints and water stress		
Climate action	• Decarbonization strategy • Climate risk and opportunity management • Climate adaptation measures		
Pollution	• Prevention of air, water and soil contamination	• Environmental Responsibility	
Circular economy and waste and resource management	• Efficient management of resources • Responsible management hazardous and non-hazardous waste		
Energy transition	• Consumption and promotion of the use of renewable energy		
Employee commitment	• Talent attraction and retention • Employee development • Occupational well-being • Diversity and inclusion	• Our People	
Contribution to health (patients and society)	• Access to treatments • Education and awareness of treatments	• Social Impact • Commitment to Donors and Patients	
Contribution to society	• Social and philanthropic contributions • Commitment to communities of operation • Foundations	• Social Impact	
Human rights	• Identification of human rights risks • Human rights due diligence	• Ethical Commitment	
Plasma and donors	• Commitment to donors • Ethical standards in plasma donation • Donor eligibility • Safety in the plasma donation process	• Commitment to Donors and Patients	
Innovation and knowledge generation	• Innovation strategy and investment • Intellectual property • Research projects	• Innovation	
Data protection and cybersecurity	• Data privacy • Cybersecurity to protect information	• Social Impact	
Product safety and quality	• Supply chain quality management • Product quality and safety standards • Traceability • Product recall management	• Commitment to Donors and Patients	
Ethical code and good management practices	• Code of ethics and whistleblowing channels • Anti-corruption, bribery and money laundering • Risk management • Responsible marketing	• Ethical Commitment	

Identify impacts, risks and opportunities

2.

The results of previous materiality analyses and context assessments were used as a baseline to identify material aspects of Grifols' activity that could affect its environment and stakeholders, both directly and through its value chain, as well as the environmental risks and opportunities that could influence its financial performance.

In line with the requirements of the new European directive on corporate sustainability reporting (CSRD), a study of different organizations and representative documentation (proxy) was carried out to make sure stakeholder needs and interests were identified and integrated into the definition and evaluation of impacts, risks and opportunities. These perspectives include those of donors, patients, employees, public healthcare systems, foundations, NGOs and local communities. Specifically, the organizations, surveys and documentation analyzed to incorporate stakeholder perspectives were as follows:

- Fundamental provisions of the International Labour Organization (ILO).
- Donor and patient resources related to the Plasma Protein Therapeutics Association (PPTA).
- Public information disclosed by the World Health Organization (WHO) on public health systems, with a focus on the U.S. and Europe.
- Public information from the World Federation of Hemophilia.
- Public information from the American Liver Foundation.
- Public information from the International Patient Organisation for Primary Immunodeficiencies (IPOPI).
- Impact analysis on communication outlets, with the specific focus on local communities where Grifols operates.
- Results of Grifols' most recent global employee survey.

In line with CSRD requirements, next year's double materiality analysis will include direct consultations with Grifols' main stakeholders to isolate and evaluate related impacts, risks and opportunities.

Evaluate and prioritize material aspects according to identified impacts, risks and opportunities

3.

Material issues are prioritized by taking the arithmetic average of each identified impact, risk and opportunity, and calculating its probability and severity. Based on these results, the degree of materiality can be assessed from both impact and financial perspectives.

Impact evaluation

For each of the aforementioned impacts, the following indicators are analyzed:

- **Probability** of the impact's occurrence: This indicator is not evaluated for current impacts since they are happening in present time. Similarly, this indicator is not assessed for human rights-related impacts in accordance with best practices to assure a greater preponderance of severity. .
- **Severity** of the impact taking into account the following factors:

– Scale: level of severity of the impact.

– Scope, extent of the impact, e.g., the number of individuals affected or magnitude of environmental damage.

– Irremediability: degree of difficulty involved in counteracting or correcting the resultant damage. For the positive impacts, this indicator has not been evaluated.

Evaluation of risks and opportunities

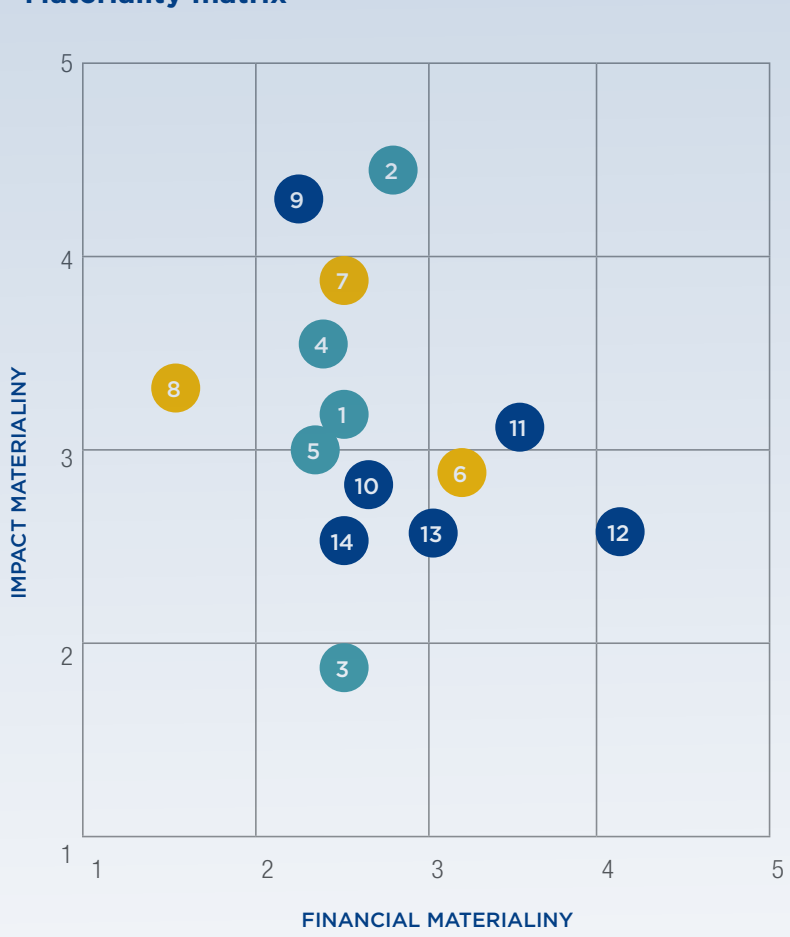
Risks and opportunities are derived from the previous phase and evaluated using the following variables:

- Probability of occurrence of each risk and opportunity
- Magnitude or scale of each risk and opportunity in terms of their degree of significance in the case of occurrence.

The results of this evaluation were validated by both Grifols managers and industry experts.

Each issue encompasses the most relevant impacts, risks and opportunities and is represented through a materiality matrix, which interrelates the results from impact and financial perspectives.

Materiality matrix



ENVIRONMENTAL ASPECTS

1. Water
2. Climate action
3. Pollution
4. Circular economy and waste and resource management
5. Energy transition

SOCIAL ASPECTS

6. Employee commitment
7. Contribution to health
8. Contribution to community

GOVERNANCE ASPECTS

9. Human rights
10. Plasma donors
11. Innovation and knowledge generation
12. Data protection and cybersecurity
13. Product safety and quality
14. Ethical code and good management practices

1. Minimum 2. Low 3. Medium 4. High 5. Very high

The materiality of each type of impact is defined as follows:

1. The degree of materiality of a real negative impact is determined by scale, scope and irremediability.
2. The degree of materiality of a potential negative impact is determined by scale, scope, irremediability and probability.
3. The degree of materiality of an actual positive impact is determined by scale and scope.
4. The degree of materiality of a potential positive impact is determined by scale, scope, and probability.

Worth noting in 2023 is the inclusion of two new topics in the double materiality analysis: water and pollution. Also, energy efficiency was reclassified as energy transition to reflect all issues entailed in the shift to a low-carbon economy and the growing use of energy from renewable sources. Finally, Circular Economy and Resource Management was renamed Circular Economy and Waste and Resource Management to place greater emphasis on Grifols' management of impacts, risks and opportunities derived from the waste it generates, which it already oversees.

Based on the results of the double materiality analysis carried out for the 2023 fiscal year, Grifols' priority material are outlined in the next page.

In relation to the risks identified in the double materiality analysis, these are fully integrated into the company's ESG risk management system, and are developed in the "Risk management and control" section of this report.

Grifols' priority material matters

Matters	Climate action	Human rights	Contribution to health (patients and society)
Topics included	Decarbonization strategy Climate risk and opportunity management Climate change adaptation measures	Identification of risks Due diligence	Access to treatments Education and awareness on treatments
Why is it material?	For Grifols, promoting decarbonization of the economy and minimizing the environmental impact of its direct activity and value chain is a core strategic priority. The company understands the risks caused by the climate emergency and their global impact on human health and, by extension, on all of its stakeholders.	Promoting and fostering respect for human rights is a transversal and organization-wide effort articulated by various strategic priorities and commitments to donors, patients, employees and other main stakeholders.	Supporting and improving people's health is Grifols' core mission and the bedrock of its business model. For this reason, all health-related commitments are essential in the development of its business activities and stakeholder relations.
Impact on the company	Grifols recognizes the risk that climate change poses to its business model and the potential ramifications on its production capacity and supply chain. As part of its analysis of climate risks and opportunities and in line with TCFD recommendations, Grifols identified nine physical risks and 20 transition risks with a possible organizational impact. In addition, Grifols reserves a portion of its environmental program's financial resources to reduce atmospheric emissions and energy.	Grifols understands the need for fundamental bioethics principles to always underpin its activities and shape its decision-making and management systems. The company allocates financial resources for due-diligence processes and audits in which human rights issues are thoroughly reviewed.	Grifols understands that its ability to advance and sustain its business depends on trust with donors, patients and other main stakeholders. To this end, it dedicates resources and efforts that have a financial impact to reinforce its stakeholder relations.
Business strategy	Grifols adopted several objectives and targets as outlined in its 2023-2026 Environmental Plan to manage the impacts, risks and opportunities related to this issue and maximize its corporate performance. The company monitors the compliance of each objective noted in the "2023-2026 Environmental Plan" section of this report. Moreover, it has also committed to establishing SBTi-aligned reduction targets. Grifols' Climate Action Policy details its core commitments in this area, which are incorporated into its Sustainability Policy, Environmental Policy and Energy Policy.	Grifols has a due diligence process based on its Human Rights Policy to guide the management of related impacts, risks and opportunities. At the same time, it also has detection, evaluation, management, mitigation, complaint and redress processes. In this way, Grifols defines its commitments, objectives and action plans regarding the respect and promotion of human rights.	The management of the potential impacts, risks and opportunities of Grifols' activity, both directly and throughout its value chain on patients and society, is detailed in the "Our Commitment to Patients" section, including diverse commitments and programs to broaden access to treatment and other actions.
Tracking metric	tCO_2e €M allocated to reduce atmospheric emissions, energy and others.	Number of complaints regarding human rights violations.	Number of donors. Number of patients treated. Social value created for donors, communities and patients (€M). Number of inspections carried out by regulatory bodies in plasma donations centers. Number of plasma donation centers.
Integration in risk management	The risks included in the climate change issue are fully integrated into Grifols' risk management system. The risks identified and their corresponding mitigation actions are further developed in the "Environmental Responsibility" chapter.	The risks identified under the material matter of human rights are fully integrated into Grifols' ESG risk management system and described in greater detail in the "Sustainability and Human Rights" section.	The risks identified regarding this material matter are fully integrated into Grifols' ESG risk management system and described in greater detail in the "Corporate Governance" chapter.
Main impacts, risks and opportunities detected	**Main impacts**: - Adaptation to climate change - Contribution to climate action (scopes 1,2 and 3) - Reduction of GHG emissions **Main risks and opportunities:** - New legal requirements related to GHG emissions and climate risk management The strategy and action plans to manage these impacts, risks and opportunities are further developed in the "Environmental Responsibility" chapter.	**Main impacts**: - Human rights violations in the supply chain - Cases of human rights violations - Promotion and protection of human rights **Main risks and opportunities:** - Human rights violations on behalf of Grifols suppliers - Grifols employees who violate human rights (ex: gender discrimination claims) The strategy and action plans to manage these impacts, risks and opportunities are described in greater detail in the "Ethical Commitment" section.	**Main impacts**: - Increasing people's life expectancy - Improving the quality of life of patients, including children and young people **Main risks and opportunities:** - More public information related to health - Possible side effects of treatments The strategy and action plans to manage these impacts, risks and opportunities are further developed in the "Commitment to donors and patients" chapter.

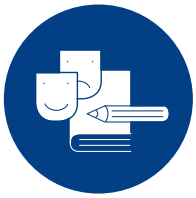
Stakeholder relations

Grifols recognizes the crucial role that stakeholders play in its long-term success and sustainability. Through its stakeholder engagement strategy, the company strives to build relationships of trust founded on transparency and effective dialogue. By reinforcing these critical relationships, Grifols is able to identify the most relevant stakeholder issues and detect new sustainability-related trends.

Grifols' stakeholder management

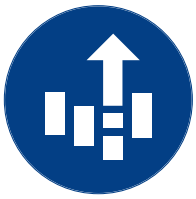
COLLABORATION

- We foster collaboration with our stakeholder groups to advance our purpose and progress on achieving Grifols 2030 Agenda objectives.



DIALOGUE

- We encourage the participation and involvement of our stakeholders by offering platforms for dialogue and forums that foster active listening.



CONTINUOUS IMPROVEMENT

- We routinely review stakeholder relationship mechanisms to ensure they respond as efficiently as possible to their current needs.

TRANSPARENCY

- We assure transparency in stakeholder relations and financial and non-financial disclosures by sharing truthful, relevant, complete, comparable, clear, up-to-date and useful information.
  The primary reporting platforms on Grifols activities include the Integrated Annual Report; quarterly earnings presentations; specific reports, primarily those generated to comply with legal requirements in the U.S., where Grifols securities are also traded (20F); publications on global and local websites; and social media outlets (LinkedIn).

COMMITMENT

- Grifols provides information to its stakeholders in a clear, concise and ethical manner.

Primary communication channels with stakeholders

Grifols has identified and implemented solid communication channels to promote dialogue and interaction with stakeholders and detect their needs and expectations. The following table offers a summary of Grifols' communication outlets for its different stakeholder groups:

PATIENTS AND PATIENT ASSOCIATIONS	• Grifols' lines of communication include electronic and phone channels. The company contacts patient associations every month to discuss topics of interest and update them on Grifols' activity. In addition, the company occasionally organizes meetings and visits to its corporate headquarters, production facilities and museums.
PLASMA DONORS	• Grifols informs plasma donors via its website, educational videos and other communication outlets. Donors can also contact the company at its plasma collection centers and corporate website. Grifols conducts surveys to discern donors' level of satisfaction and detect areas for improvement.
CLIENTS	• Grifols engages with customers (public and private sector; wholesalers, distributors, group purchasing organizations (GPOs), blood banks, hospitals, and healthcare institutions (public health/social security systems) to provide clear and comprehensive information all of its products and plasma needs.
REGULATORY BODIES	• Grifols uses formal channels to communicate with regulators such as the FDA, EMA, AEMPS and other regulatory authorities on issues relating to clinical trials, authorizations for plasma donation centers, validation of production facilities and other related clearances for the sale of plasma-derived therapeutic treatments, including new medicines and indications.
SUPPLIERS (NON-PLASMA)	• Formal communication channels are used during certification, evaluation and auditing processes, while informal channels are used for day-to-day communication.
LOCAL COMMUNITIES AND NGOs	• Grifols collaborates with several NGOs, both directly and through its foundations, to support community initiatives in its markets of operation.
MEDIA OUTLETS	• Grifols maintains clear and transparent communication with journalists and other media representatives. The company publishes press releases to announce important events such as quarterly and annual results, and hosts at least one meeting per year to coincide with its General Shareholders' Meeting.
SCIENTIFIC COMMUNITY AND RESEARCH COLLABORATIONS	• For Grifols, collaborations with research partners and other scientific institutions play a critical role in driving the continuous innovation of its products and processes. The company participates in R&D initiatives, investments and partnerships with members of the scientific community, among other activities.
FINANCIAL COMMUNITY	• Grifols discloses significant information in compliance with the legal norms established by regulators and the securities markets on which it is listed (CNMV, SEC, NASDAQ, ISE), using the appropriate channel for each entity. • Grifols also communicates with shareholders, investors, analysts and other stakeholders by organizing and attending meetings, including the General Shareholders' Meeting, business meetings, analyst calls and roadshows. The company also publishes an annual report, quarterly reports and press releases on its corporate website, which are sent, if necessary, to interested parties subscribed to its distribution lists. • Every year, Grifols holds a meeting exclusively for analysts and investors, which features more in-depth presentations. The company also has a dedicated email channel for the investment community to receive and respond to feedback and queries.
EMPLOYEE POOL	• Grifols has a continuously updated employee intranet and viewing screens in several facilities featuring general-interest information. The company communicates with its employees via an internal magazine, semi-annual meetings and other official channels, and informal outlets for daily interactions. It also holds regular meetings with legal workforce representatives. • The Human Resources team periodically conducts a climate survey to gain a deeper understanding of workforce needs. It has an email channel for HR queries and dedicated email for sustainability-related issues.
INSTITUTIONAL ENTITIES	• The company establishes relationships with institutional bodies, trade groups and other professional organizations through both formal and informal channels. These interactions include the organization of forums, congresses and other business-related meetings.

Objectives with a clear timeline: Grifols 2030 Agenda

As part of its sustainability strategy, in 2021 the company established the Grifols 2030 Agenda, which contains 30 SDG-aligned corporate objectives. The company ratified these commitments again in 2022, establishing intermediate milestones with 2024 targets that are tracked and evaluated every year.

In 2023, the company advanced at a progress rate of over 90% on its intermediate targets, significantly narrowing the gap to achieving its Grifols 2030 Agenda objectives.

Commitment to donors and patients	**Intermediate 2024**	**Status**
• Achieve EUR **18** million per year in donations to support patient programs	€13M/year	✔
• Increase donations of clotting factors to **240** million IU	90M IU	✔
• Achieve **90%** approval among donors for positive customer service (good or excellent rating)	n/a	n/a*
• Attain **80**% referral rate from active donors	n/a	n/a*
• Increase ratings via the Donor Hub by **45%**	Same 2030 target	n/a*

Environmental responsibility	**Intermediate 2024**	**Status**
• **55%** decline in GHG emissions per unit of production	-15%	✔
• **15%** increase in energy efficiency per unit of production	+5%	✔
• **100%** electricity consumed from renewable sources	27%	✔
• Promote **decarbonization** in business travel and work commutes	Same 2030 target	✔
• Increase **circular economy** measures at each stage of the operational life cycle	Same 2030 target	✔
• Protect **biodiversity** in the company's natural areas to capture CO_2	Same 2030 target	✔

Social Impact	**Intermediate 2024**	**Status**
• Increase the number of social outreach initiatives and investments by **50%**	35%+ (initiatives) 13%+ (investments)	✖
• Allocation of **25%** of social initiatives for STEM scholarships for women	20%	✔
• Reach **$1** million in donations of products and medicines for emergency relief efforts	$750k	✔
• Increase funds for José Antonio Grifols i Lucas Foundation by **10%**	10%	✔
• Increase by **10%** the amount allocated to bioethics grants and by **20%** number of activities developed by Víctor Grífols i Lucas Foundation	10%	✔

*During 2023, the donor satisfaction measurement system was under review, and there is not enough information available to assess progress against the initially set goals, although progress up to 2022 has been positive.

Ethical commitment	Intermediate 2024	Status
• Implement ESG criteria among suppliers up to **60-80%** of total spending volume	25%	✔
• Maintain Biopharma claims ratio in ≤ **1/50,000**	Same 2030 target	✔
• Maintain <1 critical deficiencies identified by external audits (health regulatory authorities)	Same 2030 target	✔

Innovation	Intermediate 2024	Status
• Promote **in-house and external innovation** in core therapeutic areas	• Achieve 80%+ of milestones defined in key innovation projects • Allocate at least 75% of R&D investment to new products and market development	✔

Our people	Intermediate 2024	Status
• Impart **100** hours of training hours/year/person	Same 2030 target	✔
• Deliver annual training to **70-80%** of the workforce	Same 2030 target	✔
• Increase percentage of women in Senior Manager roles to **50%**	41%	✔
• Increase percentage of people with disabilities to **3-5%** of total employee pool	Same 2030 target	✔
• Ensure women comprise **50%** of interviews for managerial positions	45%	✔
• Maintain employee **turnover rate** below industry average*	Same 2030 target	✔
• Achieve **70%** overall employee engagement rate per department	63%	✔
• **75%** increase in installations certified as healthy workplaces	54%	✘
• **15%** decrease in LTIFR (lost time injury frequency rate)	5,3%	✔
• **75%** of installations with ISO 45001 certification	54%	✔

* Not including employees at Grifols plasma donation centers.

Sustainability governance in Grifols

Promoting sustainability is a core priority for Grifols' corporate governance structure, which includes various mechanisms to ensure the compliance, coordination, execution and review of organizational objectives to continue to grow as a responsible, transparent company committed to its diverse stakeholder groups.

Grifols' main sustainability governance bodies

Approval	Board of Directors
Supervision	Sustainability Committee Audit Committee Appointments and Remuneration Committee
Follow-up	Sustainability Steering Committee
Implementation	Business Areas and Corporate Support Areas

Sustainability Committee members

James Costos
President
Independent
Montserrat Muñoz Abellana
Member
Independent
Enriqueta Felip Font
Member
Independent
Núria Martín Barnés
Secretary (non-member)

Sustainability Committee rules of procedure

Grifols has taken important steps in recent years to strengthen its corporate governance bodies

- **Formed by Grifols' Board of Directors in 2020, the Sustainability Committee** oversees the compliance of company's ESG principles and commitments and good governance practices, while ensuring their alignment with its corporate culture. Its oversight ensures the upholding of stakeholder transparency policies, including financial and non-financial disclosures. The committee held four formal meetings in 2023.

- The **Sustainability Steering Committee** is a multidisciplinary and international team created in 2021 coordinated by the Investor Relations and Sustainability Department, which reports to the Sustainability Committee. Among its functions, the committee fosters ongoing dialogue to identify, establish, implement and confirm compliance with Grifols Master Plan objectives, and generates and coordinates the reporting of non-financial and corporate sustainability information.

Incentives to promote sustainability

The Appointments and Remuneration Committee conducted an in-depth review of the directors' compensation policy and the company's overall remuneration system, taking into consideration feedback received from shareholders, investors and other stakeholders.

In general, remunerations for executive directors (executive chairperson and CEO, COO and CCO) include the following elements: (i) fixed remuneration to reward the performance of executive functions and (ii) variable remuneration to reward the fulfillment of corporate objectives (financial and non-financial), established to support Grifols' long-term strategy and interests.

Grifols' COO and the CCO remuneration system also includes options on Class A shares to incentivize the attainment of its long-term strategic priorities, performance over time and sustainable value creation for stakeholders.

Variable remuneration is subject to financial and non-financial metrics and parameters, among others, including a specific metric for environmental, social and governance (ESG) objectives. In 2023, 10% of variable remuneration was linked to ESG factors, 25% of which are environmental, 40% social and 35% good governance.

More information: Remuneration Policy

More details on Grifols' remuneration system: "Corporate Governance" section.

In 2023, 10% of variable compensation is linked to ESG factors: 25% environmental, 40% social and 35% good governance.

Human rights: an essential pillar

Respect for the intrinsic rights and dignity of every person is an essential prerequisite for Grifols. The key principles of bioethics guide the company's research, development, manufacturing and marketing of its products, with the overarching aim of protecting the safety and dignity of everyone involved in the process, and promoting scientific progress within an ethical framework.

Several regulations, declarations and codes govern the adoption of these principles, including the Universal Declaration of Human Rights (1948), the Helsinki Declaration (1964) and the UNESCO International Declaration of Bioethics and Human Rights (2005).

In line with the foremost international benchmarks (United Nations Global Compact, United Nations Guiding Principles of Business and Human Rights, OECD guidelines for multinationals, and the ILO Declaration for Multinationals), Grifols has a comprehensivestrategy to promote and guarantee responsibility and commitment to human rights throughout all its activities.

The 2030 Agenda for Sustainable Development and its Sustainable Development Goals highlight entrepreneurship, investment and innovation are the primary drivers of productivity, inclusive economic growth and job creation. Respect for human rights in business operations is another element common to many SDGs.

We promote and guarantee human rights at the highest level of the organization:

Board of Directors
Sustainability Committee

Four areas of action

Grifols made significant efforts in 2022 and 2023 to analyze and review its due diligence processes, and integrate internal and external best practices in its business model.

1. Culture of understanding and respect for human rights	2. Human Rights Policy	3. Due diligence	4. Grievance mechanisms
• Reinforced corporate governance • Increased awareness and education • Promote transparency • Concrete and measurable action plans	• Compiles and updates the values outlined in the Code of Conduct, which governs the behavior of everyone who works and collaborates with the group. • Establishes the foundational principles on human rights governance and a general framework to detect, prevent, mitigate and correct negative impacts (actual or potential). • Outlines clear principles to forge a culture of respect for human rights that guide all of Grifols' stakeholder interactions.	• Integrates respect for human rights into management and policy-making systems. • Analysis and identification of actual and potential adverse impacts. • Manages the prevention, minimization and mitigation of impacts. • Reporting of the results and remediation of human rights violations.	Grifols Ethics Line

Due diligence

Grifols bolstered its human rights due-diligence processes in 2022 and 2023 by performing a thorough analysis to identify, prevent and mitigate related impacts and main risks. These findings were published in the 2023 Human Rights Due Diligence Report, which takes the entire value chain into consideration.

This due diligence process and resultant reporting follows the Human Rights Based Approach (HRBA) and UN and OECD guidelines. By integrating international standards into its plans and processes, Grifols ensures adherence to the OECD's due diligence phases and the human rights impact assessment (HRIA) created by the Danish Institute of Human Rights, a globally recognized methodology to detect actual and potential human rights impacts.

In line with these frameworks, Grifols carried out the following actions:

i) Considered not only the geographies where the company is most active but also those regions where the risk of human rights violations is inherently greater. This approach aligns with OECD recommendations and serves to enhance Grifols' commitment to responsible business practices.

ii) Assessed the adverse impacts of Grifols on the rightsholders across the entire value chain of the company, including tier I suppliers, joint ventures and others. This focus extends to the most vulnerable groups, including employees, third-party employees, local communities and other relevant rightsholders.

iii) Identified mitigation and remediation measures related to the adverse impacts on human rights to understand Grifols' ability to address and avoid those risks and support the disclosure of how they are managed.

The evaluation process included the following phases:

Integration

Phase 1. Integrate respect for human rights into management and policy-making systems.

On February 25, 2022, Grifols approved its Human Rights Policy under the supervision of the Sustainability Committee. The company's Internal Audit Department periodically audits its systems to ensure compliance with the policy and improve procedures as necessary.

In collaboration with other departments, the Investor Relations and Sustainability Department oversees the integration of respect for human rights into Grifols' processes and activities in its markets of operation. The company has developed specific policies to address identified risks and reinforce its commitment to its main stakeholders[1].

Indentification and evaluation

Phase 2. Identify and evaluate real and potential adverse impacts associated with Grifols' operations, products or services.

2.1. Identify actual and potential impacts

To identify actual and potential impacts on human rights, Grifols conducted a review of industry organizations, statements on conceptual frameworks, international frameworks and applicable human rights agreements.[2]

These were compared to the 35 human rights included in the Human Rights Impact Assessment and Management (HRIAM) Guide. After consolidating the list of human rights, 99 risks potentially relevant to Grifols' activities were identified.

Interviews were conducted with various departmental teams to compare the list of risks and assure alignment with current risk assessment procedures. The list resulted in 17 groups of risks associated with rights holders, countries that may be affected and their decision-makers.

"In 2023, Grifols prepared a human-rights due diligence report, taking into account the entire value chain.

"Grifols' due diligence analysis includes six phases to integrate, identify, assess, manage and report human rights issues.

1. Plasma Donor Policy, Patient and Patient Organization Policy, Environmental Policy and Anti-Corruption Policy, among others.

2. ICCPR (International Covenant on Civil and Political Rights), ICESCR (International Covenant on Economic, Social and Cultural Rights), Universal Declaration of Human Rights (UDHR) and International Labour Organization (ILO), along with principles that Grifols supports, such as the Declaration of Helsinki and the Universal Declaration on Bioethics and Human Rights (UDBHR).

2.2. Assess actual and potential impacts

The methodology followed by Grifols to assess current and potential human rights-related risks determines criticality by considering the severity and probability of an impact. Grifols' internal audit area and enterprise risk management team worked closely together to align this methodology with the global corporate risk assessment.

Meetings were held with the affected areas to help them evaluate and determine the criticality of both of actual and potential risks.

Risk management and monitoring

Phase 3. Detain, prevent and mitigating adverse impacts

Grifols has a robust control environment to address adverse impacts, with a three-tiered approach that includes organizational controls such as the Code of Conduct and the whistleblowing channel. This system extends to human rights, diversity and anti-corruption policies, with a detailed accountability matrix to guarantee an integral risk management process.

Phase 4. Track implementation and its results

The company actively tracks the proper execution and effectiveness of its due diligence activities. Grifols' comprehensive approach includes actions to identify, prevent, mitigate and, if necessary, remediate impacts. This continuous monitoring boosts the efficacy of mitigation measures by quickly implementing corrective measures to address the challenges detected in the analysis phase.

Reporting and remediation of violations

Phase 5. Reporting on how impacts are addressed

Grifols discloses the results of its human rights due diligence both internally and externally. Publicly available on Grifols' corporate website and on the employee intranet, these findings underline the company's commitment to transparency and the robust risk management.

Phase 6. Take corrective action or cooperate in its implementation where appropriate

Grifols offers solid remediation mechanisms to help affected parties voice their concerns and seek solutions. The company recognizes this responsibility by establishing clear channels for filing complaints and resolving human rights-related disputes.

> **Grifols discloses the results of its due diligence on human rights internally and externally.**

More information: "Due Diligence Report on Human Rights".

Indentified risks

The following table details the impacts resulting from very high and high inherent risks, including the associated rights holders and mitigation measures in place to address these risks.

		Mitigation measures		
Identified Inherent Risk	**Rightsholder**	**Entity level**	**Policies, procedures and training**	**Specific controls**
Negative impact of processes on health	• Donors • Participants in clinical trials	✓ ✓	✓ ✓	✓ ✓
Breach Business Integrity (corruption)	• Local communities	✓	✓	✓
Not complying with the quality and safety of the product	• Patients	✓	✓	✓
Modern slavery	• Suppliers' employees	✓		
Not respecting children's rights	• Suppliers' employees	✓		
Violence at work	• Suppliers' employees	✓		
Failure to respect collective bargaining and the right of association	• Suppliers' employees	✓		
Not respecting privacy	• Suppliers' employees	✓		
Discrimination, lack of inclusion and diversity	• Donors • Patients • Employees	✓ ✓ ✓	✓ ✓ ✓	 ✓
Unhealthy atmosphere	• Local communities	✓	✓	✓
Failing to consider the dignity and security of participants in clinical trials	• Participants in clinical trials	✓	✓	✓
Failure to deliver accessible and affordable medicines	• Customers	✓	✓	✓
Inequitable and unfavorable working conditions	• Suppliers' employees	✓		

Grifols' value chain

Further integrate environmental, social and governance principles into our value chain to reinforce a differential patient- and donor-oriented business model that promotes quality, sustainability, transparency, respect for human rights, non-discrimination and equal opportunities.

OUR ROADMAP. GRIFOLS 2030 AGENDA

- Evaluate suppliers using ESG criteria
- Maintain claims ratio in Biopharma: ≤ 1 per 50,000 units distributed
- Achieve zero critical issues in external audits

CORE FEATURES OF OUR VALUE CHAIN

- Vertically integrated, from donor to patient
- Global and diverse
- Major strides in process optimization
- Continuous improvement

OUR PRIORITIES

ETHICS	TRANSPARENCY	HUMAN RIGHTS
SAFETY AND QUALITY	SUSTAINABILITY	LEGAL COMPLIANCE

In pursuit of excellence

Grifols has a range of policies and procedures to advance its sustainable and responsible value chain, with quality and safety standards that far surpass regulatory compliance. In its ongoing quest for excellence, the company follows due-diligence procedures to prevent or mitigate all detected or potential adverse effects on human rights or the environment.

Safety and quality are top priorities

As a leader in global health care, Grifols does its utmost to guarantee the highest levels of quality and safety of its products and services. This core commitment is driven by senior management, ratified in the Code of Ethics and extensive to the entire organization. The Chief Quality Officer (CQO) makes sure that all safety and quality control processes are effectively managed and implemented.

Grifols' Corporate Quality Policy reflects its commitment to conduct all operations in adherence with the highest standards of quality and safety, and advance its mission of improving people's health. In this way, Grifols creates sustainable long-term value for patients, donors, the healthcare community, collaborators and society as a whole.

Grifols' business units have robust policies and procedures to assure the highest quality, safety and efficacy throughout the value chain. Encompassing all corporate functions, the quality-assurance system delivers continuous employee training and development initiatives to continually advance Grifols' quality and safety performance. Several internal committees routinely evaluate corporate processes and quality systems, including the monitoring of key performance and quality indicators.

In 2023, Grifols received favorable outcomes from the audits and inspections carried out by global health authorities and organizations, evidence of its steadfast commitment to quality and safety. The company had no reported cases of regulatory non-compliance, monetary penalties, warnings or non-compliance with voluntary codes.

> **Grifols' business units have robust policies and procedures to assure the highest quality, safety and efficacy throughout the value chain.**

More details on Grifols' Quality Policy

Supplier relations

Grifols Corporate Procurement Policy defines common guidelines and procedures for purchasing processes and supply strategies, assuring all acquired goods and services are founded on transparent, objective, timely and cost-effective decision making. This policy ensures a more structured, consistent and homogeneous framework for purchasing processes throughout the organization, bolstering risk management and compliance with all policies, procedures, and internal and external controls.

This policy places special emphasis on ethical, social, environmental and privacy criteria in alignment with the company's health, safety and environmental policies. At the same time, it promotes the principles of sustainable procurement and topmost transparency in supplier relations, as defined in Grifols' Human Rights and Sustainability Policies.

Ethical compliance and respect for human rights are cornerstones of Grifols' activity. To this end, the company requires all employees, external collaborators involved in its procurement processes to adhere to several core principles: compliance with rules and regulations; integrity, impartiality and fairness; transparency, confidentiality; and due diligence. The policy also encourages the integration of social and environmental requirements, specifications and criteria in all purchasing processes.

In 2023, the company implemented a common procurement platform for all Grifols companies to bolster the group's operational control and monitoring of supplier relations.

Grifols is also rolling out new procedures and IT systems to improve supplier assessment and due diligence processes, and other measures related to recent regulatory changes under the Proposal for a Directive of the European Parliament and the Council on Corporate Sustainability Due Diligence (CSDDD). This proactive approach boosts Grifols' ability to adopt industry best practices and adapt its systems to reflect the latest regulatory shifts, as well as better detect ESG risks and develop measures to minimize and resolve them. Through these actions, the company seeks not only to mitigate risks, but to support suppliers less versed in critical ESG aspects, including respect for human rights and emissions reduction, among others.

The new Procurement Policy integrates ESG standards and promotes maximum transparency with suppliers.

More details on Grifols' Procurement Policy.

Continuous improvement in the identification and management of risks in the value chain

Grifols strives to incorporate greater sustainability, resilience and efficiency in its supply chain. To this end, the Global Procurement team recently implemented an automated supplier management system to identify and manage potential ESG risks and improve visibility throughout the supply chain.

These robust analytical and data-driven resources allow Grifols to better detect supply risks and manage suppliers, leading to deeper connections and greater negotiation leverage. Using this system, the company expanded its monitoring scope of suppliers, which collectively account for over 50% of its procurement volume in 2023.

Supplier qualification and evaluation

Grifols' Supplier Qualification Management System assures all raw materials are subject to rigorous and continuous evaluation processes, including plasma from external suppliers and critical non-plasma suppliers.

Grifols conducts routine supplier audits to guarantee compliance with GMP regulations and quality standards in all of its business units.

In parallel, its Corporate Procurement Policy defines common guidelines for purchasing processes and supply strategies in order to promote long-term relationships and compliance with ethical standards. The Global Procurement area ensures the application of supplier management practices and performance metrics, as well as defines which are significant and, in turn, subject to greater ESG scrutiny. For this segmentation, Grifols bases its analysis on their category and the annual expenditure generated with the supplier.

"+390 supplier audits performed in 2023.

Summary of Audits in 2023 - GRIFOLS

Business unit/Area	Type of supplier	Result			
		No. of quality audits	Favorable	Not favorable	Pending evaluation and final report
Plasma Procurement and Bio Supplies	Raw materials suppliers	49	43	6	0
	Distributors	3	3	0	0
	Transport companies	4	4	0	0
	Service suppliers	7	7	0	0
Biopharma	Raw materials suppliers	98	94	4	0
	Distributors	5	5	0	0
	Transport companies	9	9	0	0
	Service suppliers	32	31	1	0
Diagnostic	Raw materials suppliers	28	24	0	4
	Transport companies	2	2	0	0
	Service suppliers	3	2	0	1
Grifols global subsidiaries	Raw materials suppliers	1	1	0	0
	Distributors	17	17	0	0
	Transport companies	14	14	0	0
	Service suppliers	11	11	0	0
Others	Raw materials suppliers	67	67	0	0
	Transport companies	1	1	0	0
	Service suppliers	2	2	0	0

Summary of Audits in 2023 - BIOTEST

Plasma Procurement	Raw materials suppliers	0	0	0	0
	Service suppliers	4	4	0	0
Biopharma	Raw materials suppliers	12	12	0	0
	Service suppliers	24	24	0	0

Supplier relations: promoting ESG and human rights criteria

Code of conduct for suppliers

Grifols has a code of conduct defining the minimum standards of ethical, social and environmental behavior for its suppliers, which are also required to comply with applicable country-specific legislation in their regions of operation.

Framed from an ethical compliance perspective, the code of conduct regulates conflicts of interest, fair competition and commercial controls, the fight against bribery, corruption measures, the acceptance of gifts, and money laundering, as well as product quality and safety, clinical trials and animal welfare, among others. In terms of employee and human rights, it emphasizes respect for human rights and fair treatment, the elimination of forced or compulsory labor; and the effective abolition of child labor, among other criteria. At the same time, it addresses aspects related to health and safety, the environment and managerial systems.

Grifols code of conduct for suppliers is publicly available at our corporate website.

More information on Grifols' human rights commitment: "Corporate Governance".

> **Grifols' supplier management model is continually being enhanced to ensure its main collaborators adhere to and conduct their operations in alignment with sustainable development policies and standards.**

This effort includes compliance with human rights; efforts to reduce greenhouse gas emissions; climate-change risk management; circular economy strategy; strategies to advance the United Nations Sustainable Development Goals (SDGs); and other ESG criteria used to measure corporate responsibility along environmental, social and governance dimensions.

Due diligence in Grifols' supply chain

Biotest and Haema rolled out new management systems to comply with the recently enacted German Supply Chain Due Diligence Act (LkSG). In this regard, both companies developed new processes while enhancing existing ones to identify and analyze humans-rights and environmental risks throughout their value chains.

These activities comprise both ad hoc and annual evaluations, with particular emphasis paid to risks with a higher likelihood of occurrence. Results are incorporated into the firms' management processes, especially their supplier-management systems.

On a broader level, the Global Procurement team makes ongoing efforts to ensure the firm's supplier-relation procedures align with the most recent regulatory shifts.

More information on Biotest's regulatory compliance.

More information on Haema's regulatory compliance: Haema.

Biopharma, a differential value chain

Each Grifols business unit has its own unique value chain. Biopharma–the unit responsible for producing Grifols' plasma-derived medicines–is the most relevant, accounting for 85% of the firm's total revenues and the majority of its critical suppliers.

Grifols' value chain is characterized by the essential role of plasma donors (920,000-plus per year); lengthy production times (9-12 months); and rigorous controls in every stage of the value chain, both mandatory and voluntary.

From Donors

Plasma procurement

Plasma

Plasma collection

ONLY QUALIFIED DONORS

- Grifols has a donor safety corporate policy in place to ensure the health and safety of donors, as well as to guarantee the highest quality of donated plasma for the benefit of patients.

Analysis of donated plasma

SCREENINGS FOR VIRAL ANTIGENS OR ANTIBODIES

- Analysis per unit of plasma: hepatitis A, B and C, HIV, parvovirus B19, etc.
- Use of NAT, ELISA and other highly sensitive techniques.
- Laboratories approved by FDA, EMA and other global health authorities.

Inventory hold

INVENTORY HOLD BEFORE USED IN PRODUCTION ACCORDING TO APPLICABLE REGULATIONS

- New verification of samples to guarantee the absence of viral or pathogenic markers.

Over 920,000 donors per year make it possible for us to serve more than 800,000 patients.

to Patients

Biopharma

Production

Quality management systems in manufacturing facilities

PRODUCTION WITH SUITABLE PLASMA

- Production stages include fractionation or separation of proteins, purification, specific stages of viral inactivation, dosage and conditioning. Adherence to Good Manufacturing Practices (GMP).

Elimination of viruses and other pathogens

EVERY STAGE OF THE PRODUCTION PROCESS

- Testing and elimination processes for potential pathogens, viral inactivation and virus removal techniques. Depending on the product, may also include pasteurization, heat treatment, solvent/detergent treatment and/or nanofiltration.

Sterile filling

FOLLOWING PURIFICATION

- Sterilization and dosing executed with an exclusive system developed and patented by Grifols Engineering.

Post-sales

Product tracking and traceability

- Identification of vials with a unique code and a retractable band on the capsule to ensure its inviolability and authenticity.
- Packaging marked with a holographic seal to assure inviolability and authenticity. Assignation of unique and traceable numerical series to prevent counterfeiting.
- PEDIGRI® system to provide healthcare professionals with detailed information on specific plasma used.

More information: “From Donors to Patients”.

Plasma Procurement Regulation

- WHO: recommendations for the manufacture, control and regulation of human plasma for fractionation (WHO Technical Report Series, No. 941).
- Directive 2002/98/CE, which establishes quality and safety standards for processes relating to human blood and its components.
- EMA Guideline on Plasma-Derived Medicinal Products.
- 21CFR Part 640: additional standards for human blood and blood products.
- Local regulations in countries where hemoderivatives are distributed.
- PPTA standards which Grifols adheres to voluntarily.
- European Pharmacopoeia.
- American Pharmacopoeia.

Biopharma Regulation

- Good Pharmacovigilance Practices, EMA.
- Code of Federal Regulations (CFR): 21 CFR 11, 21 CFR 210, 21 CFR 211, 21 CFR 600, 601, 610, 630 and 640.
- Good Manufacturing Practices, Pharmaceutical Inspection Co-operation Scheme (PIC/S).
- European Pharmacopoeia.
- United States Pharmacopeia.
- Local regulations in countries where hemoderivatives are distributed.

Internal control system

Grifols ensures a robust quality control and safety system through a highly qualified staff; rigorous process and product designs; innovative Grifols-engineered technologies; and complete traceability from plasma donation to commercialization. The company's quality assurance area supervises the materials and procedures used at every stage of the supply chain. This oversight includes controls in manufacturing processes and final products; review and follow-up of manufacturing procedures to ensure compliance with GMPs; and systems to escalate relevant events and take corrective actions through Grifols Quality Committees, which evaluate key performance indicators and quality markers.

Grifols is a member of the National Donor Deferral Registry (NDDR), a voluntary self-regulatory initiative to guarantee the safety and quality of donated plasma, applicable to all U.S. donors.

More information

100% of Grifols' team involved in quality control and safety processes receive specialized training.

External certifications

External entities certify the quality systems of all Grifols' production plants, including the manufacture of both medicines and medical devices.

- Certifications of Good Business Manufacturing Practices from the European Union, the United States and other countries where required.
- IQPP & QSEAL Certifications from the Plasma Protein Therapeutics Association (PPTA).
  - International Quality Plasma Program (IQPP) Certification, a voluntary standards program including the management of donors and plasma centers.
  - Quality Standards of Excellence, Assurance and Leadership (QSEAL) Certification, with voluntary membership and certification, applicable to the manufacture of plasma-derived medicines.

More information

Internal and external quality-control audits

- Grifols' leadership team defines and maintains the company's quality management system, including routine in-house audits of plasma centers, laboratories, production facilities and warehouses to monitor quality standards and applicable regulation.
- The Quality Audit area conducts routine reviews of all operations.
- All plasma centers, manufacturing plants, warehouses and laboratories are routinely inspected by health authorities in the U.S. (FDA), Europe (EMA) and other countries in accordance with current regulations.
- Plasma centers and fractionation plants are subject to regular PPTA audits.

Patients and healthcare professionals: relationships built on trust

Health, safety and pharmacovigilance measures

As outlined in its Quality Policy, Grifols identifies the critical attributes of its products and carries out exhaustive controls on the quality of raw materials, manufacturing processes, and finished product testing.

Grifols has pharmacovigilance agreements with all distributors, including those operating in countries with less advanced pharmacovigilance regulations, to ensure compliance with Grifols' standards in this area.

The pharmacovigilance program monitors for any adverse effects or reactions resulting from its plasma-derived medicines, while its surveillance system detects adverse reactions stemming from the use of its medical and in vitro devices. Both programs feature systems to report safety issues and suspected cases of adverse reactions.

All activities and requirements of Grifols' pharmacovigilance and surveillance systems are outlined in standard operating procedures and subject to routine reviews. The company conducts regular internal audits of these systems under its quality compliance protocols, which also undergo external inspections by the competent health authorities.

Grifols never outsources its pharmacovigilance and surveillance of medical and in vitro devices to third parties.

> **Grifols oversees a pharmacovigilance system to monitor plasma-based medicines and a surveillance system to monitor healthcare products.**

Packaging, leaflets and labeling

The information in Grifols' product packages, leaflets and labels complies with the standards and regulations applicable in its countries of operation, the Good Manufacturing Practice (GMP) guidelines for pharmaceuticals, and country-specific regulations in other markets.

In terms of Grifols medical and in vitro devices, their labeling, instructions for the use of reagents, and instrument user and software manuals comply with country-specific regulations (EN ISO 15223, among others), and incorporate mitigating measures detected via medical-device risk management systems (EN ISO 14971 Medical Devices) or measures required by global health authorities. All printed material is translated to the corresponding language, updated as required and accessible to users.

"Grifols' system for claims and recalls is guided by standard operating procedures and internally audited to confirm their effectiveness and compliance with current legislation. It also undergoes inspections by the competent healthcare authorities.

Product recall system

The product recall system is governed by the corporate policy for patient and customer safety. Additionally, this system is developed through standardized work procedures and is internally audited by the company to verify its effectiveness and alignment with current regulations. It is also inspected by competent health authorities.

All Grifols teams involved in potential product recalls, whether voluntary or mandatory, receive specific training in proper incident management. Furthermore, Grifols conducts periodic product recall simulations to ensure that all crisis management procedures and protocols are functioning effectively and to identify any potential areas for improvement

The product claims and recall system includes procedures to notify healthcare authorities, patient associations and healthcare professionals regarding the potential risks of a recalled product. Grifols operates a customer service call center and has dedicated webpages for specific products to communicate potential risks. It also prohibits the use of any recalled product in clinical trials.

In 2023, Grifols did not have any mandatory product recalls due to quality or safety concerns. The company's and Biotest voluntarily recalled two batches of products. Grifols' stringent controls ensure comprehensive compliance with quality and safety standards.

Claims system

Grifols' claims system, described in the corporate policy, registers and reviews all notifications received from healthcare centers, patients and users regarding consumer appraisals of possible quality issues. For medical devices, the management system for technical services is linked to the claims management system to ensure all client requests are evaluated.

When subsidiaries or authorized call centers receive a complaint regarding a Grifols medicinal product or service, they immediately notify the relevant production installation, ensuring all complaints are properly channeled and analyzed through the claims system.

The quality area of each business unit oversees the complaint process, which includes conducting the relevant investigations; verifying the implementation of corrective and preventive actions, if necessary; notifying relevant health authorities, if applicable; and informing the customer of the claim investigation's findings.

CLAIMS RATIO PER BUSINESS UNIT

Biopharma

1 per **97,895** units distributed

2022: 1 per 77,806 units distributed

Diagnostic

1 per **559,298** diagnostic tests

2022: 1 per 482,302 diagnostic tests

Bio Supplies

1 per **2,777** units distributed

2022: No claims received

Other (Medicines)

1 per **14,972,662** units distributed

2022: 1 per 5,848,478 units distributed

Other (Medical devices)

1 per **50,005** units distributed

2022: 1 per 31,210 units distributed

Biotest

1 per **26,111** units distributed

2022: 1 per 32,532 units distributed

Counterfeit drug prevention system

Plasma medicines are prescription drugs that are primarily administered in hospital settings. As such, counterfeit products pose a grave risk to public health.

Grifols collaborates with regulatory authorities to investigate and analyze suspected cases of counterfeit, and has an internal policy to prevent, detect and report counterfeit products. In this regard, any suspicious and identified cases of counterfeit medicines must be duly and expeditiously reported to the relevant authorities in adherence to the applicable regulations in force.

Grifols uses track-and-trace technology to comply with product serialization and aggregation specifications required in certain countries and regions. These requirements include marking vials with a unique code before any plasma product is sold, and marking containers with a holographic seal to guarantee their inviolability and authenticity.

Grifols conducts routine internal audits and inspections to confirm regulatory compliance, and performs due diligence on customers and distributors to verify they possess the requisite licenses to distribute products. Its anti-counterfeiting measures are also detailed in third-party contracts and quality agreements when applicable.

Since 2021, Grifols is unaware of any actions resulting in raids, seizures, arrests and/or the filing of criminal charges related to counterfeit products.

> **Grifols' anti-counterfeiting measures include unique codes and holographic seals.**

More information: Grifols' Anti-Falsification Policy

Responsible marketing practices

Grifols ensures its promotional and educational collateral complies with applicable laws and regulations; aligns with industry policies and voluntarily adopted codes; adequately addresses the target audience and end users; and contains truthful, accurate, comprehensive and balanced information.

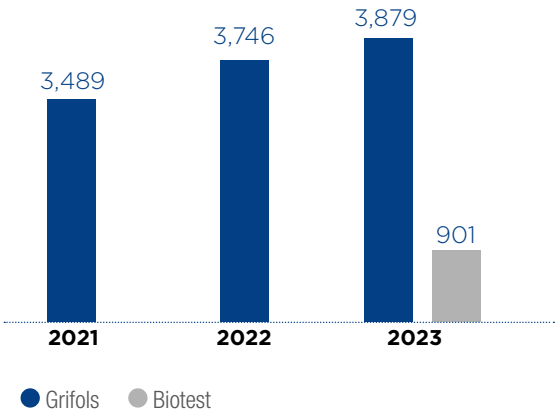
The company has a standard operating procedure–the Grifols Review Process (GRP)–that specifies all activities and responsibilities related to the approval, review and control of promotional and educational materials used to communicate its products and services. Representatives from the legal, medical and regulatory departments review and approve all marketing collateral using a GRP-adapted electronic system. Marketing material and contents are solely approved for specific uses and countries, and may only be used with no alterations. The contents of all promotional and educational materials are regularly reviewed to confirm their validity and compliance with the standards and codes in force.

The company delivers appropriate training on responsible marketing and sales practices in line with its Code of Conduct and Anti- Corruption Policy.

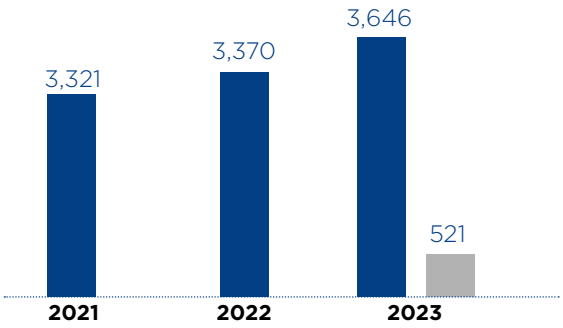
In 2023, only one marketing complaint was received and handled according to established procedures. The complaint did not result in any monetary impact or loss.

All promotional or educational material is reviewed regularly to ensure that the information is truthful, reliable, complete and balanced.

Materials reviewed



Materials approved



Overview of audits and inspections

PLASMA PROCUREMENT

Internal audits

256 (Grifols)
14 (Biotest)

Inspections by healthcare authorities and accredited inspection organisms

529 (Grifols)
9 (Biotest)

Favorable supplier audits

57 (Grifols)
4 (Biotest)

BIOPHARMA***

Internal audits

53 (Grifols)
20 (Biotest)

Inspections by healthcare authorities and accredited inspection organisms

22 (Grifols)
8 (Biotest)

Favorable supplier audits

139 (Grifols)
36 (Biotest)

DIAGNOSTIC

Internal audits

52

Routine inspections by official institutions

14

Favorable supplier audits

28

OTHER****

Internal audits

76

Routine inspections by official institutions

27

Favorable supplier audits

70

Incidents related to the suspension, revocation or loss of any license or certification; warning letter, imposed suspension of any regulated activity**

0

BIO SUPPLIES

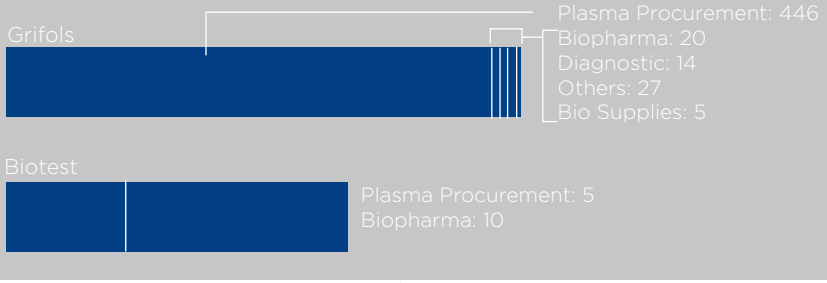
Internal audits

2

Routine inspections by official institutions

6

GOOD MANUFACTURING PRACTICES



* Includes inspections by health authorities and accredited inspection bodies, as well as in-house inspections.

** Includes Grifols and Biotest.

***Former Bioscience Division.

**** Others: includes Former Hospital Division.

Donors and patients

Guarantee the supply of plasma and promote countries' self-sufficiency to expand access to plasma-based treatments, while upholding our globally recognized standards of quality, safety, transparency and engagement.

OUR ROADMAP. GRIFOLS 2030 AGENDA

- Increase product donations to patient programs
- Increase donations of clotting factors in developing countries
- Boost product donations for emergency relief efforts
- Achieve "excellent" or "good" service ratings from donors
- Encourage more donors to recommend the donation process to family and friends
- Increase ratings on donor applications

PRIORITIES

DONORS	PATIENTS	PATIENT ASSOCIATIONS	ACCESS TO TREATMENT AND SELF-SUFFICIENCY

WE SUBSCRIBE TO THE PRINCIPLES OF BIOETHICS

unesco

AUTONOMY
Each person is able to make decisions freely and independently.

BENEFICENCE
We work to optimize benefits for patients and diminish potential harm.

JUSTICE
Healthcare resources are allocated equitably and fairly.

NON-MALEFICENCE
Our actions cannot intentionally create a harm or injury to the patient.

Serving as a bridge between donors and patients

Grifols transforms donor plasma into life-enhancing medicines, ensuring responsible operations at every stage of the value chain.

Committed donors

I like helping people. Donating plasma has a positive impact, and I feel good knowing I contribute to improving people's lives.

Trent H., Texas, United States

Patients whose lives benefit

I enjoy things a bit more because I haven't always been able to have a normal life.

Josh, United States.

Patient living with Primary immunodeficiency

We need nine to 12 months to transform plasma into plasma-based medicines

DONORS

920,000+
donors

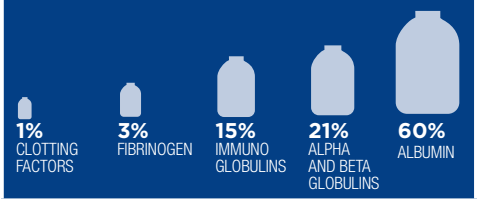
2,579 M$
Positive impact on donors

PLASMA

55% of whole blood

90% of water

7% are essential proteins



PATIENTS

800,000+
patients treated

27,370 M$
positive impact on patients

- Dozens of conditions are treated with plasma therapies
- Proactive promotion of access to treatment
- Numerous patient support programs

More information: "A Differential Value Chain" section.

We work to guarantee the procurement of plasma

Awareness

Campaigns and collaborations in the U.S. and Europe.

Support for International Plasma Awareness Week (IPAW), organized by the Plasma Protein Therapeutics Association (PPTA).

Outreach with local communities, policymakers, and patient associations.

Action

Promote science-based policies to increase plasma donations around the world:

- **Support EU policies that encourage strategic plasma self-sufficiency**: new Substances of Human Origin (SoHO) regulation in Europe.
- **Expand funding for the U.S. Health and Human Services** plasma-awareness campaign.
- **Promote the Congressional Plasma Caucus**, formed by U.S. legislators who aspire to raise awareness of the critical importance of plasma therapies and plasma donations.
- **Eliminate state regulatory barriers** that hinder the operations of U.S. plasma donation centers.

More information: "Corporate Governance"

Plasma centers

Grifols has the **world's largest private network of plasma centers.**

Global and diversified presence

More information on the network of plasma centers: "About Grifols"

Self-sufficiency

In **Egypt**, first plasma-based products manufactured with Egyptian plasma.

Agreement signed with Canadian Plasma Resources (CPR) to open plasma centers in **Canada** as part of Grifols' alliance with Canadian Blood Services.

More information: "Access to Treatments"

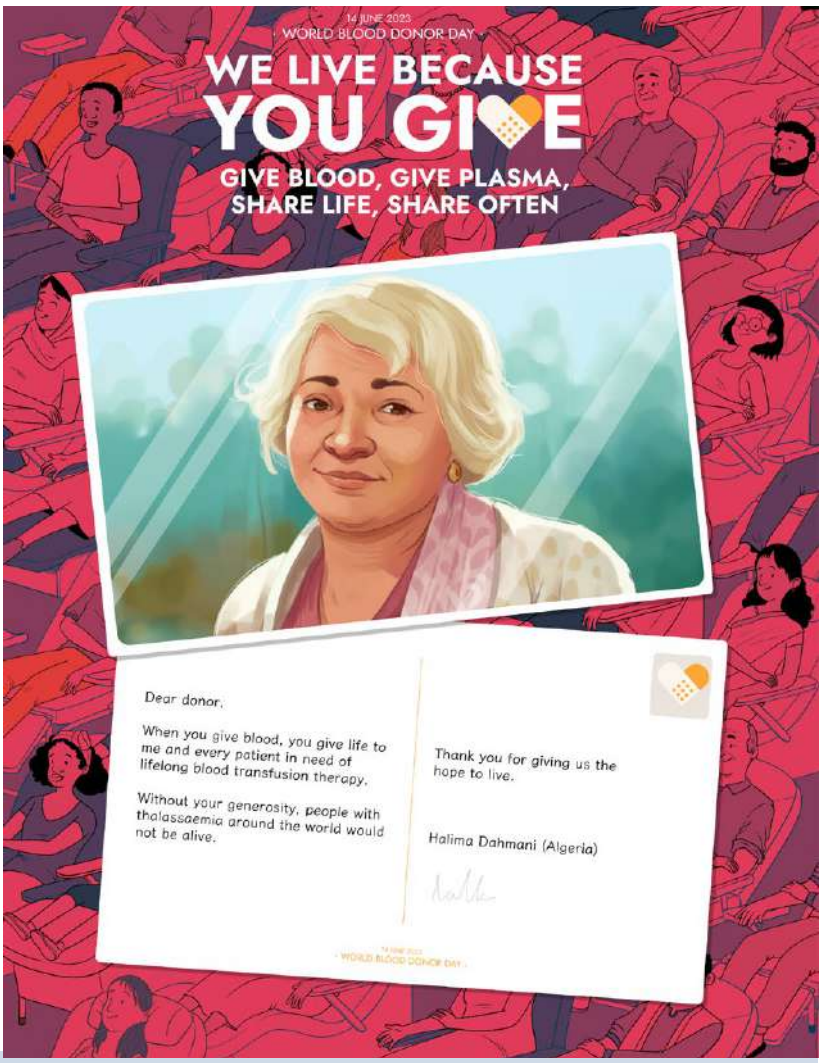
Our plasma supply platform encompasses integrated plasma centers within our network and strategic collaboration agreements with third parties

Our commitment to donors

Respect for people's intrinsic dignity and human rights is a cornerstone of all Grifols' activities, aligning with the core principles of the Universal Declaration of Human Rights (1948), Declaration of Helsinki (1964), and UNESCO Universal Declaration of Bioethics and Human Rights (2005).

As outlined in Grifols' Code of Conduct, all company interactions with stakeholders, including donors, are grounded on a fundamental respect for human rights. This principle is articulated in Grifols' Donor Policy, which stresses the need to respect country-specific legal regulations, ensure non-discrimination, and implement measures to protect donors' health and safety.

Grifols provides clear and reliable information for donors at every stage of the donation process, and prior informed consent is mandatory.



8 commitments

Safeguard donors' health, safety and well-being.

Ensure donors provide informed consent before donating plasma.

Support local communities where donor centers are located.

Promote open lines of communication and awareness about the benefits of plasma medicines.

Respect donors' human rights and ensure equal treatment following the principles of non-discrimination.

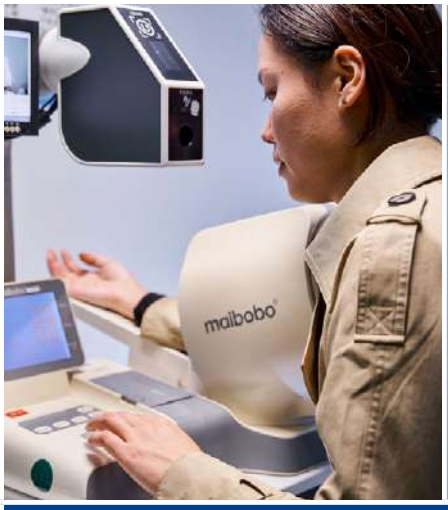
Respect legislation in each country regarding donor compensation and the frequency of plasma donations.

Comply with personal data legal requirements and implement all necessary measures to protect donors' privacy and personal data.

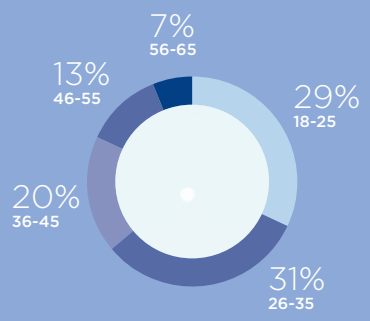
Ensure every interaction with donors is professional, respectful, helpful and engaging.

Access to the "Plasma Donor Policy"
Access to the Code of Conduct

GRIFOLS DONORS REPRESENT A CROSS-SECTION OF SOCIETY



Age



Balanced distribution

44%
Women

56%
Men

Education and employment

62%
college graduates

26%
current university students

11%
high school graduates

95%
full-time employees

The plasma donation process is safe and its collection is highly regulated.

In 2023, Grifols surveyed over **1,300 qualified U.S. plasma donors** to learn their primary incentives for donating plasma, among other issues. While donors cited financial compensation as the motivating factor for their first donation, they said **altruism and the service and care given** at Grifols donation centers were what **turned them into frequent donors.**

73%
of donors who left reviews in Grifols' plasma centers*, assigned a top review

*Grifols plasma donation centers

Donors and donations

Donor regulations

Plasma is procured from whole blood donations (recovered plasma) or through plasmapheresis (sourced plasma), a specific technique for plasma donation developed by José Antoni Grifols i Lucas.

Plasma collection for the manufacture of plasma-based medicines is subject to strict regulations by global healthcare authorities and good manufacturing practices (GMP). The Food and Drug Administration (FDA) is the maximum health authority in the United States, while in Europe, the European Agency for Medicine (EMA) oversees this function. The Plasma Protein Therapeutics Association (PPTA) defines and monitors additional quality standards as part of its voluntary IQPP (International Quality Plasma Program) certification.

Donating plasma is extremely safe, with few or no side effects. Using the plasmapheresis technique, plasma is extracted from whole blood, and blood cells, platelets and other components are returned to the donor. The body regenerates the volume of collected proteins in about 48 hours, in contrast to a two-month regeneration time for red blood cells obtained from whole blood donations.

In 2023, Europe developed a new regulation to ensure the safety and quality of substances of human origin (SoHO), including plasma donations. This directive aims to improve access to SoHO therapies, which play a critical role in the healthcare systems of all EU Member States.

More information on related FDA regulations

More information of the SoHO Regulation and agreements signed

“It is impossible to synthetically produce or manufacture plasma in a laboratory. Hundreds of donors and their donations are required to make a single year’s supply of plasma-derived medicines for just one patient.

Quality control in Grifols donation centers

Grifols’ plasma donation centers adhere to the highest quality and safety standards while also undergoing routine regulatory inspections to guarantee donor safety and the quality of donated plasma. In 2023, Grifols has not received any administrative action in plasma centers due to suspension, revocation or loss of any license or certification; warning letter, imposed suspension of any regulated activity.

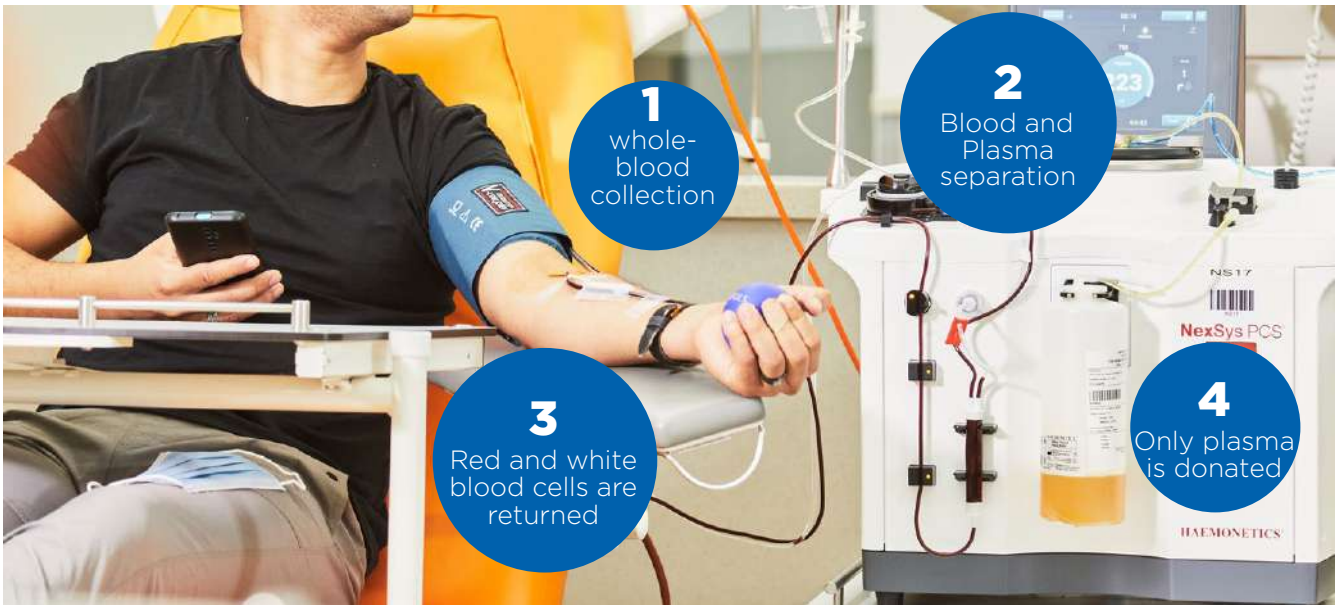
Regulatory inspections in Grifols plasma donation centers

No. of inspection days	2023	2022	2021
FDA*	137	119	80
EMA	196	182	196
CLIA-COLA	169	108	145
PPTA	97	123	117
TOTAL	**599**	**532**	**538**

Includes Biotest.

* More than 95% of FDA inspections resulted in zero observations.

Plasmapheresis, a safe procedure for donating plasma



Conditions for donating plasma

Grifols follows all the regulatory requirements of global health authorities and comprehensive evidenced-based processes to establish peoples' eligibility for donating plasma. Donors must postpone the donation process if medical exams reveal abnormal levels or irregular parameters to exclude the possibility of an underlying health issue. These biomarkers include:

- Irregular heartbeat
- High body temperature
- High or low hematocrit
- High or low total protein
- Lipemic plasma

Grifols safeguards donors' health

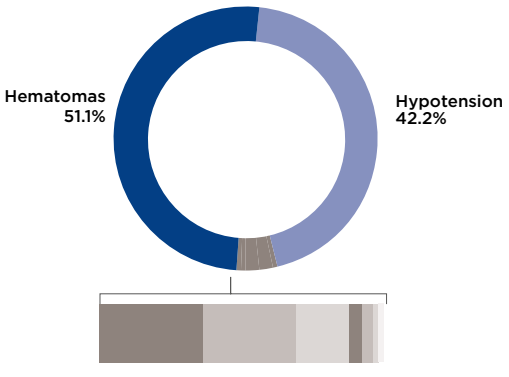
Grifols only uses plasma from qualified donors and never from occasional donors. Once qualified, donors undergo annual physical exams and thorough assessments of their medical, surgical and travel history, in addition to medical-history evaluations every time they donate.

This information is registered in the donor's file and treated confidentially in line with Grifols' Global Privacy and Data Protection Policy principles. Before each donation, a specialized Grifols staff member checks the donor's vital signs and weight, as well as blood and plasma protein levels to confirm they can safely donate. In this way, Grifols monitors donors' overall health and well-being, a long-standing corporate priority.

Plasmavigilance

As in previous years, Grifols' U.S. plasmavigilance data in 2022 revealed minimal donor adverse events (DAE)*, with side effects in only 0.3% of donations. Most adverse effects were minor, resulting in hypotensive events or phlebotomy-related injuries like hematomas. Severe reactions requiring medical assistance were extremely rare, representing only 0.008% of Grifols' total donations.

Data on donor side effects continues to confirm the safety of plasma donation.



Other 2.4%
Citrate reactions 2.1%
Allergic reactions 1.2%
Hyperventilation 0.3%
Hemolysis 0.2%
Major cardiovascular or respiratory 0.1%
Immunization 0.1%
Air Embolus 0.0%

* Plasma surveillance data in 2022 according to the DAE categorizations established by the PPTA (Plasma Protein Therapeutics Association) IQPP Standard for reporting donor adverse events. This data is published with a one-year lag according to the required reporting cycles.

ELIGIBILITY REQUIREMENTS TO DONATE PLASMA

Qualified donors

Donate at least **2 times within 6 months**

Maximum **2 times every week**

Between **18-69 years old**

+50 kg

Medical examination with normal levels

Documentation

Valid picture ID: driver's license, passport, etc.

Proof of **Social Security Number**

Proof of **address**

Donor health screening

Weight
Blood pressure
Pulse
Temperature
Anemia
Protein levels

Every donation is treated

VHC, VHB, VHA, VIH and B19 **virus detection**

Screening for hepatitis B, hepatitis C and HIV antibodies

Other **routine tests**

In 2023, Grifols worked to implement the FDA Individual Risk Assessment guidance for evaluating donor eligibility into its donor health questionnaire by early 2024, although many of Grifols' current criteria are even stricter.

Access to more information about:

Plasma donations in the U.S.

Plasma donations in Europe: Haema, Plasmavita, Biotest

Plasma donations in Egypt

Protecting donors' health is our top priority

Several studies have shown that frequent donation does not affect donor health or produce serious adverse effects.

As part of its commitment to donor health and safety, Grifols directly supports the research by diverse scientific institutions and associations to gain a deeper understanding of the potential effects of plasmapheresis on donors' health.

Donations and donor health

Regular donations have no adverse effects

Published in Transfusion magazine in 2023, this transversal study was conducted by the Plasma Protein Therapeutic Association (PPTA) to determine if plasma donation at FDA-defined frequency and volume levels has an impact on donor health. Donors from 14 U.S. plasma donation centers, including several Grifols plasma donation centers, took part in the study, which concluded that paid plasma donations at these levels are consistent with donor health and well-being. Even at the highest frequency, plasmapheresis alone has no associated negative health effects.

Study: Effects of donation frequency on U.S. source plasma donor health

Plasmavigilance study in the U.S.

The rate of side effects from plasma donations via plasmapheresis is insignificant

More than 1.1 million donors, who collectively account for 72% of the U.S. source plasma collected over a four-month period, took part in the first industry-wide, multi-company study on the incidence, frequency and type of adverse effects of plasmapheresis. Promoted by the PPTA, in cooperation with various industry firms, the study confirmed the overall safety of plasmapheresis.

Following FDA standards of collection volumes and donation frequency, the rate of adverse events (AE) was 1.58 per 10,000 donations. Moreover, 90% of AEs were minor, such as hypotension and phlebotomy-related hematomas, with no reports of serious or severe adverse events. The study's findings were published in 2021 in the scientific journal Transfusion.

Study: Plasmavigilance: Source plasma joins the call to arms

Cholesterol levels

Research findings suggest a decline in cholesterol levels

Apheresis or low-density lipoprotein extraction is used to treat patients with familial hypercholesterolemia. In some donors, the low-volume plasmapheresis used in plasma donations may also lower cholesterol levels. This research analyzed the effect of plasmapheresis on total LDL and HDL cholesterol levels among healthy plasma donors, concluding that total and LDL cholesterol levels may decline in donors with elevated baseline cholesterol levels following regular voluntary plasmapheresis. In donors with low baseline HDL levels, HDL cholesterol levels may increase.

Study: Prospective multicentre study of the effect of voluntary plasmapheresis on plasma cholesterol levels in donors

Iron levels

Plasma donation has no effect on iron reserves

This study found no loss of iron or decline in ferritin levels because of regular plasma donations – even in the case of long-term donors – as opposed to whole blood donations. These findings deem it unnecessary to monitor donors' iron levels or recommend iron supplements.

Study: Frequent source plasma donors are not at risk of iron depletion: The Ferretin Levels in Plasma Donor (FLIPD)

Blood pressure

The results suggest a beneficial effect for donors with high blood pressure

Grifols led a study to discern the potential effects of plasmapheresis on blood pressure, finding a beneficial effect among donors with high baseline blood-pressure levels, whose systolic and diastolic blood pressure decreased significantly when their donation intervals are under 14 days. No decline in blood pressure was observed among donors with normal baseline blood pressure levels.

Study: The effect of plasmapheresis on blood pressure in voluntary plasma donors

Reasons to stop donating

Health reasons, either real or perceived, are not main motivating factors to stop donating

In 2023, Transfusion published the results of a study to discern donors' rationale when deciding to no longer donate plasma. The survey was conducted among donors in 14 plasma donation centers of several companies, Grifols included, who had stopped donating for at least six months. Lack of time (30.2%), insufficient compensation (14.7%) and procrastination (14.3%) were among the most common reasons cited, showing that real or perceived negative health impacts generally were not primary drivers of their decision to stop donating.

Study: Why do U.S. source plasma donors stop donating?

Studies have shown that plasmapheresis can reduce cholesterol levels and have a beneficial effect on donors with increased blood pressure.

Donation centers in committed communities

In 2023, Grifols operated 286 plasma centers in the U.S., 94 in Europe, and 11 in the rest of the world, all based in communities dedicated to driving positive change.

Grifols' U.S. plasma donation centers are located throughout the country, with no particular concentration in specific areas.

When evaluating suitable plasma-center sites, Grifols considers areas with a solid commitment to community progress, active chambers of commerce, and a strong vocation to advancing social progress. For Grifols, a community's active participation in the plasma donation process is paramount to securing patients' access to life-sustaining plasma-based treatments.

Grifols' employees work proactively to forge ties with community residents by organizing educational, social and awareness-raising events on the vital need for plasma donations. Plasma centers also collaborate with local businesses and non-governmental organizations to raise awareness on plasma and the manufacturing process of plasma treatments.

The company considers other criteria when choosing communities for its plasma donation centers, including low viral markers, below-average crime statistics and community heterogeneity, which is critical to ensuring a diverse donor pool.

More information on value creation by Grifols plasma donation centers: "Sustainable Growth"

More information on our social action with donors: "Impact on Society"

Our commitment to patients

1. Safety and quality	2. Transparency and independence	3. Access to treatment
• Offer the best possible therapies, products and services through continuous innovation and leadership in safety and quality standards	• Engage and support of patients and organizations by serving as a reliable and transparent source of information	• Advocate and advance the principles of justice and equality in health care, with special emphasis on increasing access to plasma therapies.

Guided by the utmost respect for human rights, Grifols adheres to three unwavering commitments when interacting with patients and patient organizations.

Patient notification system

Grifols has supported and participated in the Plasma Protein Therapeutics Association's (PPTA) Patient Notification System (PNS) since 1998. This system is free of charge, confidential and exclusively offered to patients and registered users, who receive notifications regarding the voluntary or mandatory withdrawal of plasma medicines.

More information on the PNS

Grifols subscribes to international principles

- **International Bill of Human Rights** (includes the Universal Declaration of Human Rights, International Covenant on Civil and Political Rights, and International Covenant on Economic, Social and Cultural Rights).
- **Declaration of Helsinki.**
- UNESCO Universal **Declaration on Bioethics and Human Rights.**
- United Nations Guiding **Principles on Business and Human Rights.**
- OECD **Guidelines for Multinational Enterprises.**
- United Nations **Global Compact.**

We produce life-enhancing medicines

An estimated two million people in Europe[1] suffer from one of the 12 most common rare diseases, including hemophilia and primary immunodeficiency (PIDD), which may be treated and managed with plasma-derived therapies.
At the same time, scientific advances continue to broaden the range of high-prevalence diseases that could benefit from plasma-based therapies. Plasma proteins are also used in everyday medical treatments, emergency services and surgical interventions, among other uses.

Diseases and conditions treatable with plasma-based medicines[2]

ALBUMIN
– Liver cirrhosis
– Surgery (cardiac and major)
– Intensive care (e.g. sepsis, burns)

IMMUNOGLOBULINS
– Immunodeficiencies
  – Primary (PIDD)
  – Secondary (SID)
– Neurological conditions
  – Chronic inflammatory demyelinating polyradiculoneuropathy (CIDP)
  – Acute demyelinating polyneuropathy (Guillain Barré)
  – Multifocal motor neuropathy (MMN)
– Hematological conditions
  – Immune thrombocytopenia (immune thrombocytopenic purpura or ITP)
– Neuromuscular diseases
  – Myasthenia Gravis (MG)
– Post-exposure prophylaxis for rabies
– Post-exposure prophylaxis and treatment for tetanus
– Immunoprophylaxis of hepatitis B

ALPHA-1 ANTITRYPSIN
– Alpha-1 antitrypsin deficiency disorder

CLOTTING FACTORS
– Bleeding disorders
  – Hemophilia A and B
  – Von Willebrand disease (VWD)
  – Rare clotting factor deficiencies
– Trauma/injury-related hemorrhaging
– Overdose of anticoagulants or toxic substances that induce bleeding

More than 800,000 patients benefited from a plasma-based treatment in 2023.

(1) Silvia Rohr and Rianne Ernst, "Key Economic and Value Consideration for Plasma-Derived Medicinal Products (PDMPs) in Europe," PPTA.
(2) This information does not assume that Grifols' products have the necessary regulatory approvals to treat the aforementioned indications.

Benefits of plasma-based medicines by disease**

	Immunodeficiencies and neurological diseases	Bleeding disorders	Alpha-1 antitrypsin deficiency
Increase in life expectancy	●	●	●
Improvement/ positive impact on quality of life	●	●	●
Disease prevention	● For IDP and IDS		
Positive effect on disease progression	●	●	●
Prevalence	PIDD: 1/13,500 CIDP: 1/200,000 in children 1-7/100,000 in adults PTI: 9.5/100,000	Hemophilia A: 25/100.000 Hemophilia B: 5/100.000 EvW: 1/8,500-1/50,000	AADT: 123,7/100,000

** General information on the benefits of plasma-based therapies. Source: PPTA
More information: How plasma-derived medicines boost health value

Plasma-derived medicines may offer significant and lifelong benefits to patients, increasing their life expectancy and quality of life, while reducing the risk of life-threatening complications among those with plasma-protein deficiencies. For this reason, most plasma-derived medicines are designated as essential medicines for adults and children by the World Health Organization, while numerous others are included on the EU essential medicines list.

Access to treatment and diagnosis

Program to promote countries' self-sufficiency in plasma and plasma-derived medicines: leading the change

The World Health Organization (WHO), the Council of Europe and other institutions have stressed the urgent need for countries to increase their self-sufficiency in plasma medicines to ensure patients have adequate access to these life-sustaining treatments.

As per the WHO[1] resolution WHA 63.12, Member States should "take all the necessary steps to establish, implement and support nationally-coordinated, efficiently-managed and sustainable blood and plasma programmes according to availability of resources, with the aim of achieving self-sufficiency." According to the World Health Organization , only 65 of the 171 reporting countries fractionate nationally collected plasma to produce plasma-derived medicines, and in 91 countries, plasma-based medicines are imported.

Grifols supports and collaborates with countries to increase their levels of self-sufficiency as part of its ongoing efforts to promote and improve access to treatment. The company leads this change through the Grifols Self-Sufficiency Program, reinforcing national healthcare systems and lessening their dependence on third parties.

Advances in the strategic alliance in Canada

Grifols reached a long-term collaboration agreement with Canadian Blood Services (CBS) in 2022 to accelerate the country's immunoglobulin (Ig) self-sufficiency from 15% to 50% in the shortest timeframe possible, reducing the volume of plasma-medicine imports.

In 2023, Grifols made further inroads in meeting the needs of Canadian patients by bolstering its vertically integrated supply chain, comprised by new donation centers and the Montreal production facilities. Production will take place at Grifols' Clayton facilities (North Carolina, U.S.) until the Montreal facility is fully operational in 2027.

Increasing Egypt's self-sufficiency

In 2020, Grifols began developing the first integrated platform in the Middle East and Africa to supply plasma therapies at national and regional levels as part of its strategic alliance with the Egyptian government. Through this collaboration, the company will promote Egypt's self-supply of plasma medicines through a pioneering public-private partnership.

Grifols Egypt currently operates nine plasma centers, as well as analysis and storage facilities that employ 625 people. The company plans on opening a total of 20 centers. Meanwhile, it continues to oversee the construction of a plasma fractionation plant, purification plant and other installations, expected to be operational in 2025. Until then, all plasma collected (up to 1 million liters per year) will continue to be processed in Spain and returned to Egypt as finished product.

In 2023, Grifols Egypt received the first medicines made with Egyptian plasma: immunoglobulins, factor VIII and albumin. Thanks to the upturn in national donations, Egypt will be self-sufficient in immunoglobulins in 2024, and albumin and factor VIII, in 2025.

> **"Grifols works with countries to increase their self-sufficiency levels and improve access to plasma medicines for patients.**

1. https://www.who.int/es/news-room/fact-sheets/detail/blood-safety-and-availability

Direct initiatives to support patients

Grifols actively works to promote availability to its essential treatments, especially when unforeseen circumstances may affect or limit its access. Since 2006, Grifols has led initiatives to support patients in the U.S. during lapses in their insurance coverage. The company also supports patients by providing treatment access to those who require temporary assistance and comprehensive programs to help them better manage their disease.

World Hemophilia Organization

An estimated 400,000 people around the world suffer from severe hemophilia, yet 75% remain untreated. To address this issue, Grifols began collaborating with the World Federation of Hemophilia (WFH) Humanitarian Aid Program in 2014, donating clotting factors for hemophilia patients in need of treatment. Grifols' donations also support the WFH's Global Alliance for Progress (GAP) program. In its second decade, this initiative aims to increase the number of patients diagnosed and treated for bleeding disorders, especially in developing countries.

In 2023, Grifols donated more than 2.8 M IU to the Syrian Hemophilia Society following the earthquakes in Turkey and Syria, providing treatment for hemophilia patients who were seriously injured in the affected areas.

Patients treated from 2014-2023*

8,861

Patients treated in 2023*

1,693

Countries

33

Million IU donated in 2023**

4.7

"Grifols provides direct support to patients who, due to extraordinary circumstances, are unable to access treatments.

Commitment with the WFH for 2022-2030: Donate 240 million IU for 10,300 doses to treat 3,000 patients per year**

*Source: WFH data/ **IU = international units

Emergency aid

Grifols provides medical resources to healthcare professionals in the aftermath of natural disasters, extreme poverty and other humanitarian emergencies in collaboration with Direct Relief, a humanitarian relief organization present in more than 80 countries. In all cases, the company does its utmost to guarantee the rapid availability of donated product.

In 2023, Grifols also collaborated with Lebanon, where an economic crisis has led to a widespread shortage of medicines. The company donated 2,100 vials of factor VIII, equivalent to six months of treatment for 350 hemophilia patients, to the humanitarian aid organization Anera.

Value of medicines donated from 2019-2023

€2.7 million

Value of medicines donated 2023

€0.7 million

Patients treated in 2023

+16,000

Units of products donated in 2023

+23,000

Support for AADT patients

AlfaCare is a holistic support program for alpha-1 antitrypsin deficiency (AATD) patients, offering training, emotional support and resources to help them better manage their condition by promoting new habits and initiatives to enhance their physical and psychological well-being. The program was launched in Spain in 2018 with the collaboration of the Alpha-1 Spain Association and the support of a multidisciplinary clinical team, including psychologists and patient mentors. Since then, it has expanded to Germany under the name AlphaCare and to Italy as GriCare.

AlfaCare has been proven as a high-value resource for AADT patients. As of December 2023, it supports 265 patients in Spain, who receive psychological support and respiratory physiotherapy, among other services. Among these patients, 32 benefit from at-home infusions. Outside Spain, the initiative supports 712 patients in Germany and 88 patients in Italy.

AlfaCare Program

1,000+

patient beneficiaries in 3 countries

More information on AlfaCare: www.grifols.com

> **AlfaCare offers emotional support to patients with AATD and is supported by a multidisciplinary clinical team.**

Enhancing diagnostics

Safe transfusions

Grifols supports the integrated strategy promoted by the WHO in the realm of specialized diagnostics. Through its Diagnostic unit, the company works to increase the availability of NAT screening tests in blood banks to detect human immunodeficiency virus (HIV), hepatitis B and C, and emerging viruses such as babesiosis, the Zika virus and the West Nile virus.

In parallel, the company strives to extend transfusion diagnostic solutions in lower-middle-income countries[1], including the Philippines, India, Egypt and Indonesia. According to the WHO, 50% of donated blood is collected in lower-middle or low-income countries , which account for 80% of the world population. Many of these countries lack basic measures to guarantee safe transfusions. This is also the case in China, where Grifols collaborates with Shanghai RAAS to progressively raise transfusion safety standards in the country's donation centers.

As of 2023, over 38 million blood donations had been tested using Grifols NAT technology and over 42 million blood-typing gel cards had been supplied.

1. https://datos.bancomundial.org/nivel-de-ingresos/paises-de-ingreso-bajo

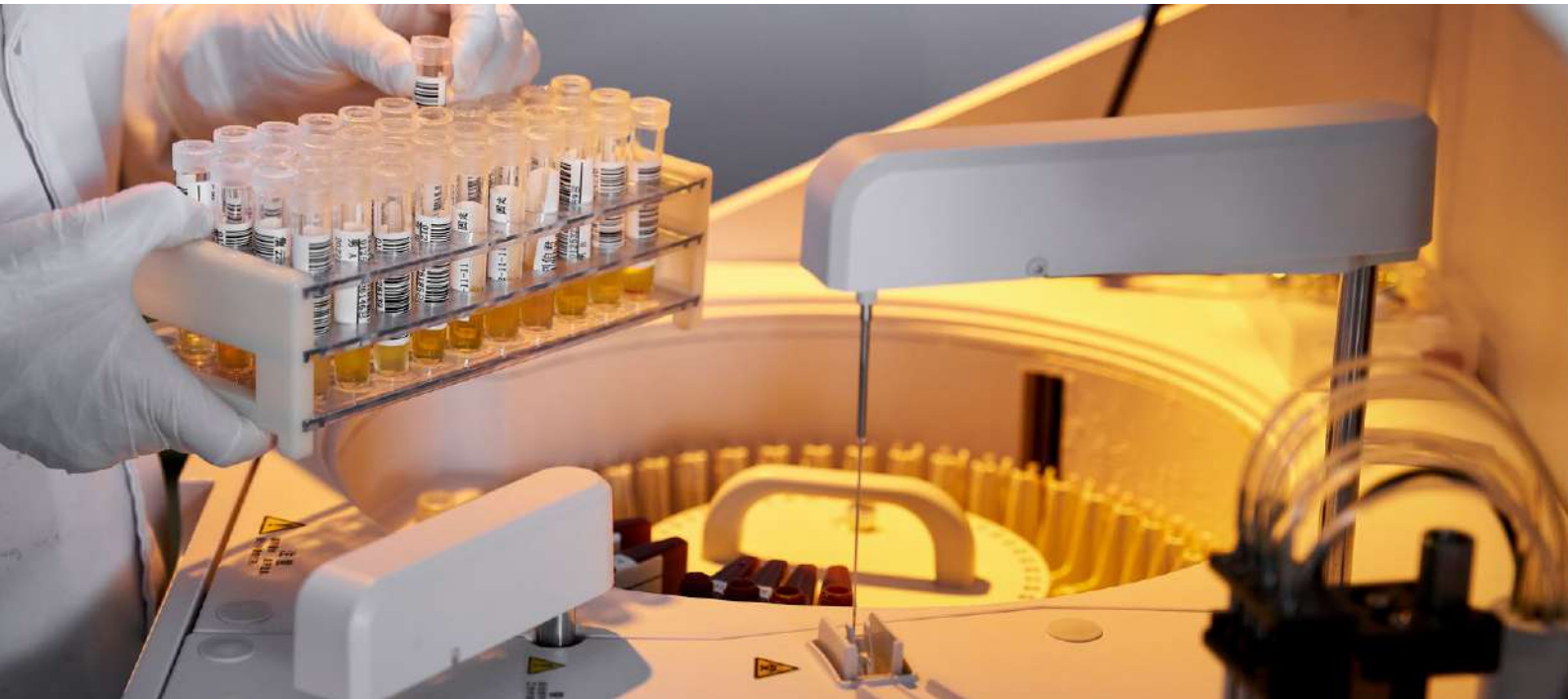
First free and patient-direct program to detect AADT

In 2023, Grifols launched the AlphaID At Home Genetic Health Risk Service, the first free, direct program for U.S. residents to assess their genetic risk of alpha-1 antitrypsin deficiency (AATD). With symptoms similar to COPD, AATD affects an estimated one in 2,500 Americans and may cause lung disease and liver disease.

Using the innovative AlphaID™ oral test, people can detect their risk of AATD through a saliva sample, with no need to visit a healthcare professional.

By 2023, dozens of people have benefited from both the AlphaID At Home in the U.S. and the Alpha ID kit in many other countries enabling the detection of DAAT and helping patients to take the appropriate measures to address this health problem.

Grifols is also working to develop new diagnostic tests for personalized medicine for the prognosis, response prediction and monitoring of biological drugs, as well as novel molecular diagnostic and prognostic tests in oncology, autoimmunity, cardiovascular and central nervous system medicine.



Patient associations

Patient associations and advocacy groups play a fundamental role in global healthcare systems by giving patients a voice. At Grifols, they form an essential part of the firm's decision making, with actions coordinated and managed by the Global Patient Affairs team.

The company's interactions with patient associations respect country-specific regulations and transparency principles. Grifols also has standardized operating procedures to establish eligibility, compliance, ethics and transparency guidelines for all of its collaboration agreements, grants and donations. These criteria are defined in the Patient and Patient Organizations Policy.

Grifols publishes country-specific reports on its contributions to global patient organizations.

More information on Grifols' contributions to patient groups

> **The relationships that Grifols establishes with patient organizations are guided by the transparency and regulations of each country.**

Broad scope in 2023

Grifols interacts with more than 80 global patient organizations in core therapeutic areas. In 2023, the company allocated more than EUR 16 million for product donations and resources to support nearly 60 of patient associations and their diverse programs and activities. The company has focused on Europe to increase patient organization involvement.

Therapeutic Areas/Diseases

Pulmunology Immunology	Neurology Alzheimer's disease	Liver disease Bleeding disorders

4 geographic regions

North America::
- Focus on the U.S. and Canada

Europe:
- Focus on Spain, France, Germany, Italy and Scandinavia

Latin America:
- Focus on Brazil and Argentina

Asia-Pacific::
- Focus on Australia

Interaction with 80+ patient associations

How Grifols collaborates

- **We educate** patients and patient organizations about the unique nature of plasma therapies and the complex processes to produce them.
- **We advocate** side-by-side with organizations to improve access to life-enhancing plasma therapies.
- **We engage** with patient communities as trusted source of information and expertise on plasma therapies.
- **We support** patient organizations through volunteer efforts and financial resources in accordance with relevant laws and regulations.

Guiding principles of Grifols' patient interactions

- **Mutual benefit:** Demonstrate a clear benefit for patients
- **Transparency:** Public disclosure of financial contributions to patient associations and encouragement that they do likewise
- **Integrity:** Commitment always in alignment with corporate objectives and priorities
- **Compliance:** Compliance with all legal norms, rules and guidelines, as well as Grifols policies
- **Independence:** The right not to support Grifols' actions

See Policy on Patients and Patient Organizations

See details on Grifols' contributions to patient advocacy groups

> **Grifols actively engages with patient associations to benefit the communities it helps.**

Collaborations and programs

Donation programs to patient associations

Grifols supports projects and initiatives developed by patient organizations in four core areas:

- **Education and empowerment:** Efforts to involve patients in making decisions regarding their health. In the case of rare diseases, training medical professionals is also key to reduce the time to diagnosis and improve the approach to these conditions. To this end, Grifols collaborates in various seminars and scientific conferences.
- **Greater awareness and visibility:** Initiatives to give visibility to patient communities and commemorate their related International Days to forge community ties and help get their needs and challenges included on political agendas. Grifols takes part in creating and maintaining different communication channels and informational collateral.
- **Patient experience and welfare:** Grifols collaborates with projects aimed at improving disease management and patient experience, including programs to facilitate the administration of treatments and promote a healthy lifestyle and nutritional habits, among others. In 2023, the company supported Spanish hemophilia associations by offering physiotherapy services to address patients' musculoskeletal challenges and functional capacity, as well as other associations to provide psychological support programs for pediatric and adult patients.
- **Advocacy and access:** Patient organizations work to ensure equity in access to treatment, and in the case of plasma treatments, to ensure there is sufficient plasma. The shortage of plasma-based medicines continues to be an urgent global challenge. In 2023 Grifols continued to support various plasma awareness and education campaigns to increase donations, especially in view of the SoHO review by the European institutions. These initiatives were also launched by associations of other pathologies, such as primary immunodeficiency or alpha-1 antitrypsin deficiency.

Examples of programs and initiatives

- **Supporting patients' needs**

In Spain, Grifols supports the Spanish Association of Primary Immune Deficiencies (AEDIP), which is leading the "Spanish Consensus for the Sufficiency of Plasma and its Derivative Treatments". This group is working to promote a national strategy for plasma and plasma-derived treatments which promotes far-reaching solutions to make Spain a benchmark in the collection, management and use of plasma. Therefore, guaranteeing the sufficiency of medicines for patients.

- **Plasma education program for European patient associations**

In 2023, Grifols has promoted several educational initiatives with patient communities in Europe. Of particular note was a new edition of the "Plasma Awareness Education Program" which, among others, included specific update sessions on the new Substances of Human Origin (SoHO) regulation. The recently created European Alpha-1 Alliance is one of the patient organizations that participated in the program with 23 attendees and held its first General Assembly during the event.

- **Community outreach**

Grifols is committed to building trusting relationships, educating and supporting the patient communities it serves.

To reinforce this commitment, Grifols has its "Open House" educational program originally initiated in the United States and more recently also promoted in Europe. It includes giving participants a first-hand look at the production of plasma medicines at its facilities in Spain, Ireland and the U.S. and discussion on the issues impacting access. Participants include patient representatives of different patient associations.

- **Raising awareness**

In 2023, Grifols has brought the voice of patients to its employees by offering them the opportunity to see the impact of their daily work. Grifols' professionals have been able to hear patient testimonials, in internal sessions, in forums such as IPAW (with inspiring patient stories in the two webinars organized) or onboarding and HR programs.

In addition, Grifols celebrated "Alpha-1 Month" to raise awareness of DAAT, which included visits to facilities in Barcelona (Spain) and Clayton (U.S.), among others.

Innovation at Grifols

Drive progress in plasma science by promoting new knowledge and research capabilities, guided by a robust ethical approach and utmost respect for human rights.

OUR ROADMAP. GRIFOLS 2030 AGENDA

- Promote internal and external, plasma and non-plasma projects in key therapeutic areas

PRIORITIES

ACCELERATE PROGRESS

- New therapies, products and solutions
- Improvements and new indications for existing products

SUPPORT

- Healthcare systems
- Competitiveness

COOPERATE

- Support scientific cooperation, education and research capabilities to drive progress in scientific knowledge

OPTIMIZE

- Achieve greater efficiencies
- Improve in-house productivity

First-place recipient of the *Gartner Eye on Innovation Awards 2022* in the "Healthcare and Life Sciences" category

MAIN THERAPEUTIC AREAS + DIAGNOSTIC

- Immunology
- Neurology
- Infectious diseases
- Pulmonology
- Hepatology & Intensive Care
- Hematology
- Other therapeutic opportunities
- Diagnostic

A robust innovation ecosystem

Grifols promotes scientific advances in line with its overriding mission to enhance people's health and well-being. The company encourages research cooperation and competencies across several fronts, including in-house initiatives, investee collaborations, public-private partnerships and financial contributions to third-party programs. At the same time, it works continually to optimize the efficiency and productivity of its internal systems.

Our innovation ecosystem strives to advance scientific knowledge and discover new opportunities and collaborations.

3 core objectives in 2023

Accelerate and prioritize projects

Optimize the innovation infrastructure

Forge new innovation models

Two-pronged approach to broaden horizons and expedite projects

IN-HOUSE SCOPE

- Digital innovations
- Grifols Scientific Innovation Office (SIO)
- R&D+i and new platforms
- Grifols Engineering

Digital transformation committee

Committees to assess R&D+i projects

EXTERNAL SCOPE

- Co-innovation programs
- Sponsorship of research programs
- Investment in research companies
- Collaborations with excellence centers
- Grants and awards: Grifols Scientific Awards
- Strategic alliances
- Academic collaborations

New leadership

The company manages its R&D+i aimed at discovering new treatments through the Grifols Scientific Innovation Office (SIO). In 2023, these functions were restructured and organized to prioritize Grifols' core strategic projects.

Scientific Innovation Office 2023

Greater efficiency

- Ongoing review of progress and opportunities
- Focus on quality control
- Two-tier approach

Results oriented

- Promotion of Biotest projects

Centralized and global

- Led by new Chief Scientific Innovation Officer (CSIO)

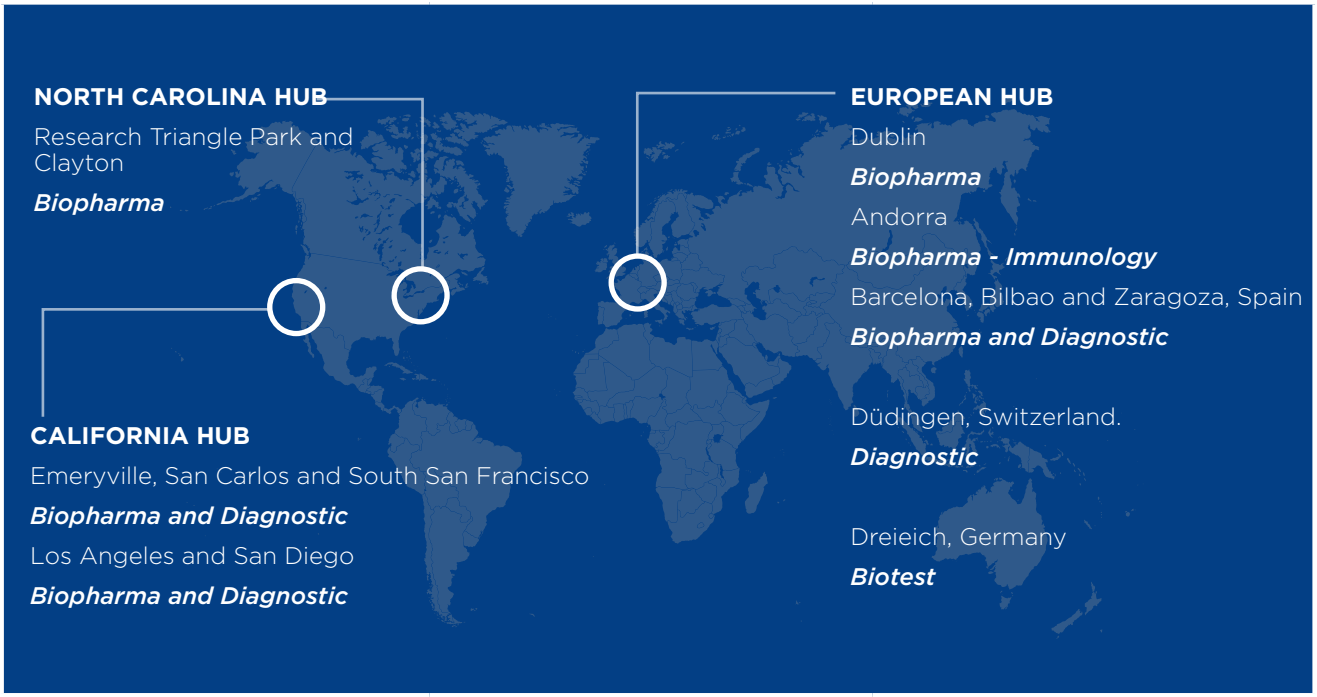
RESEARCH AREAS

Discovery Plasma	Discovery Recombinant	Drug Development	External Innovation	Scientific & Medical Affairs

SUPPORT AREAS

Global Intellectual Property	Scientific Business Development	Controlling	Project Management Office & Strategy

Resources allocated to R&D+i



R&D+i INVESTMENTS

€382M

6% share of revenues
€1,682M+ invested over the last five years

RESOURCES

1,260+

people dedicated to R&D+i

90+ external researchers

PATENTS

2,705

patents

858 patent applications
1,283 patents that expire in the next 10 years

Research lines

- Plasma proteomics, fractionation and purification
- Single-cell transcriptomics
- Machine learning AI platform for target discovery
- Neuronal functional assay platform
- Therapeutic target selection and validation
- Polyclonal recombinant expression and manufacturing
- Mammalian cell line for site-directed integration
- Platform for discovery monoclonal antibodies

Investee companies

- Araclon -Spain: Specialized in the research and development of new treatments and diagnostic tests for Alzheimer's disease.

*This data includes Biotest.

Ethics, science and innovation

For Grifols, advances in life sciences should never be severed from their intrinsic humanistic component, emerging always from an ethical and social construct. The Víctor Grífols Lucas Foundation is the entity that translates this firm commitment into action.

Grifols SIO committees supervise and monitor of all issues related to clinical trials, including their ethical ramifications.

In this regard, the company subscribes to three fundamental and universal principles, which together govern the ethics of its clinical trials as defined in its Human Rights Policy.

We subscribe to three fundamental and universal principles

	**RESPECT FOR PEOPLE**	• Respect for an individual's ability to make decisions freely and independently, and protection of at-risk groups of people who participate as research subjects. This principle is expressed through informed consent forms.
	**WELFARE**	• Guarantee the health of people who participate in clinical trials. Risks must be minimized and benefits maximized for all participants. For Grifols, protecting people's health takes precedence over professional and personal interests, research advances and the search for knowledge.
	**JUSTICE**	• Research must strike a balance between benefits and risks. All subjects must be treated with equal consideration and there must be no discrimination in the selection of subjects. Under this principle, participants are never exposed to unsafe situations to benefit another person. There is an obligation to safeguard the rights of vulnerable groups.

Grifols' Human Rights Policy is available on its corporate website

Our commitments

Clinical trials

Grifols is committed to protecting the rights, safety and well-being of patients who take part in the clinical trials it conducts or sponsors. All clinical research led by Grifols or on its behalf adheres to the standards defined in the International Conference on Harmonization of Good Clinical Practice (ICH GCP); the protection of human beings under the Declaration of Helsinki (1964); and applicable local laws and regulations.

Clinical trials are described in a detailed protocol and evaluated by regulatory authorities and external ethics committees. They only begin once a favorable decision has been handed down.

Participants submit a written, signed and dated informed consent form. The lead researcher (or assigned healthcare professional) provides appropriate information, resolves any doubts and gives potential clinical-trial subjects sufficient time to make an informed decision on their participation.

To maintain quality control, Grifols has standard operating procedures that guarantee the proper execution of its clinical trials and documentation of their related trial data according to protocol, ICH GCP principles and applicable regulatory requirements. In addition, Grifols has detection procedures that enable its clinical professionals to detect and document possible fraud or misconduct in clinical investigations.

The company has several measures to ensure the transparency of data collected in its clinical trials, as well as protecting subjects' anonymity and personal data. Grifols also subscribes to the principles of the codes of conduct regulating the processing of personal data from clinical trials and other applicable clinical and pharmacovigilance research.

Additional information on the protocol, status and results stemming from Grifols' clinical trials are disclosed on publicly accessible registries, including www.clinicaltrials.gov and the EudraCT website, which records findings of clinical trials carried out under the European Medicines Agency (EMA). The findings of many of Grifols' clinical trials are shared in international conferences and scientific journals.

More information: ClinicalTrials.gov and EudraCT

Responsible testing

Grifols is committed to the responsible use of laboratory animals when required for the development of new life-sustaining therapies.

Whether studies are carried out in university settings or in external laboratories, Grifols researchers work closely with regulatory agencies and the Institutional Animal Care and Use Committee (IACUC) to ensure the safe and ethical treatment of animals.

All facilities are approved by the competent authorities where research is conducted. In the U.S., Grifols facilities are certified by the Association for Assessment and Accreditation of Laboratory Animal Care or equivalent organizations, and hold the highest accreditation possible for animal-testing laboratories.

In Europe, all laboratories comply with Directive 2010/63/EU relating to protecting animals used for scientific purposes and undergo country-specific inspections by country-specific authorities.

Grifols research adheres to the "Alternatives and the 3Rs" (Replacement, Reduction and Refinement) protocol, which advocates (i) Replacing the use of animal-testing for alternative techniques or avoiding it completely; (ii) Reducing the number of animals used; and (iii) Refining how experiments are performed to ensure animals suffer as little as possible.

All clinical research conducted by Grifols adheres to ICH-GCP standards and regulations.

Treatment innovations

6 core therapeutic areas

		Pre-clinical	Phase 1	Phase 2	Phase 3	Phase 4 / Regulatory	LCM
Immunology	recIG – IDP	■					
	Xembify® – CLL	■	■	■	■		
	Xembify® – Biweekly dosing - PID	■	■	■	■	■	
	Xembify® – Pre-filled syringes						■
	Yimmugo® (IVIG NextGen) – PID	■	■	■	■	■	**
Hepatology / Intensive case	Albumin-20% - Cirrhosis - PRECIOSA	■	■	■	■		
	Albumin-5% - Acute on chronic liver disease – APACHE	■	■	■	■		
	FlexBag® (U.S., EU)						■
Pulmonology	Alpha-1 AT in non-cystic fibrosis bronchiectasis	■					
	Alpha-1 AT 15% (SC) – AADT	■	■	■			
	Prolastin-C® - AADT - SPARTA	■	■	■	■	■	
	Prolastin® vials 4-5 g. (EU)						■
Hematology	ATIII – Sepsis[1]	■					
	Fibrinogen - Cong. deficiency & severe hypofibrinogen	■	■	■	■		
	Fibrinogen – Acquired deficiency	■	■	■	■		
	Fostamatinib[2] - ITP – Refractory patients	■	■	■	■	■	
	Yimmugo® (IVIG NextGen) ITP	■	■	■	■	■	**
Infectious diseases	GIGA 2339 - VHB	■					
	Trimodulin (IgM) – EScCAPE	■	■	■	■		
	Cytotec® pregnancy – CMV infection	■	■	■	■		
Neurology	GRF6019 – Alzheimer's	■	■	■			
	GRF6021 – Parkinson's with dementia	■	■	■			
	Aβvac40[3] - Alzheimer's	■	■	■			
	AKST4290 – Parkinson's	■	■	■			
	AMBAR-Next – Alzheimer's	■	■	■	■		
Others	GIGA564 - Anti-CTLA-4 mAb Oncology	■					
	AKST4290 - Neovascular age-related macular degeneration (AMD)	■	■	■			
	VISTASEAL™ (fibrin sealant) - Biosurgery pediatric use	■	■	■	■	■	
	OSIG – Dry eye disease	■					

1 Association with Endpoint Health; 2 Rights licensed by Rigel Pharmaceuticals in the EU and other countries; 3 Project led by Araclon (Grifols investee).
** Commercialization started.

Projects Biotest

More information on Grifols research pipeline: https://www.grifols.com/es/key-therapeutic-areas

Maximizing Biotest's full potential

In 2023, Grifols continued to promote Biotest's R&D projects that expand and enrich its innovation portfolio, and support its aim of increasing the availability of plasma therapies for patients worldwide.

Core projects in the pipeline

Fibrinogen

Phase 3 study Adjusted Fibrinogen Replacement Strategy (AdFirst) in patients with elevated blood loss while undergoing spinal surgery or during abdominal surgery as a treatment for pseudomyxoma peritonei (PMP).

Trimodulin

A new polyclonal antibody preparation with high content of immunoglobulins (IgM, IgA and IgG) to treat severe community-acquired pneumonia (sCAP).

Milestones and advances in 2023

- **Completion of recruitment and treatment of 200 patients for the Phase 3 AdFirst study with fibrinogen.** Findings are expected to be presented in 2024.
- **First patient with severe community-acquired pneumonia (sCAP) treated with Trimodulin** in the Phase 3 of the EScCAPE clinical trial, expected to enroll 590 adult patients from up to 20 countries. The EScCAPE study will test whether mortality is reduced in Trimodulin-treated sCAP patients following the promising results of the Phase 2 CIGMA clinical trial of sCAP patients with invasive mechanical ventilation treated with Trimodulin.
- **Expansion of the TRICOVID trial for patients with community-acquired pneumonia (CAP)** The Phase 3 TRICOVID (Trimodulin against COVID-19) trial analyzes the impact of Trimodulin as adjunctive therapy in over 330 hospitalized adult patients with moderate to severe COVID-19. This research will assess whether Trimodulin is effective in activating a broad spectrum of antibodies against bacteria, fungi, viruses and other pathogens that may lead to lung infections.
- **First shingles patient treated with the herpes zoster virus-specific hyperimmunoglobulin Varitect® CP (VZV-IG)** as part of the prospective, multicenter, observational VARIZOSTA study. This study, comprised by 160 subjects from 15 German centers, aims to expand data on the efficacy and safety of routine use of Varitect® CP in patients with complex herpes zoster compared to standard therapy.
- **FDA accepts marketing authorization application for Yimmugo®,** Biotest's IgG Next Generation, marking an important step in its U.S. market approval process. The application covers the indication primary immunodeficiencies (PID), with plans to expand it to include chronic primary immune thrombocytopenia (ITP) after receiving this initial clearance. The FDA's decision is expected in June 2024.
- **Yimmugo® receives clearance in the United Kingdom** for the treatment of patients with congenital and acquired immunodeficiencies and for immunomodulation.

More details on Biotest's research pipeline (biotest.com)
More information on Yimmugo

We promote wide-ranging in-house initiatives

Xembify® to prevent infections in CLL patients

linical trial for subcutaneous immunoglobulin Xembify® to help prevent infections in patients with secondary immunodeficient chronic lymphocytic leukemia (CLL), which affects more than 375,000 people in the U.S.

Phase 3 double-blind clinical trial

380+ participants

100 Health Centers

First patient treated in 2023

This trial is being conducted in the **U.S. and Europe**

Alpha-1 in pulmonary emphysema

SPARTA evaluates the efficacy and safety of two weekly intravenous alpha-1 dosing schedules in subjects with pulmonary emphysema caused by alpha-1 antitrypsin deficiency (AATD).

Phase 3/4 double-blind clinical trial

2 dosing regimen

60 and 120 weekly/mg/kg

Recruitment finalized with **339** patients in 2023

Albutein in decompensated cirrhosis

PRECIOSA clinical trial to evaluate the efficacy and safety of Albutein® in conjunction with standard medical therapy to increase survival in patients with decompensated cirrhosis and ascites awaiting transplantation.

Phase 3 clinical trial

69 participating centers

Recruitment finalized with **400** patients

Results in 2024

Milestones and advances in plasma therapies

- **Encouraging findings from the Phase 4 XEMBIFY® study,** which evaluated biweekly dosing of Grifols' subcutaneous immunoglobulin (SCIV) at 20% concentration in patients with primary immunodeficiencies. The study showed similar safety and tolerability profiles between biweekly and weekly administrations. This will support FDA clearance of biweekly dosing, which is already approved in certain European markets. The FDA's decision is expected by mid 2024.

- **Global collaboration and licensing agreement with Selagine,** a company dedicated to developing novel therapeutics for ocular diseases, to explore the potential of immunoglobulin (Ig) eye drops to treat dry eye disease, known to affect more than 100 million people globally.

- **Grifols meets enrollment target of 339 patients for SPARTA** (Study of ProlAstin-c Randomized Therapy with Alpha-1 augmentation), a phase 3 clinical study to assess if alpha-1-antitrypsin deficiency (DAAT) patients with emphysema have a slower disease progression if treated with two separate weekly doses of Prolastin®-C. The study will move onto the next stage, with core findings expected in 2026.

- **Completion of Prolastin 4-5g (alpha-1) project,** which will enable 2024 launch of a more convenient presentation of this plasma treatment in several European markets, in benefit of both patients and healthcare professionals.

- **Positive topline results from phase 3b study of its fibrin sealant** to treat surgical bleeding in pediatric patients. Known commercially as VISTASEAL™ in the U.S. and VERASEAL™ in Europe, this sealant combines two plasma proteins (fibrinogen and thrombin), and is applied with an airless spray technology to rapidly form clots. Grifols' fibrin sealant is marketed and distributed by Ethicon, a Johnson & Johnson MedTech company as part of the strategic collaboration between the two companies. Regulatory authorities are expected to rule in 2024.

- **BMC Neurology publishes the results of the GAMEDIS study,** which evaluated fatigue, depression and product tolerability during long-term treatment with intravenous immunoglobulin (Gamunex® 10%) in patients with chronic inflammatory demyelinating polyneuropathy (CIPD). GAMEDIS was a multi-center, prospective, non-interventional study of 148 adult CIDP patients in Germany, who were treated for a mean of 83 weeks. The study found the treatment to be safe and well-tolerated.

Main product launches

- Launch of XEMBIFY® in Spain, Australia and Wales (UK)
- Expansion of TAVLESSE® (fostamatinib) in Europe
- More markets for VISTASEAL™

Xembify® (immune globulin subcutaneous human-klhw) 20%

Tavlesse® Film-coated tablets fostamatinib

VistaSeal™/MC

More information on product launches: "Financial Performance".

Grifols aspires to address patients' mental health and well-being, beyond the physical aspects of their disease.

R&D PROJECTS BASED ON THEIR DEVELOPMENT PHASE

	2023*	2022*	2021
Discovery	24	19	21
Pre-clinical	23	28	30
Clinical	22	23	22
Post-commercialization studies	14	39	9
Other projects	16	14	14
Total Biopharma R&D projects	**99**	**123**	**96**

* Includes Grifols and Biotest.

Other initiatives in neurodegenerative diseases

ALKAHEST

Through its investee Alkahest, Grifols continues to drive new knowledge of the plasma proteome to determine plasma proteins associated with aging, a discovery that could extend its therapeutic benefit to other diseases, including those related to the central nervous system.

There are ongoing clinical programs with plasma fractions and small molecules in patients with Alzheimer's disease, Parkinson's disease and neovascular age-related macular degeneration (AMD).

ARACLON and Alzheimer's disease

Grifols became an Araclon Biotech shareholder in 2012. Since then, it has supported and promoted its consolidation as a pioneering developer of projects to diagnose and treat Alzheimer's disease.

Results from phase 2 clinical study of ABvac40 Alzheimer's vaccine

Positive results were reported in the phase 2 trial of ABvac40, an active vaccine against the Aβ40 peptide to treat patients with early-stage Alzheimer's disease (AD). Findings show that ABvac40 had a favorable safety profile, elicited a robust immune response against Aβ40, and showed some potential cognitive benefits in early-stage AD patients, meeting primary endpoints and showing differences between the vaccine- and placebo-treated groups in some secondary exploratory endpoints.

ABvac40 is uniquely designed to target the C-terminal end of the Aβ40 peptide, believed to prevent harmful reactions and avoid immune triggers responsible for meningoencephalitis, a complication observed in earlier AD vaccines.

While the trial was not designed to find efficacy on neuropsychological scales, the ABvac40-treated group exhibited up to a 38% reduction in disease progression, as reflected by the Mini-Mental State Examination (MMSE) score. These findings suggest the potential efficacy of ABvac40 in addressing the cognitive decline associated with AD.

These clinical data were presented at various scientific conferences, including the 2023 European Alzheimer's Disease Consortium, the CTAD 2023 Alzheimer's Disease Clinical Trials Conference and the 75th Annual Meeting of the Spanish Neurology Society.

More details:
https://www.araclon.com

Complete details on the phase 2 study on Abvac40

ABtest-MS to detect early-onset Alzheimer's

Araclon's ELISA Abtest-IA assays analyzed β-amyloid peptides in human plasma, proving their potential to help identify cognitively normal individuals with Alzheimer's disease (AD)-related pathological changes in their brains. Following these positive findings, it developed ABtest-MS, an innovative assay to simultaneously determine total Aβ40 and Aβ42 levels in plasma by liquid chromatography tandem mass spectrometry.

In 2023, *Alzheimer's Research & Therapy* magazine published findings on a trial on the effectiveness of ABtest-MS testing in detecting early AD disorders. A collaboration between ACE Alzheimer Center (Barcelona, Spain) and Samsung Medical Center (Seoul, South Korea), the study analyzed plasma samples from 200 people with subjective memory complaints and monitored them over a two-year timeframe.

The trial successfully identified individuals at higher risk of disease progression, confirming the robustness and utility of ABtest-MS demonstrated in previous studies as a potential pre-screening tool for clinical trials, prevention strategies and clinical practice.

GigaGen, non-plasma innovations

GigaGen is dedicated to the discovery and development of recombinant polyclonal antibody-based drugs to treat immunodeficiencies, infectious diseases and immunotherapy-resistant cancers. Its proprietary technology platforms advance the discovery of potent monoclonal antibody therapeutics and a new class of drugs: recombinant polyclonal antibodies.

Phase 1 clinical trial for GIGA-564, GigaGen's first oncology drug candidate

In 2023, GigaGen received FDA clearance for an Investigational New Drug (IND) designation to start a phase 1 clinical trial to evaluate the company's oncology candidate, GIGA-564, for the treatment of advanced solid tumors.

Scheduled to begin in 2024, the study will be led by researchers from the National Cancer Institute (U.S.) in close collaboration with GigaGen under their recently signed collaboration agreement.

Expansion of GigaGen's research contract with the U.S. Department of Defense

GigaGen will collaborate with the U.S. Department of Defense to demonstrate the utility of its first-in-class recombinant human polyclonal antibody discovery platform against biological threats including botulinum neurotoxins (BoNT) A and B. The expanded agreement will facilitate further research on GigaGen's next-generation platform capabilities to rapidly create synthetic human antibodies that surpass natural immune responses. The agreement's value now stands at USD 11.8 million for transformative projects, including manufacturing support and novel studies to prove the increased potency of GigaGen's BoNT hyperimmune product.

The contract expansion reaffirms the Department's confidence in GigaGen's technology and ability to develop key therapies against high-priority pathogens.

More information: GigaGen https://www.gigagen.com/

Innovation in Diagnostics

Milestones and product launches in 2023

First IVDR certifications for class D Diagnostics products

Grifols received the first certifications for its class D Diagnostic products under the new European Union Regulation on In Vitro Diagnostic Medical Devices (IVDR). These include all red blood cell reagents and some of the gel cards, such as DG Gel ABO/Rh (2D) + Kell.

U.S. market launch: AlphaID™ At Home

Grifols launched AlphaID™ At Home Genetic Health Risk Service (AlphaID™ At Home) in the U.S. market in May 2023. This free service allows patients with chronic obstructive pulmonary disease (COPD) to detect their genetic risk of alpha-1 antitrypsin (alpha-1) deficiency through a small saliva sample, with no need to visit a healthcare professional. Alpha-1 affects an estimated one in every 2,500 Americans.

Innovation in creating the laboratory of the future

For the first time, the Procleix Panther System featuring ART technology was connected to a fully automated laboratory sample processing platform through a collaboration between Grifols Diagnostic and Lifeblood, the Australian Red Cross entity in charge of the collection, screening and distribution of the country's blood and biological products. The automation of these processes enhances safety and quality, while offering future-forward insights for global laboratories.

New solution to facilitate pre-transfusion compatibility testing in multiple myeloma patients

In 2023, the company launched Grifols sCD38, the first soluble recombinant protein designed to block anti-CD38 antibodies in multiple myeloma patients treated with daratumumab. This innovation ensures the speed and accuracy of blood transfusion tests, critical for high-quality treatment.

Digital innovation

Digital innovation is a core hub in Grifols' operations, allowing the company to detect market opportunities and better compete in today's fast-paced business landscape. With the objective of exploring, and enhance digital tools that add value to the business model, the company continues to advance under the leadership of the Chief Digital Information Officer (CDIO).

In 2023, the company continued to advance in its digital transformation process by leveraging the knowledge and experience acquired since 2018 to spearhead a comprehensive redesign of its community and ecosystem, guided by a local approach with a global vision.

Grifols' digital strategy is based on three key pillars:

1. **Digital Boost:** driving the implementation of innovative initiatives

2. **Literacy and Spread:** effective communication of core actions to proactively foster cultural change

3. **Digital Networking & Open Innovation:** encouraging open-mindedness to new ideas and cultivating an innovation-friendly environment

Grifols created "Digital Innovation Local Hubs" within each business unit to reinforce these core pillars. These hubs will serve as catalysts for cultural change, helping the company better address challenges and seize new opportunities.

This holistic strategy allows Grifols to drive innovation internally and boost its renown as a proactive agent in adopting new ideas and industry practices. Grifols advances these innovation efforts through collaborations with several external entities. In 2023, the company joined the Barcelona Health Hub (BHH), dedicated to fostering innovation and interaction in the digital health space. The BHH's 350 members include startups, healthcare institutions, universities, large corporations and investors. This participation allows Grifols explore and fast-track the adopting of leading-edge digital health platforms and technologies.

DIGITAL INNOVATION: AREAS OF IMPACT

Commercial
Client
+ value

Industrial
Value chain and operations
+ optimization

Plasma
Donors
+ experience
+ efficiency

R&D
New sources of value

Quality
+ safety

Corporate
+ processes
+ employee experience

Harnessing the power of artificial intelligence

As a firm believer in the immense impact and business potential of artificial intelligence, Grifols continuously explores new AI solutions to maximize its manufacturing efficiency and sustainability, as well as enhance its R&D initiatives and other strategic areas. The main projects of 2023 have been:

AI systems to optimize industrial energy consumption

Grifols rolled out an AI application in its cooling system to monitor internal and external parameters and discover patterns to discern the optimal time to activate the system. Armed with this information, the company can perform a smoother start-up, leading to lower energy consumption.

Grifols began exploring AI solutions in 2021 with the aim of optimizing and improving its industrial energy consumption. The significant energy savings recorded in 2022 and 2023 moves Grifols closer to its objective of improving its industrial energy efficiency by 15% by 2030.

The company intends to build on this initiative and achieve an even better energy-management system by incorporating digital-twin technology in its manufacturing operations.

AI implementation in immunoglobulins production

Grifols implemented AI platforms in its Biopharma plants with the aim of optimizing its intravenous immunoglobulin (IVIg) manufacturing performance. These systems collect data from production processes, identify critical parameters and learn how variations affect the amount of protein obtained. Based on this information, the platform proposes new thresholds to achieve higher IVIg yields.

Agreement with Google to promote AI in R&D

Launched in 2022 through the Scientific Innovation Office, Grifols Innovation with Google Academy (GIGA) promotes innovation by fostering an organization-wide digital culture and mindset. Under this umbrella, Grifols will work together with Google to implement 12 AI-driven innovations aimed at accelerating and streamlining its R&D processes. These initiatives are expected to yield promising returns on investment and benefit numerous corporate areas, including Clinical Trials, Medical Affairs, Data Discovery, Drug Discovery and Biopharmaceutical Therapies.

Manufacturing innovation

Grifols works to advance the efficiency and sustainability of its production processes in line with its growth strategy. Leveraging its in-house engineering expertise and collaborations with other institutions and organizations, it continuously explores options to integrate new technologies, automated systems, digitalization opportunities, AI and new materials. The following were among its core projects in 2023.

Virtual modeling of process bioreactors to boost plasma protein yields

In collaboration with the Barcelona Super Computing Center, Grifols is working to model the reactors used in the precipitation of the diverse protein fractions[1], with the aim of improving the purity of the paste per fraction and achieving higher plasma-protein yields.

Development of a new sterile filling machine

In the production of biological drugs, maintaining sterile conditions for the dosing and filling phase is critical. While considered a global industry standard, Grifols' system was initially designed to process small formats of up to 100 milliliters, or large formats of up to 500 milliliters. The new machine processes formats from 50 ml to 400 milliliters, offering greater flexibility.

Optimizing plasma logistics operations with SAS

Grifols developed and implemented a Supervised Aggregation System (SAS) to incorporate RFID (radio frequency identification) technology into its clients' plasma logistics operations. This system, fully integrated with the customer's donor database, improves traceability and reduces operating costs by enabling real-time wireless readings in its logistics operations.

1. Fractionation is the process of separating proteins from human plasma. In the blood products industry, Cohn fractionation is the most widely used, entailing the precipitation and subsequent separation of pastes rich in different protein groups (fractions).

"We promote internal innovation and collaborations with third parties to make our production processes more efficient and sustainable.

Research collaborations and support

Sponsorship of ISR Program

Grifols' Investigator-Sponsored Research (ISR) advances scientific knowledge of plasma proteins by supporting pre-clinical and clinical research.

$7.5M

allocated to research over the past 5 years to complement public-sector investments

More information

Grifols Scientific Awards and research grants

These distinctions recognize innovative proposals developed to enhance people's health, well-being and quality of life.

€4.7M

over the last 5 years toward scientific awards and research grants

More information

Scientific journal specialized in plasma

Grifols was a key contributor in creating *Plasmatology*, the first scientific journal dedicated to plasma science. This trailblazing publication aims to become a global industry reference by featuring the most relevant and rigorous research, from basic research to clinical applications. The journal has open access and indexed in a range of scientific databases.

34

articles published since its March 2021 launch

***Plasmatology:* SAGE Journals**

Grifols Chair for the Study of Cirrhosis and Albumin

Grifols created the Grifols Chair for the Study of Cirrhosis in 2015 to promote research and awareness of liver disease, with an emphasis on cirrhosis. A private initiative with a global reach, the Chair forms part of the European Foundation for the Study of Chronic Liver Failure (EF-Clif). Prof. Vicente Arroyo serves as the president of EF-Clif and holder of the Chair, whose executive board includes a Grifols representative.

€14M

invested over the last 5 years in liver disease research

More information