INVESTORS' & ANALYSTS' MEETING - 2016

GRIFOLS

Dublin, 2nd - 3rd June 2016

Wifi code

Thursday, June 2nd 2016 - Dublin

Time	Topic	Presenter
9:15 - 9:45	*Coffee + Welcome*	
9:45 - 10:00	Introductory remarks	V. Grífols
10:00 - 10:15	Commercial introductory remarks	R. Riera
10:15 - 11:00	Bioscience Division: Commercial overview & strategies	L. Morgan
11:00 - 11:15	*Coffee break*	
11:15 - 12:00	SIPPET study: Opportunities for plasma-derived Factor VIII	M. Salvat
12:00 - 12:45	Bioscience manufacturing capacities	V. Grífols Deu
12:45 - 13:30	*Lunch*	
13:30 - 14:00	Hospital Division: Commercial overview & strategies	P. Allen
14:00 - 14:30	Diagnostic Division: Commercial overview & strategies	C. Schroeder
14:30 - 14:45	Project Horizon	O. Duñach

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Thursday, June 2nd 2016 - Dublin

Time	Topic	Presenter
14:45 - 15:15	Research + Development + Innovation: New organization GIANT, Ltd. Presentation	D. Bell
15:15 - 15:45	Albumin new container	C. Roura
15:45 - 16:15	Q&A	
16:15 - 16:30	Introduction to the GWWO tour	A. O'Connell
16:30 - 16:45	*Coffee break*	
16:45 - 18:00	GWWO tour	C. Roura / A. O'Connell
18:00	*Transfer to hotels*	
19:30	*Pick up from hotels*	
19:45	Dinner	

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Friday, June 3rd 2016 - Dublin

Time	Topic	Presenter
9:00 - 9:30	*Coffee + Welcome*	
9:30 - 10:15	Grifols Engineering: A competitive advantage	D. Fleta
10:15 - 11:15	Financials	A. Arroyo
11:15 - 11:45	*Coffee break*	
11:45 - 12:15	Emerging Pathogen Project	D. Bell
12:15 - 12:30	Conclusions	T. Glanzmann
12:30 - 13:00	Q&A	
13:00	*Lunch or Transfers to airport*	

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This document contains forward-looking information and statements about GRIFOLS based on current assumptions and forecast made by GRIFOLS management, including proforma figures, estimates and their underlying assumptions, statements regarding plans, objectives and expectations with respect to capital expenditures, synergies, products and services, and statements regarding future performance. Forward-looking statements are statements that are not historical facts and are generally identified by the words "expected", "potential", "estimates" and similar expressions.

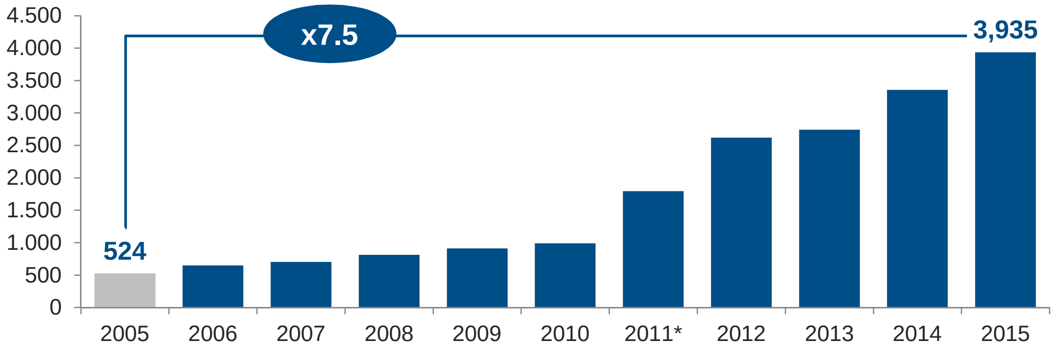
Although GRIFOLS believes that the expectations reflected in such forward-looking statements are reasonable, various known and unknown risks, uncertainties and other factors could lead to material differences between the actual future results, financial situation, development or performance of the Company and the estimates given here. These factors include those discussed in our public reports filed with the Comisión Nacional del Mercado de Valores and the Securities and Exchange Commission, which are accessible to the public. The Company assumes no liability whatsoever to update these forward-looking statements or conform them to future events or developments. Forward-looking statements are not guarantees of future performance. They have not been reviewed by the auditors of GRIFOLS.

Introductory remarks

Víctor Grífols

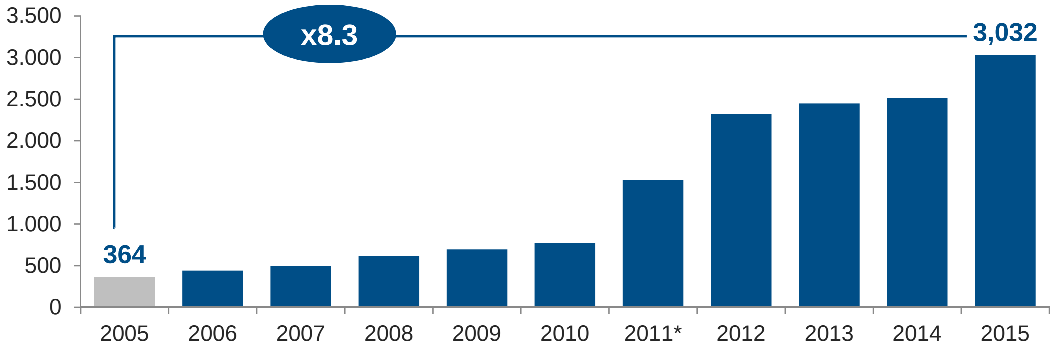
10th Anniversary as a public company

10 years in figures - Total Net Revenues



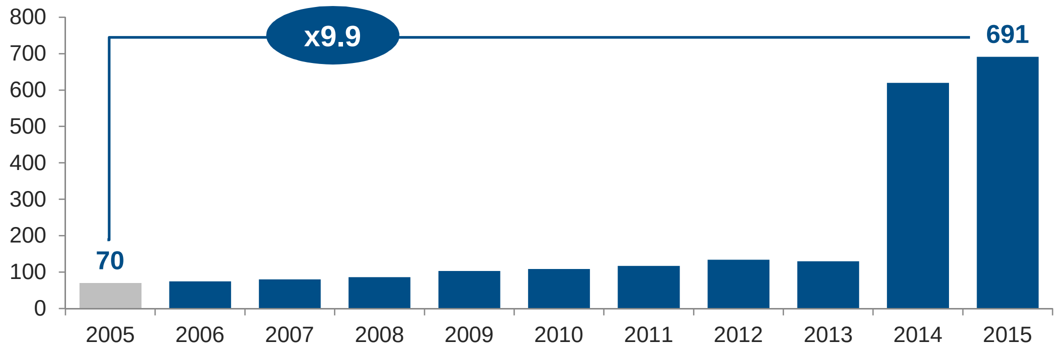
In million EUR
** It includes 7 months of Talecris figures*

10 years in figures - Net Revenues of Bioscience Division



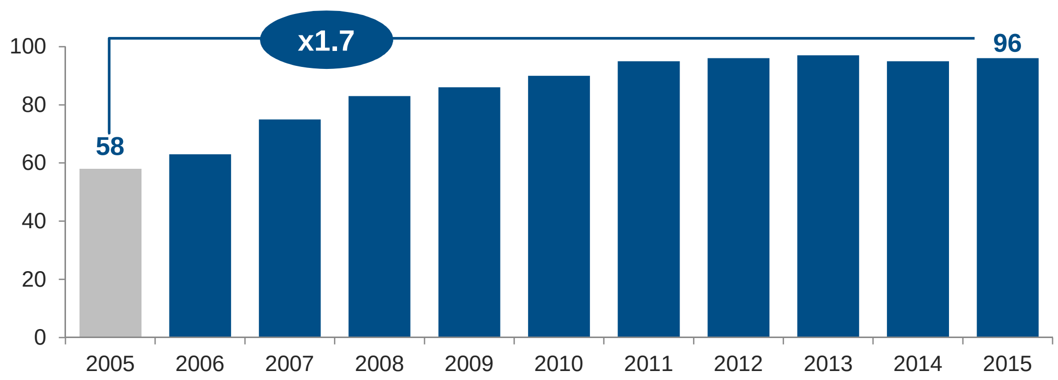
In million EUR
** It includes 7 months of Talecris figures*

10 years in figures - Net Revenues of Diagnostic Division



In million EUR

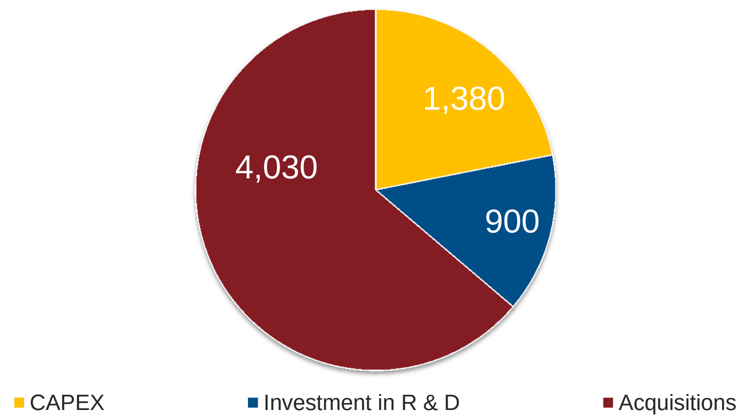
10 years in figures - Net Revenues of Hospital Division



In million EUR

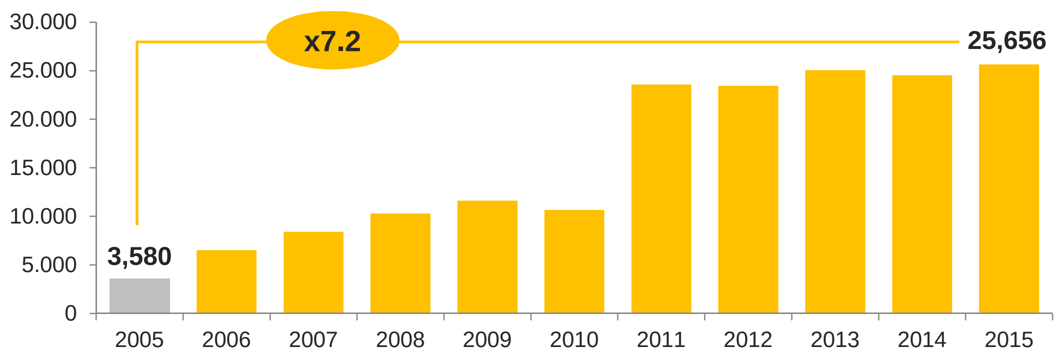
10 years in figures - Total investments

EUR 6,310 millions
Capital expenditures, R & D, acquisitions

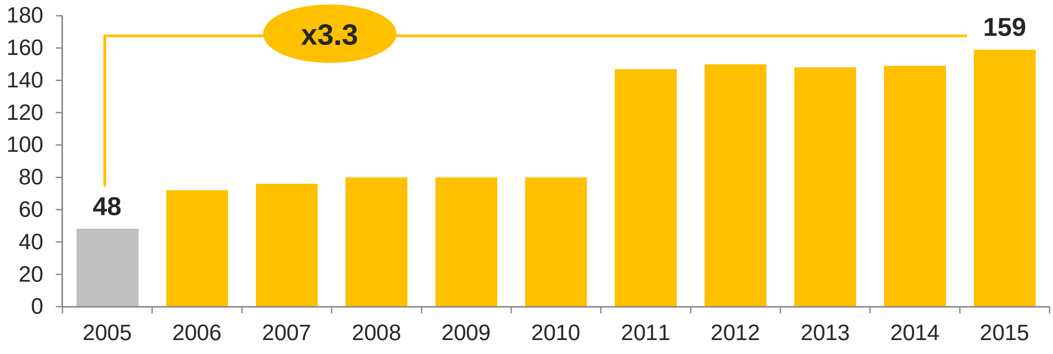


In million EUR

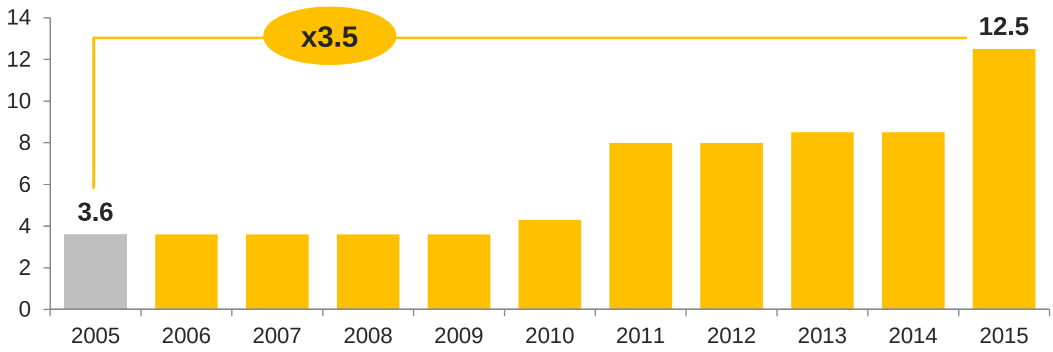
10 years in figures - Daily plasma donors



10 years in figures - Plasma collection centers

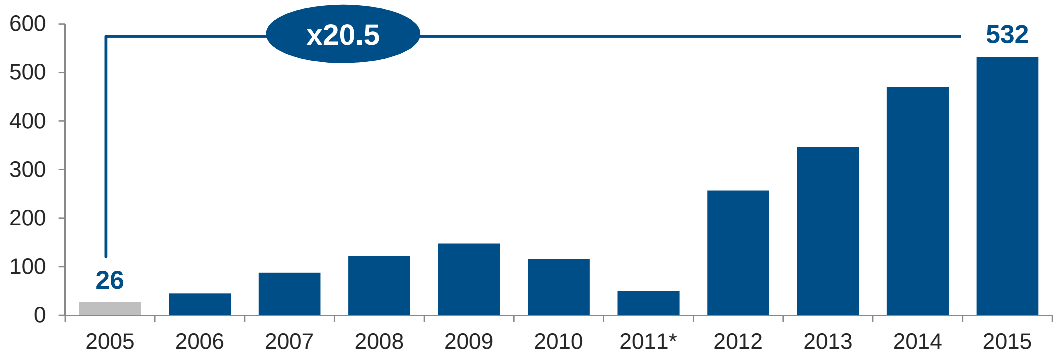


10 years in figures - Fractionation capacity



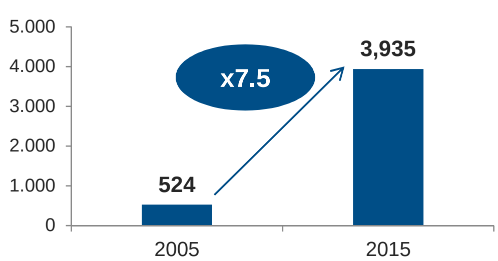
In millions of liters of capacity installed

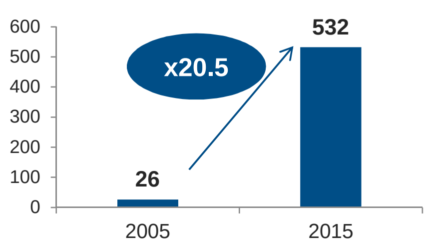
10 years in figures - Net Profit

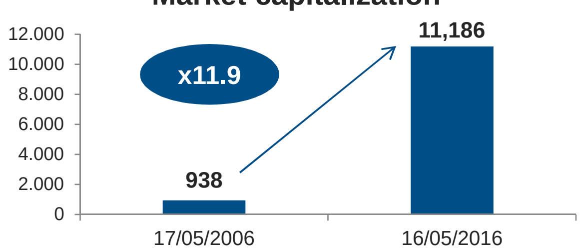


In million EUR
** It includes 7 months of Talecris figures*

10 years in figures - Market capitalization



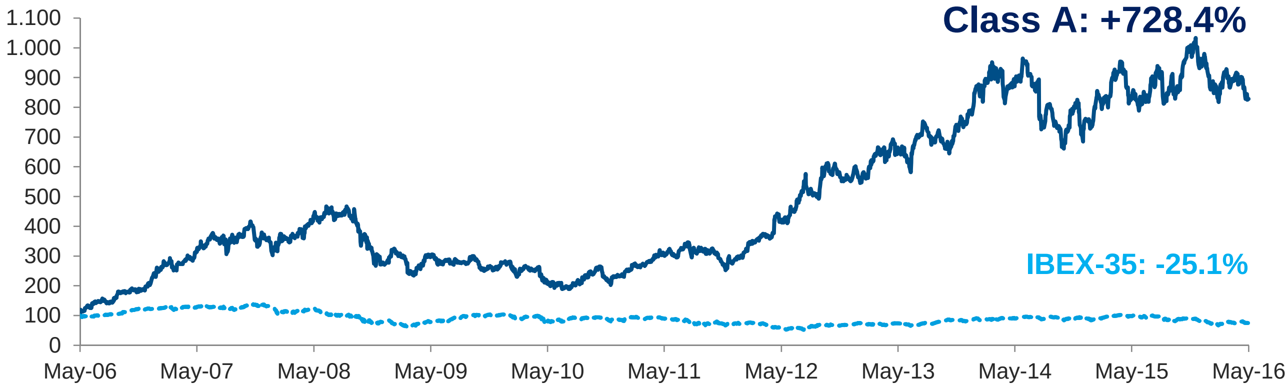




In million EUR

10 years in figures - Class A share vs IBEX-35

GRIFOLS' DAILY SHARE PRICE, CLASS A vs IBEX 35



May 17, 2016 - YTD change
Base 100: May 16, 2006 - non adjusted closing price
Source: Infobolsa

2016 Corporate video

Commercial introductory remarks

Ramón Riera

New global operations structure fully implemented

We can confirm today that the new structure announced last year has been fully implemented

Global operations today

- We have commercial teams fully dedicated to each division all around the world
- Our commercial strategies are global and consistent across geographies
- We have a Global Operations Network (GON) with 30 commercial subsidiaries around the globe to support the business divisions' activities
- The global operations center for the Bioscience Division in Ireland is already built and approved, ready to start operations
- A new President of the Hospital Division has been recently appointed

Executing our Strategy. Delivering on our Commitments

BIOSCIENCE

We have reinforced the basis of the division's sustainable growth through:

- Developing the market
- Geographic expansion
- Expanding plasma collection and industrial capacity

DIAGNOSTICS

Balancing the portfolio and expanding and upgrading manufacturing facilities in Emeryville (California, U.S.)

HOSPITAL

U.S. has been chosen as the launch scenario for the KIRO® Robotic System and the Hospital Pharmacy Compounding product line

Bioscience Division

Growing the plasma proteins market

- IVIG demand in the U.S. has been accelerated, especially in the neurological area. As a result, pull-through of Grifols IVIG products has increased significantly and continues to do so, with channel inventories significantly reduced
- SIPPET results presented in December 2015 at the 57th American Society of Hematology (ASH) Meeting. PdFVIII increases its prestige and clearly beats recombinant in the area of immunological safety
- Grifols Albumin sales growth double digit for another consecutive year, led by China and the U.S.
- New patients diagnosed with Alpha-1 deficiency and treated with Prolastin® products. Not only in the U.S. and Germany but also in Canada, Austria, Italy, Portugal, Switzerland, etc.
- Global operations center in Ireland obtained Manufacturer's License and ready to start operations in Q2 2016

Diagnostic Division

Diagnostic business in transition for long-term sustainable growth

- Immunoassay business secured, improved and extended through 2026 with a new long-term agreement with Abbott. New customers may significantly increase profitability
- Grifols keeping market leadership position in Molecular Blood Donor Screening (NAT). Global market size slightly declining. Increasing adoption of NAT testing in developing markets and growth of plasma collections not enough to offset the decrease of blood donations in developed markets
- Redefining product portfolio in Clinical Analysis segment and revising commercial strategy for Hemostasis product line. Results should be visible starting in 2017
- Immunohematology business continued to grow strongly in all geographies. Launch in the U.S. developing successfully

Hospital Division

Ready for expansion into U.S. with Pharmatech line and LVP's*

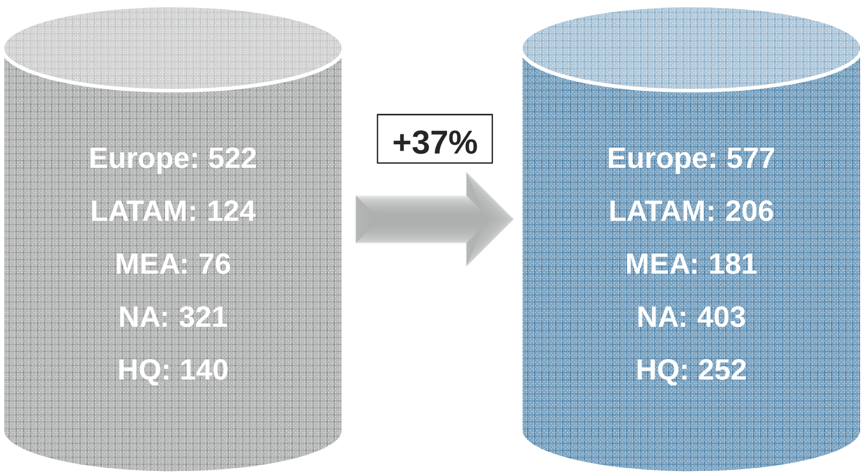
- The launch of Kiro® Oncology Robot took place at the end of 2015 after the required FDA's approval
- Reference sites already installed and operating in the U.S. and Europe
- The first year of commercialization will be focused in the U.S. with several key accounts already committed
- Contract Manufacturing agreements waiting FDA's approval to start contribution to revenues and margins
- A new President for Hospital has been recently appointed to operate the division on a standalone basis

** Large Volume Parenterals*

Global Operations Network

Subsidiaries' global structure

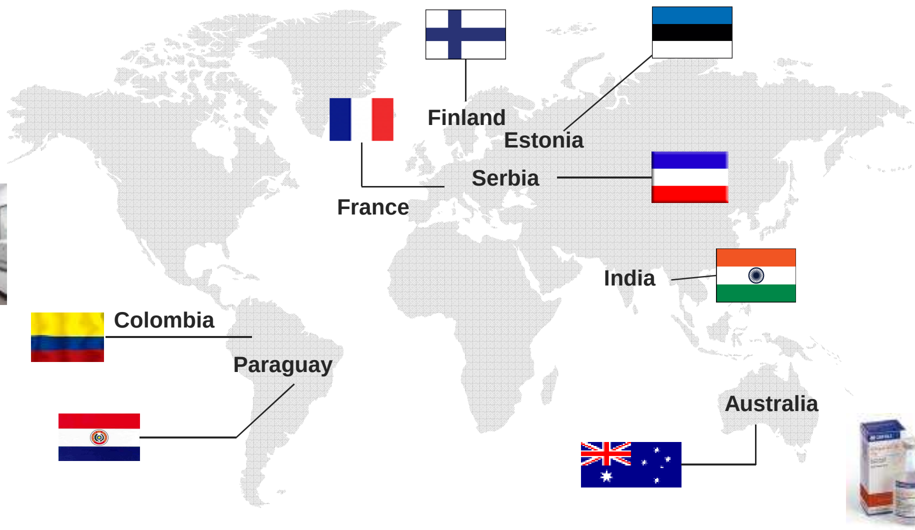
Total 2011: 1,183 employees **Total 2016: 1,619 employees**



Global commercial facilities' infrastructure

- New offices for the German subsidiary ready to be opened in Q3 2016
- It will include the European headquarter for the Bioscience Division as well as the German base for Hospital and Diagnostic
- Building of 3,320m^2 built in 4 floors
- Warehouse 1,500m^2
- 114 working spaces
- Showroom 40m^2
- Technical Service area

New commercial activities developed during 2015



Commercial introductory remarks - Takeaways

- Global operations structure based on multi-division business model
- Executing our strategy. Delivering on our commitments
- Continuously growing the plasma proteins market
- Diagnostic business in transition for a long-term sustainable growth
- Standalone Hospital Division focused in U.S. growth
- Expanding Global Operations Network (GON) to facilitate geographical reach

Bioscience Division: commercial overview & strategies

Lafmin Morgan

Market fundamentals

The fundamental elements to sustain growth for Grifols Bioscience remain strong:

- Market demand
- Grifols share position
- Balance of supply and demand
- Growth in access to healthcare

Bioscience strategies

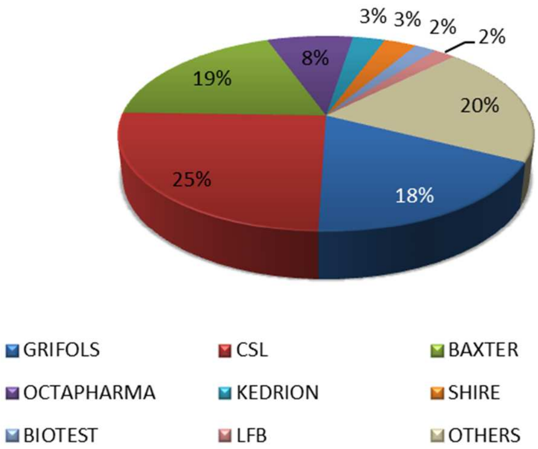
Grifols continues to deliver growth by consistent strategy execution

Current growth	Mid-term growth	Long-term growth
Increasing diagnosis & treatment • CIDP diagnosis • Continuing Alpha-1 diagnosis campaign • Support ATIII deficiency diagnosis **Supporting product differentiation** • Increasing awareness • Pharmaco-economic value • Packaging and formulation improvements • Patient support programs • Health Care Practitioner support **Grifols best in class manufacturing** **Balanced liter growth**	**Market penetration** • IVIG select market entry • Alpha-1 model expansion • Albumin development • Growth in healthcare access **New market entry** **Own network expansion** **Launch new products** • 20% SubQ Immunoglobulin • Fibrin sealant • Albumin in bags • Alpha-1 liquid • Linhaliq® (Pulmaquin®)	**Deliver on product innovation** • New indications • New products • Albumin development • Growth in healthcare access **New protein development** **Complimentary technology and product acquisition** **Capacity leadership**

Plasma proteins market

Grifols is one of the three largest manufacturers of pd-therapies

Total market 2014
(value)



Total market without including recombinants
Source: Internal data, MRB & Secondary official data year 2014

Grifols is the global market leader for three major proteins

Core business optimization

Market-leading products (value)

Product	Global market share	Grifols global position
IVIG	23%	Number 1
Alpha-1	66%	Number 1
pdFVIII	21%	Number 1
Albumin	16%	Number 2

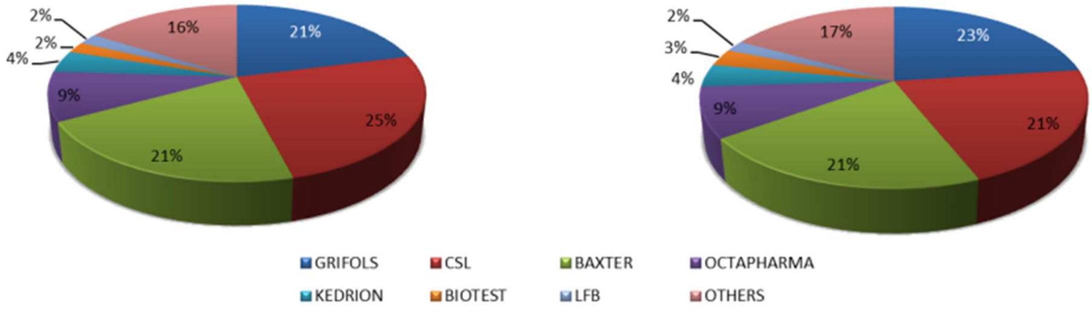
Source: Internal data, MRB & Secondary official data year 2014

Grifols Immunoglobulin

Grifols maintains the leading IVIG global market share

IV and SubQ Immunoglobulin
(value)

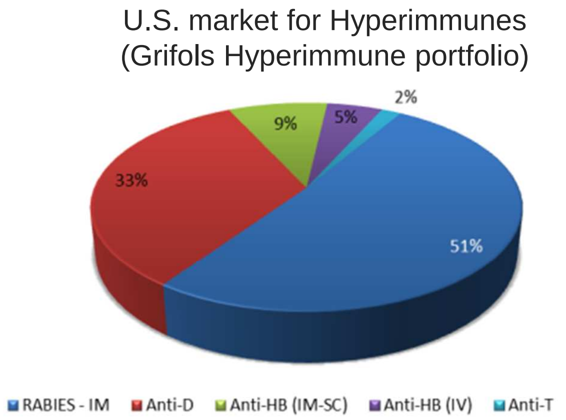
IVIG market
(value)

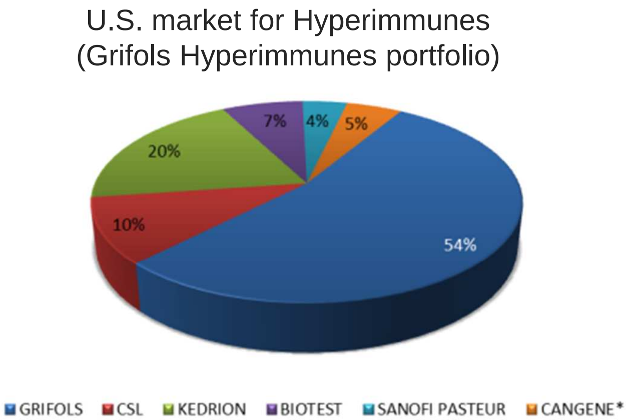


Source: Internal data, MRB & Secondary official data year 2014

Global Hyperimmunes market share (specific IG)

Grifols is the market leader in the U.S. Hyperimmunes market (value)

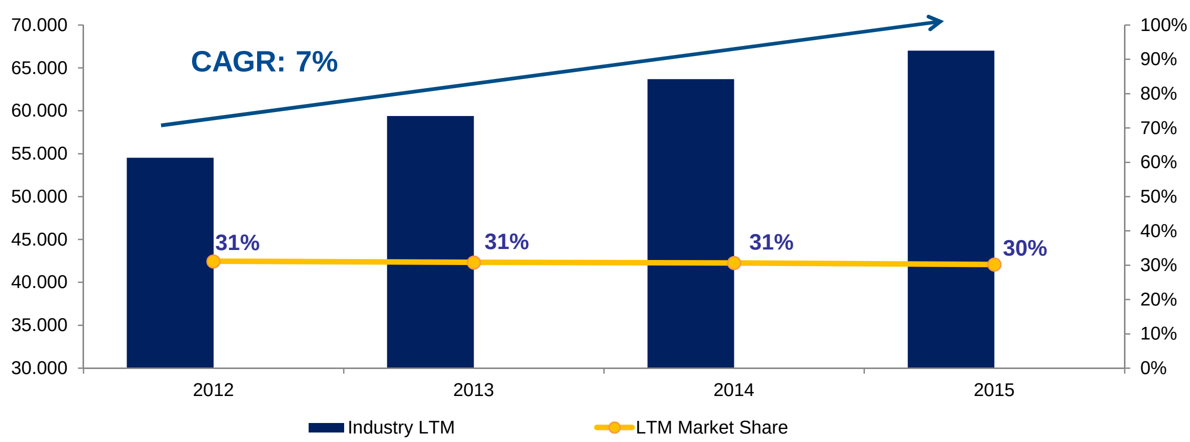




**Excluding WinRho sales*
Source: Internal data and MRB 2014

Grifols has held market leading position in U.S. since 2012

U.S. IG (includes SubQ) distribution rolling 12 months - market supply (Kg)



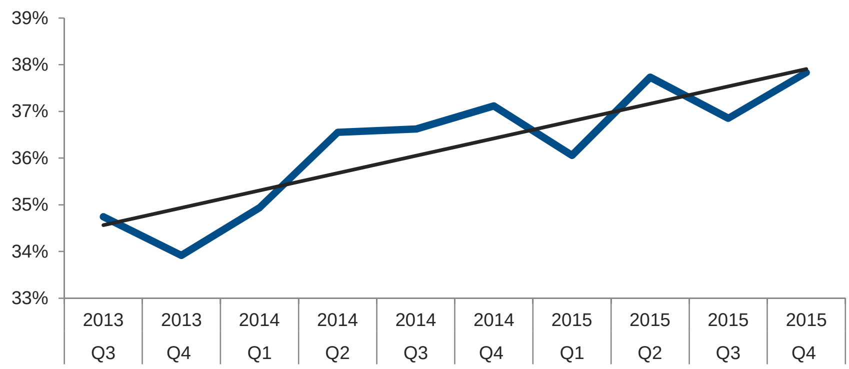
Grifols market share does not include sales to Kedrion
Source: PPTA and Internal data

Gamunex®-C market position is unique

- A proven formulation for a wide range of patient types
- Gamunex®-C is approved for both IV and SubQ administration in PIDD
- ICE trial-proven efficacy for CIDP
- Gamunex® connections support

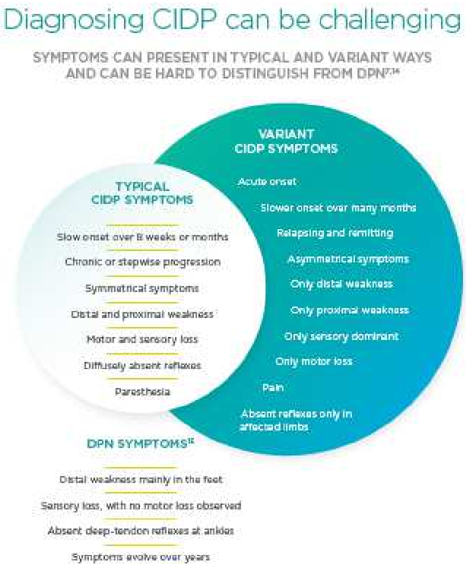
Gamunex®-C has grown procedures share in CIDP

Grifols IG brand share with CIDP diagnosis 2013-2015



Source: Lexis-Nexis, Medical claims data only

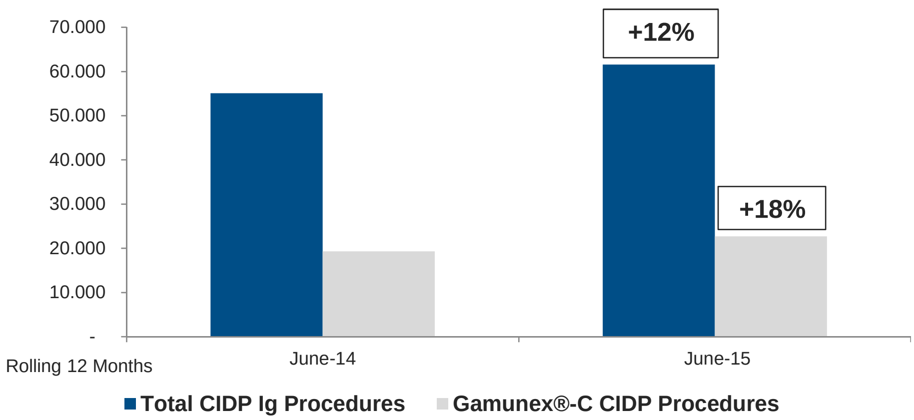
Grifols is leading efforts to improve CIDP diagnosis



- Early detection critical to prevent long-term axonal damage
- CIDP is more common than you may think
- 50% of patient may be missed due to atypical symptoms

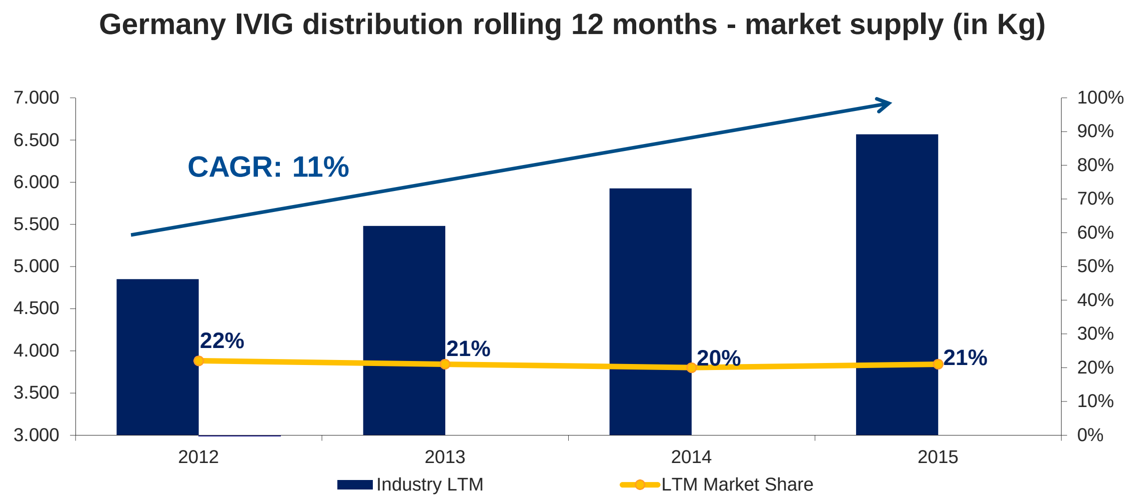
CIDP market expansion strategy in place to grow market

CIDP procedure growth



Source: Lexis-Nexis, Medical claims data only

Gamunex® leading in a growing and competitive market*



** 5 brands approved in CIDP*
Source: PPTA and Internal data

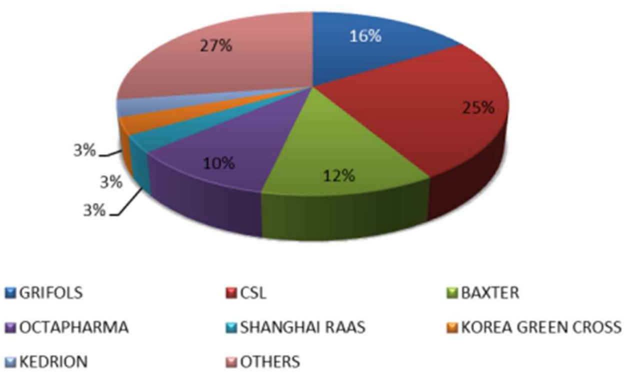
Grifols Immunoglobulin portfolio summary

- Focused product positioning for Gamunex® and Flebogamma® DIF is strengthening the leading global immunoglobulin portfolio
- Emphasis on patient diagnosis and optimal treatment creates additional growth opportunity for Gamunex®
- New market launches plus expansion in underdeveloped markets is a core part of our immunoglobulin strategy
- Grifols' Hyperimmune portfolio is an important driver of value and we are investing to increase growth through emphasis on guideline-based treatment and brand choice

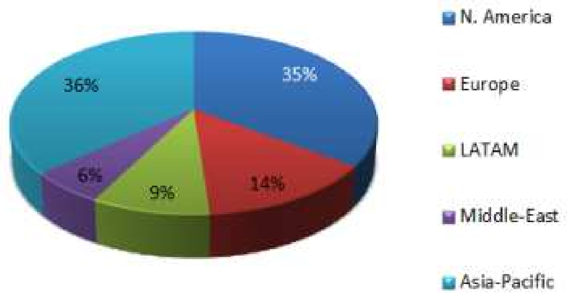
Grifols Albumin

Grifols is a global leader with strong positions in China & U.S.

Albumin market shares[1]
(value)

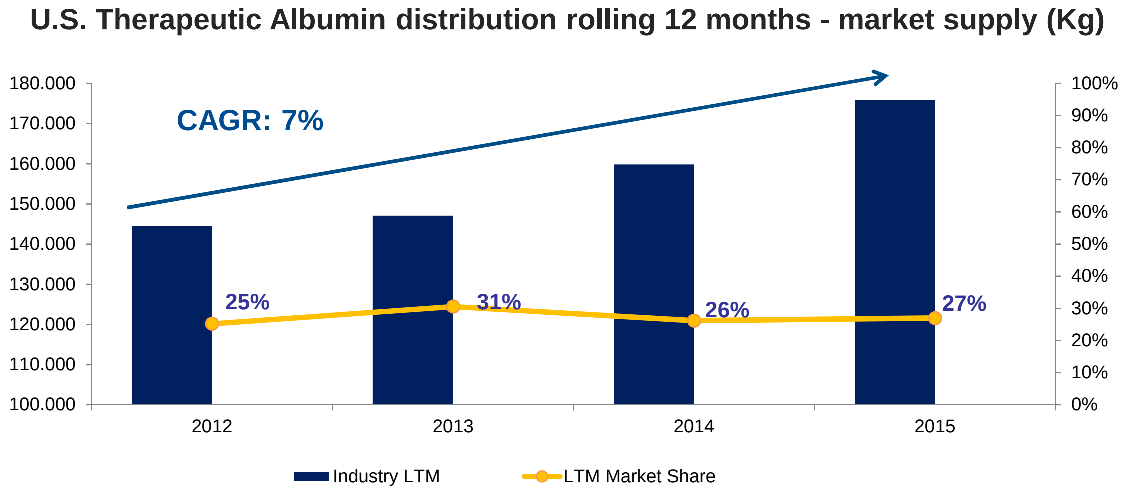


Grifols regional split[2]
(value)



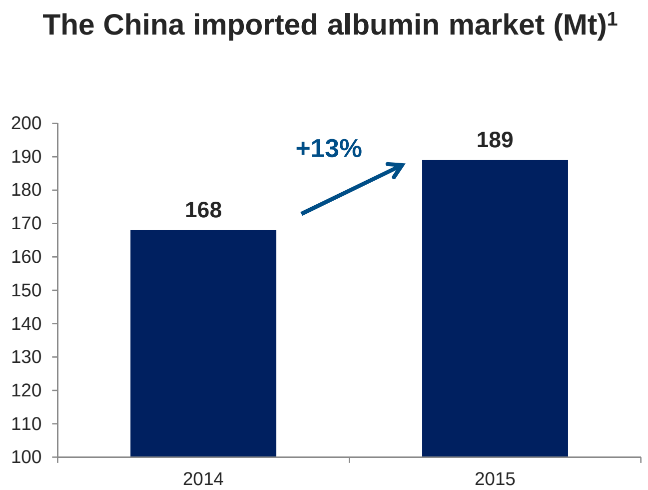
[1] *Source: Internal data, MRB & Secondary official data year 2014*
[2] *Grifols 2014 net revenues*

Grifols grew faster than the overall U.S. market for Albumin



Grifols market share does not include sales to Kedrion
Source: PPTA and Internal data

Grifols is growing faster than the market in China



- China continued to grow double digit[1]
- Grifols sales in the country grew well above the market

[1] Source: Official data

Grifols Albumin well positioned

- Grifols well positioned as market demand estimated to grow at 6% CAGR
- Growth driven by U.S. and China, where Grifols is expected to grow above the market
- Developing countries are expected to grow at double digit rate in the coming years
- Grifols is investing in Albumin:
  - New indications: Alzheimer, cirrhosis and other diseases
  - Field promotion in key markets
  - New container: Albumin in bags
  - Expanded manufacturing capacity

Grifols Albumin summary

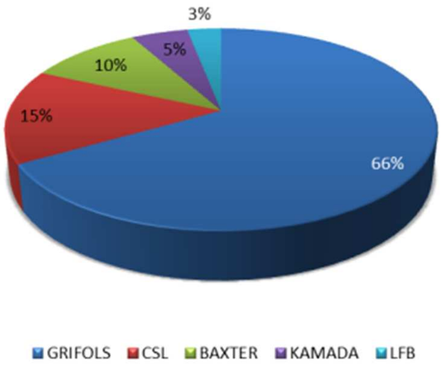
- Grifols maintains a global leading position in Albumin sales with strong positions in the largest markets: China and U.S.
- Grifols is investing in Albumin as a new therapeutic agent for Cirrhosis, Acute on Chronic Liver Failure and ALS (Amyotrophic Lateral Sclerosis). Should these clinical trials be successful this will reinforce Albumin properties beyond fluid management and could create a sales opportunity of approximately 500M+ euros over a five year period
- Albumin market demand will continue to grow and this will be driven by the U.S. and China where Grifols is expected to grow above market with specific promotion in the main identified indications

Grifols Alpha-1 Antitrypsin

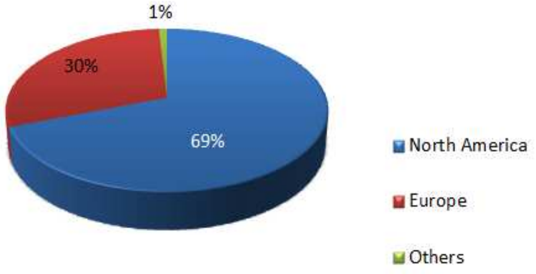
Grifols holds leading Alpha-1 position

Grifols is the leading manufacturer in the worldwide Alpha-1 business

Alpha-1 market shares[1]
(value)



Grifols regional split[2]
(value)



[1] Source: Internal data, MRB & Secondary official data year 2014
[2] Grifols 2014 net revenues

Global Alpha-1 strategy

Dedicated pulmonary teams

- Established in U.S., Germany, Canada
- Expanding to Spain, Portugal, Italy, LATAM

Focused Alpha-1 testing

- Proprietary test kits (North America, Europe)
- New targets (e.g. COPD[1] patient pilots in U.S. and Germany)

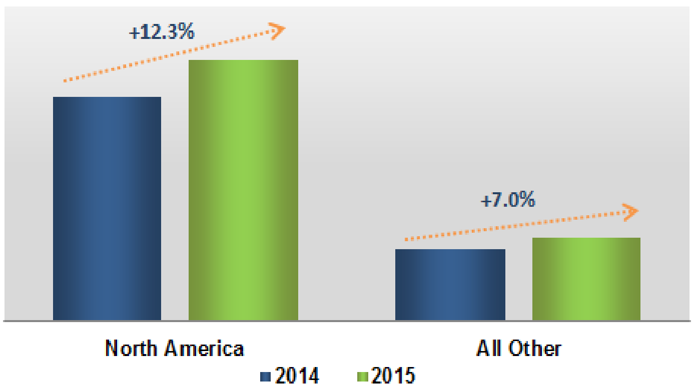
Alpha-1 disease management

- Prolastin® Direct with Alphanet® in U.S. and Canada
- AlphaCare in Germany

[1] COPD: Chronic Obstructive Pulmonary Disease

Alpha-1 diagnosis is accelerating patient identification

Prolastin® patient count



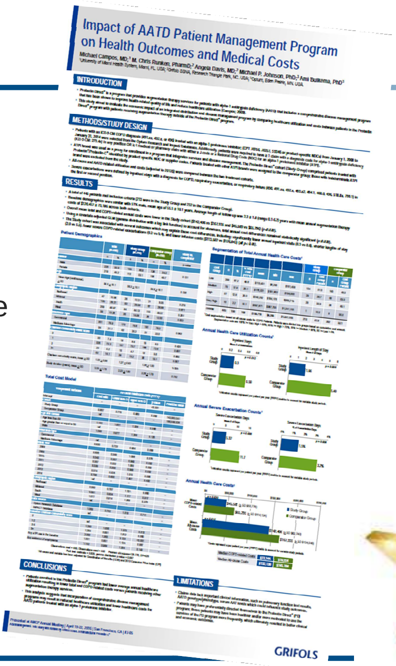
- Dedicated pulmonary sales resources in all markets
- Implementation of patient disease management program in Canada and Germany (also in U.S.)
- Extensive Grifols support to diagnose more Alpha-1 patients through testing services
- Grifols supported genetic testing resources in all countries
- Launch of AlphaKit Quick Screen - novel point of care device to screen for Z protein in 15 minutes

Prolastin®-C offers unique support

AMCP Gold Medal
Abstract Submission

The abstract concludes that COPD patients in the U.S. (treated with Prolastin®/Prolastin®-C) who were enrolled in the Prolastin® Direct (PD) program had lower average annual healthcare utilization, which resulted in lower total and COPD-related costs when compared to patients who received other augmentation therapies

The results suggest that incorporating comprehensive patient management programs may result in reduced healthcare utilization and lower healthcare costs for AATD patients treated with an Alpha-1 proteinase inhibitor



Pulmonary summary

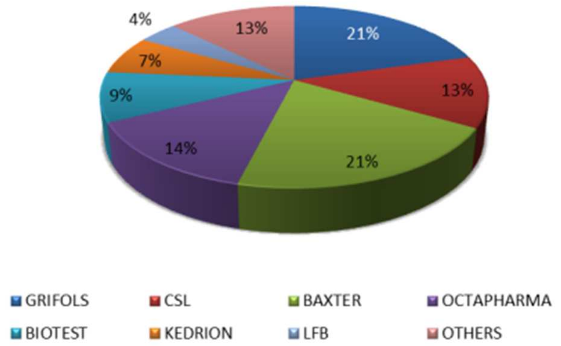
- Grifols maintains a leading position in the Alpha-1 market with 66% global share* that is increasing revenue efficiency per liter
- The global opportunity in Alpha-1 patient identification and treatment is large, making new and underdeveloped markets a core part of our growth strategy
- Our model of driving patient identification through dedicated pulmonary teams and offering disease management for Alpha-1 patients has proven successful in North America, Germany, Canada and Spain. We are expanding the strategy to new markets
- The addition of Linhaliq® for non-cystic fibrosis bronchiectasis (NCFBE) will be the first portfolio addition to take advantage of our commercial strength in the specialized pulmonary market

Source: Internal data, MRB & Secondary official data year 2014

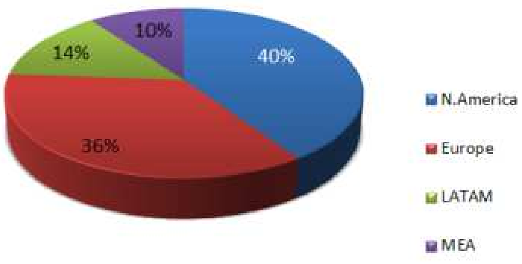
Grifols pdFactorVIII

Grifols holds leading pdFVIII position

pdFVIII global market shares[1]
(value)



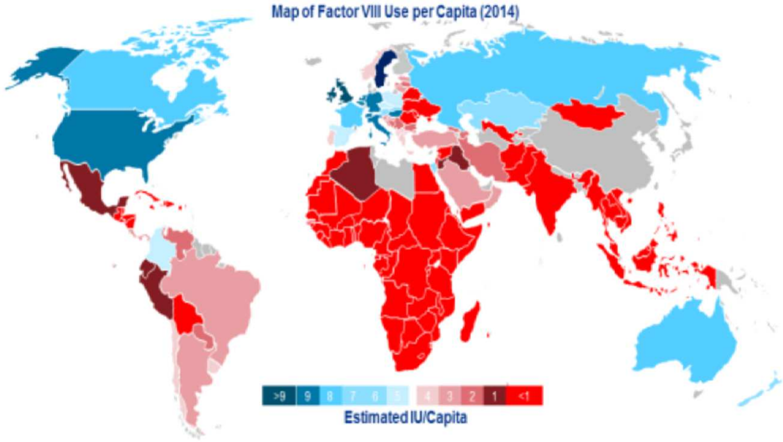
Grifols regional split[2]
(value)



[1] Source: Internal data, MRB & Secondary official data year 2014
[2] Grifols 2014 net revenues

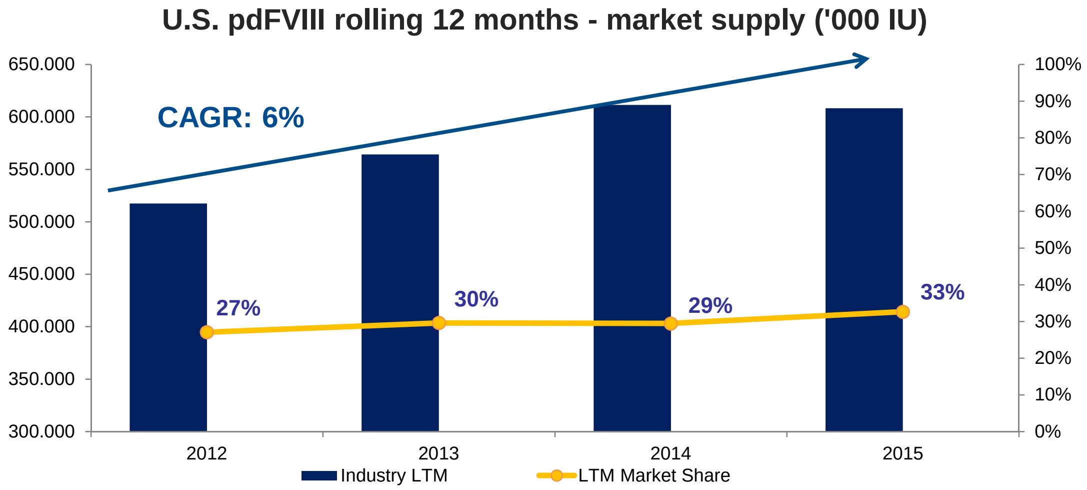
Access to treatment is still the main challenge

While main developed countries (U.S., Canada, Australia and EU) are above 5 IU/capita, access to treatment is still very far from the minimum defined by the WFH (3 IU/capita) in the rest of the world



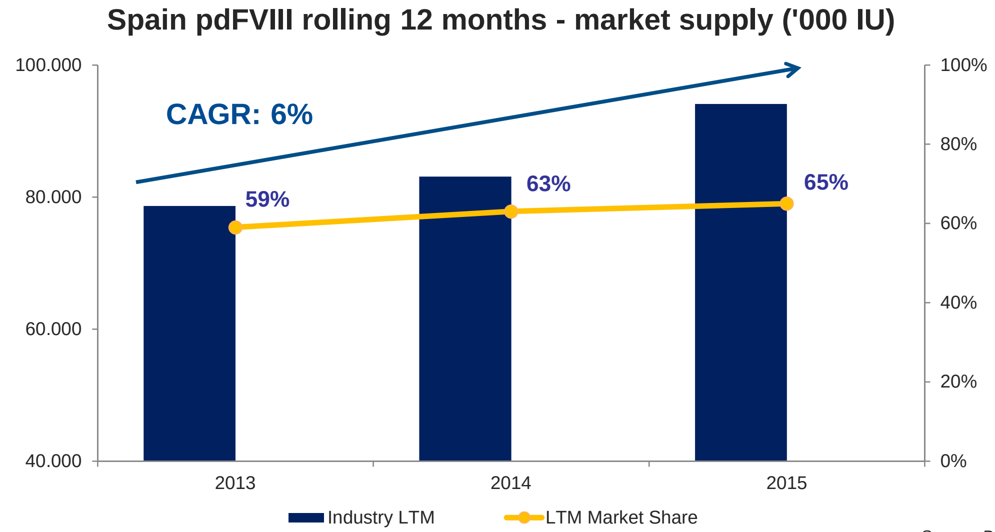
Significant Grifols' market penetration in 2015 in key emerging countries (i.e.: Russia, Indonesia, Brazil, Chile and Malaysia)

Grifols pdFVIII is growing faster than the market



Grifols market share does not include sales to Kedrion
Source: PPTA and Internal data

Leadership & continuous growth extends to other relevant markets



Source: PPTA and Internal data

Growth to continue for plasma-derived therapies - I

Key drivers of success for the commercial market
Improve brand choice in ITI treatment:

- Alphanate® is the preferred natural factor VIII among U.S. hematologists practicing in hemophilia treatment centers
  - Survey participants preferred Alphanate® over the other five available natural factor VIII products by a statistically significant margin [(p<0.05) 95% confidence interval]*
  - Alphanate® has captured the leading share of the plasma derived FVIII high volume market
- Improve Fanhdi® and Alphanate® labelling:
  - Experience labelling on ITI (extensively approved within EU, and main Latam countries and extending to more countries)
  - ITI prospective trial (Alphanate® trial)

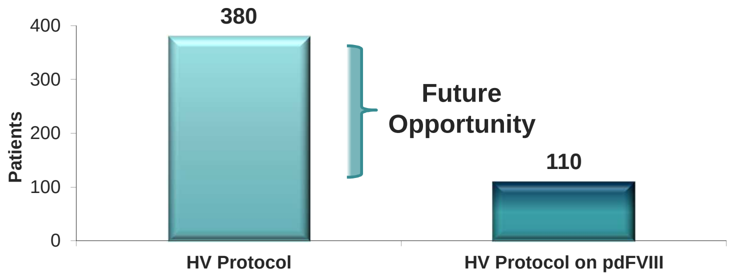
** Source: Adivo/MRB*

Growth to continue for plasma-derived therapies - II

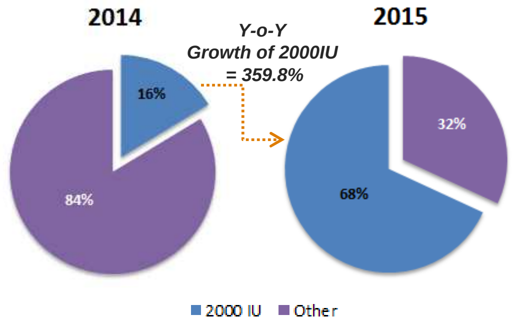
Key drivers of success for the commercial market

- Improve Fanhdi® and Alphanate® convenience:
  - High vial assays: Alphanate® 2000 IU vial
    Future projects: Higher assays, reduce the volume

Hemophilia HV U.S. patient population



Distribution of U.S. Alphanate® Sales volume by size



Source: UDC date 2011 / MRB / PPTA / Market Research

SIPPET Awareness Campaign

Inhibitorinfo.org

- Home for all content related to inhibitors and SIPPET
- The site will release breaking news regarding inhibitors e.g. SIPPET
- Four phases of content planned for 2016, so content is continually refreshed
- Partner organizations will also provide content from this site to their audience

Grifols pdFVIII summary

- Grifols maintains a leading position in the pdFVIII market with 21% global share* and volume increase above the market that keeps the FVIII as one of the key proteins to balance the liter
- Grifols pdFVIII is growing faster than the market with the dissemination of positive experiences of natural FVIII/VWF complex used to treat patients that developed inhibitors
- Alphanate® has a leadership position in the U.S. with the highest market share
- Alphanate® is the preferred natural factor VIII among hematologists practicing in hemophilia treatment centers
- Emerging countries as a relevant growth opportunity as budget allocation for healthcare resources increases


Haemophilia

ORIGINAL ARTICLE *Laboratory science*

Native plasma-derived FVIII/VWF complex has lower sensitivity to FVIII inhibitors than the combination of isolated FVIII and VWF proteins. Impact on Bethesda assay titration of FVIII inhibitors

Source: Internal data, MRB & Secondary official data year 2014

Bioscience Takeaways

Bioscience - Takeaways

- Significant growth opportunities remain for key proteins
- Strategic focus is on market growth and geographic expansion while delivering innovation
- Grifols sustains a leading position within our core business of plasma-derived therapies, being #1 in most of the major proteins
- Grifols keeps investing in the Bioscience Division to sustain growth throughout the planning period

SIPPET study. Opportunities for pdFactor VIII

Maria Salvat

What do inhibitors mean for Hemophilia A patients?

Patients with inhibitors go from being controlled with regular treatment to being uncontrolled and at risk of significant bleeding complications

- **Impact on patient's morbidity:**
  - Inhibitors double the likelihood a patient will be hospitalized for a bleeding complication[1]
- **Economic impact**
  - Inhibitors multiply the cost of treatment and hospital care by 2 to 10 times[1]
  - Inhibitors have a lifetime cost estimate of USD 19-40 million[2]
- **Impact on mortality:**
  - Inhibitors increase the odds of death by 70% compared to patients without an inhibitor in severe hemophilia A[3]

1. Soucie JM, et al. Haemophilia 2014; 20 (2): 230-237
2. Earnshaw; Haemophilia (2015), 21, 310-319
3. Walsh et al; Am. J. Hematol. 90:400–405, 2015

The risk for inhibitor development in hemophilia A is significant

- All patients with hemophilia A are at risk of developing inhibitors, regardless of age and disease severity[4]
- 25% of patients who develop inhibitors will have them for life[5]

It's estimated that

UP TO 35% OF PATIENTS

with hemophilia A can develop inhibitors, usually during infancy or early childhood[6]

4. Soucie JM, et al. Haemophilia 2014; 20 (2): 230-237
5. Valentino LA, et al; Haemophilia 2015:1-9. doi: 10.1117hae.12730
6. Oldengurg J, et al. Haematologica 2015; 100(2):149-156

Development of inhibitors is currently the major complication

- **EMA:** "In hemophilia A patients, replacement therapy with factor VIII products has become state-of-the-art. However, a serious complication in the treatment of hemophilia A is the development of neutralizing antibodies against FVIII, causing therapy resistance and increased risk of bleeding"[7]
- **FDA (Dr. Jay Epstein):** "Today, with HIV and other viral contaminants under control, inhibitor formation presents itself as the chief adverse event associated with the use of antihemophilic factor"[8]
- **MASAC:** "Inhibitor development is the single most important complication of clotting factor usage, especially in patients with hemophilia A"[9]

7. Reflection paper on Immune Tolerance Induction in HA patients with inhibitors. 21 March 2013, EMA/CHMP/BPWP/153137/2011
8. Introductory remarks. FDA workshop on Factor VIII inhibitors, transcript, page 7; Bethesda, November 21st, 2003
9. MASAC Recommendation #216, May 10, 2013

Risk factors for inhibitor development are well defined

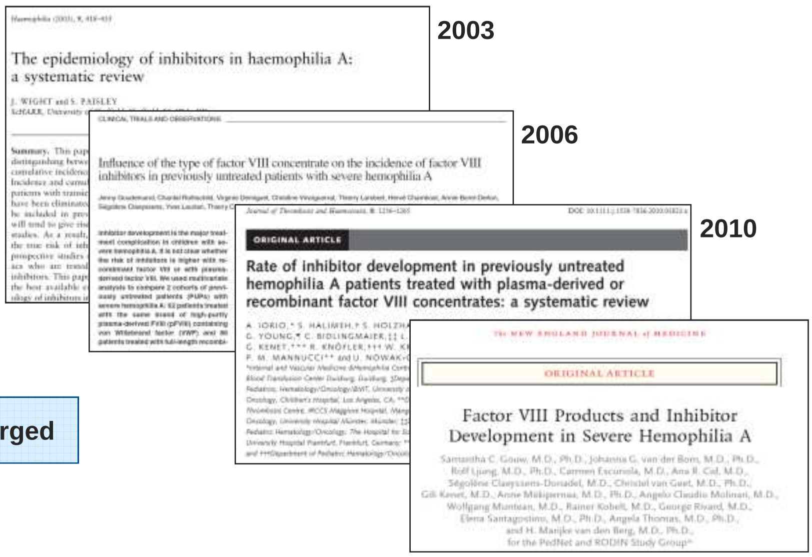
Genetic factors[10]	Environmental factors[10]
Severity of hemophilia	Intensive FVIII treatment
Large mutations of the FVIII gene	Immunologic/ inflammatory / infectious events
Family history of inhibitor	Early exposure to FVIII treatment
Ethnicity	Type of FVIII used
Unmodifiable	Modifiable

Still considered somewhat controversial

10. Peyvandi F et al; *Lancet* 2016 doi.org/10.1016/S0140-6736(15)01123-X

Immunogenicity of rFVIII vs pdFVIII a long and passionate debate

- National registries
- Retrospective studies
- Reviews / Meta-analyses
- Observational studies



2003

2006

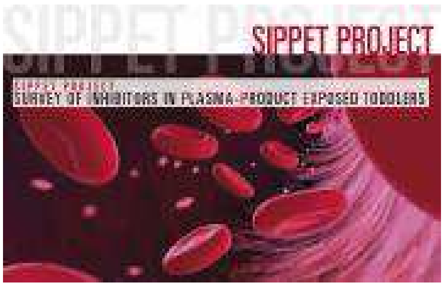
2010

2013

No conclusive evidence emerged

SIPPET study: evaluating inhibitor development

- Goal: to investigate if FVIII source (plasma-derived FVIII containing VWF or recombinant FVIII) affects the rate of inhibitor development in PUPs* with severe hemophilia A (a product class study)
- Study sponsored by the Angelo Bianchi Bonomi Foundation (Milan, Italy)
- Financial support from Italian Ministry of Health and unrestricted grants from Grifols, Kedrion and LFB



* PUPs: Previously untreated patients

Published in the New England Journal of Medicine, May 26th 2016


The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

A Randomized Trial of Factor VIII and Neutralizing Antibodies in Hemophilia A

F. Peyvandi, P.M. Mannucci, I. Garagiola, A. El-Beshlawy, M. Elalfy, V. Ramanan, P. Eshghi, S. Hanagavadi, R. Varadarajan, M. Karimi, M.V. Manglani, C. Ross, G. Young, T. Seth, S. Apte, D.M. Nayak, E. Santagostino, M.E. Mancuso, A.C. Sandoval Gonzalez, J.N. Mahlangu, S. Bonanad Boix, M. Cerqueira, N.P. Ewing, C. Male, T. Owaidah, V. Soto Arellano, N.L. Kobrinsky, S. Majumdar, R. Perez Garrido, A. Sachdeva, M. Simpson, M. Thomas, E. Zanon, B. Antmen, K. Kavakli, M.J. Manco-Johnson, M. Martinez, E. Marzouka, M.G. Mazzucconi, D. Neme, A. Palomo Bravo, R. Paredes Aguilera, A. Prezotti, K. Schmitt, B.M. Wicklund, B. Zulfikar, and F.R. Rosendaal

Peyvandi F *et al. N Engl J Med 2016;374:2054-64*

SIPPET study, the only randomized clinical trial

- **Design:** An investigator-initiated, multicenter, randomized open-label clinical trial in previously untreated or minimally treated patients with severe hemophilia A

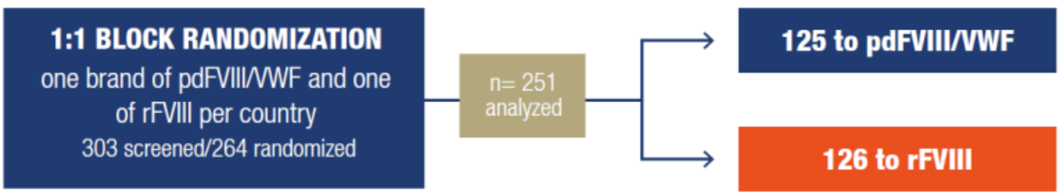
14 countries | **42 Sites** | **303 patients screened**

- **Eligibility criteria:**
  - Male sex
  - Age ≤ 6 years
  - Severe hemophilia A (FVIII:C<1 IU/dl)
  - Previously untreated with any FVIII concentrate, not or minimally treated (<5 times) with blood components*
  - No treatment with investigational drugs and negative for FVIII inhibitors

** whole blood, fresh frozen plasma, packed red blood cells, platelets, cryoprecipitate*

Randomization makes SIPPET unique

- **The value of randomization**:
  - Leads to two groups that are equal in all known and unknown factors
  - Minimizes confounding factors that could influence the outcome



- **Study period**: Randomized patients were followed for 50 exposures days or 3 years from randomization or until confirmed inhibitor, whichever occurred first

Patients' baseline characteristics evenly distributed

	pdFVIII (n=125)	rFVIII (n=126)
Age at first treatment (months) -Median (range) -Mean (SD)	 15.0 (0-67) 19.1±14.3	 16.0 (0-75) 21.3±16.3
	n (%)	n (%)
Family History -Hemophilia -Inhibitor	 59 (47.6) 13 (11.5)	 52 (42.6) 12 (10.1)
Null mutation	101 (86.3)	96 (82.1)
Previous Exposure	56 (44.8)	53 (42.1)
Treatment Regimen* -On Demand -Standard Prophylaxis (2-3 x/week) -Modified Prophylaxis (1 x/week)	 61 (48.8) 21 (16.8) 43 (34.3)	 56 (44.4) 19 (15.1) 51 (40.5)

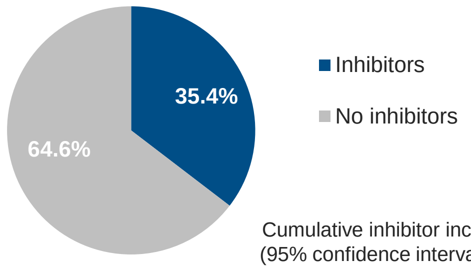
** Not considered a baseline characteristic*

Results: 35.4% cumulative incidence of all inhibitors

Primary Endpoint *:

- 76 patients developed an inhibitor
- 73% of inhibitors were persistent
- All inhibitors occurred before 39 exposure days (range 2-38)

Cumulative incidence of all inhibitors



Cumulative inhibitor incidence 35.4% (95% confidence interval 28.9-41.9%)

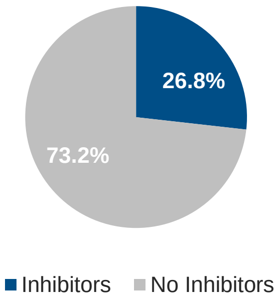
** Primary Endpoint: The development of an inhibitor 0.4 BU by Bethesda assay with the Nijmegen modification*

Nearly twice rFVIII inhibitor incidence vs pdFVIII/VWF

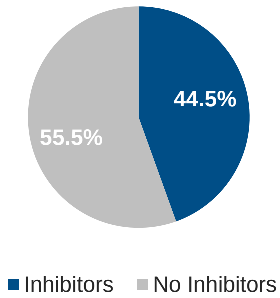
For all inhibitor formation:

The recombinant FVIII class was associated with an 87% higher incidence of inhibitors than pdFVIII containing VWF class (HR* 1.87, CI95 1.17-2.96)

pdFVIII containing VWF



Recombinant FVIII



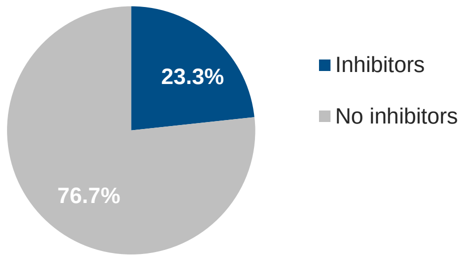
** HR: Hazard ratio*

23.3% cumulative incidence of high-titer inhibitors

Secondary Endpoint *:

- 66% (50 of 76) of inhibitors were high-titer
- 89% of high-titer inhibitors were persistent
- All high-titer inhibitors occurred before 34 exposure days (range 2-33)

Cumulative incidence of high-titer inhibitors



Cumulative high-titer inhibitor incidence 23.3% (95% confidence interval (CI95 17.6-29.0)

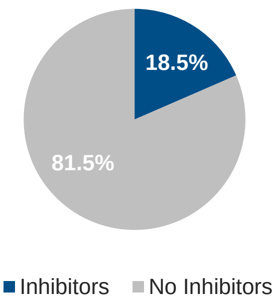
** Secondary Endpoint: High-titer inhibitors defined by peak levels ≥ 5 BU during 6 months observation*

For high-titer inhibitors the HR was 1.69

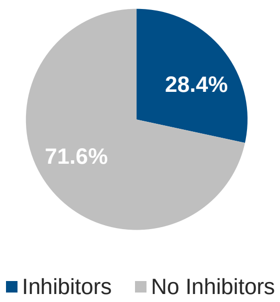
For high-titer inhibitor formation:

The rate was 69% increased for recombinant FVIII (HR* 1.69, CI95 0.96-2.98)

pdFVIII containing VWF



Recombinant FVIII



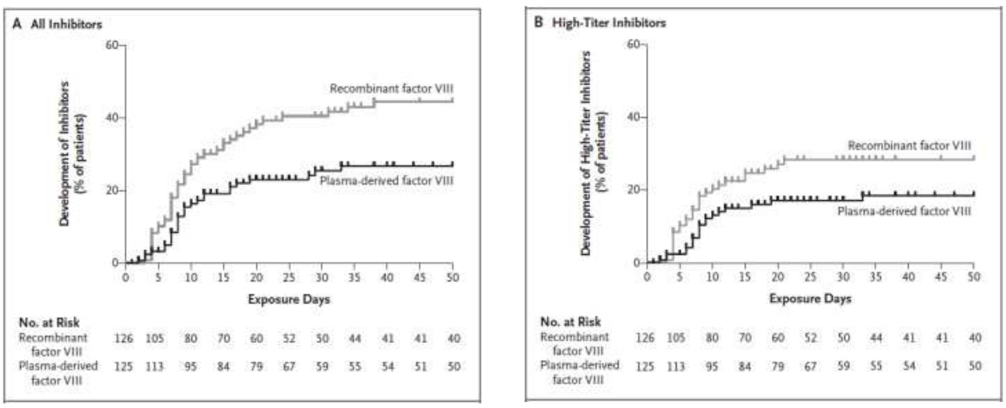
A similarly increased hazard ratio (1.69) with a slightly wider confidence interval was observed

This estimate was not significant by conventional standards, probably owing to a small sample size

** HR: Hazard ratio*

Inhibitor formation difference was evident before 5 Exposure Days

Cumulative incidence of inhibitors according to treatment group



Shown are Kaplan–Meier curves of inhibitor development for all inhibitors (≥0.4 Bethesda units; Panel A) and high-titer inhibitors (≥5 Bethesda units; Panel B). The curves depict the cumulative incidence of inhibitor development over time, which is counted as exposure days. Patients who did not complete 50 exposure days before trial termination are indicated by tick marks

No change results after confounding factors adjustment

Adjusted hazard ratios for rFVIII vs pdFVIII for all inhibitors

Adjustment variable	Hazard ratio (95% confidence interval)
None	1.87 (1.17-2.96)
Age	1.88 (1.18-2.99)
Mutation	1.97 (1.22-3.17)
Country	
5 categories	1.89 (1.19-3.00)
14 categories	1.88 (1.17-3.01)
Ethnicity	1.87 (1.18-2.97)
Family history of hemophilia	1.82 (1.14-2.89)
Family history of inhibitor	1.66 (1.03-2.67)
Previous exposure blood components	1.86 (1.17-2.95)
Treatment regimen	1.82 (1.15-2.90)
Treatment intensity	1.87 (1.17-2.97)
Surgery	1.80 (1.13-2.86)

In analyses including putative confounding variables, hazard ratios did not deviate materially from the unadjusted hazard ratio

Countries showed no deviations from overall estimate

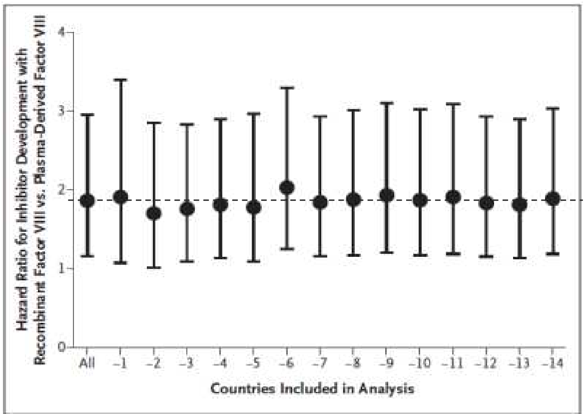


Figure 3. Sensitivity Analyses for Inhibitor Development with Recombinant Factor VIII, as Compared with Plasma-Derived Factor VIII.
In each subsequent analysis, 1 of the 14 countries (numbered 1 to 14) was left out of the analysis, which every time included the other 13 countries. I bars represent 95% confidence intervals.

To assess whether the overall results could have been derived from one specific country, sensitivity analysis was performed showing no deviations from the overall estimate

SIPPET study results - Conclusions

"The finding that native factor VIII products from human plasma are less immunogenic… has the potential to affect treatment strategies"

A sample of SIPPET reactions since the first presentation at 57th ASH Meeting (December 6, 2015)

SIPPET study results reactions

SIPPET study widely discussed in scientific congresses

SIPPET study results reactions

Raising expectation on complete results and in some cases calling for action

Main patients organizations (WFH, EHC, HFA, NHF…) and PPTA **posted news** on their website helping spread the message to all hemophilia community

http://www.hemophiliafed.org/news-stories/2015/12/update-2-sippet-study-2/
https://www.hemophilia.org/Newsroom/Medical-News/SIPPET-Study-Results-Published-in-NEJM
http://www.wfh.org/en/page.aspx?pid=769
http://www.pptaglobal.org/regions/north-america/28-news/ppta-news/964-new-study-shows-increased-development-of-inhibitors-using-recombinant-factor-viii
http://www.ehc.eu/sippet-study-conference-abstact-published/

SIPPET study results reactions

Raising expectation on complete results and in some cases calling for action

Association of Hemophilia Clinic Directors of Canada

- HFA encourage **patients to talk with doctors about the SIPPET study**
- Manuel Carcao on behalf of the inhibitor committee of the AHCDC
  - **Canadian hemophilia treaters should take into consideration the SIPPET results**
  - Given SIPPET data**, pdFVIII products should be presented to patients and families as an option for the treatment of PUP's**
  - It remains the decision of individual clinics and families in this regards

SIPPET study results reactions

Raising expectation on complete results and in some cases calling for action

NATIONAL HEMOPHILIA FOUNDATION
for all bleeding disorders

The **National Hemophilia Foundation's Medical and Scientific Advisory Council (MASAC)** will be reviewing the full study, making a thorough assessment of these findings and best determine what changes may be needed to the current MASAC recommendations for PUPS

http://www.hemophiliafed.org/news-stories/2015/12/update-2-sippet-study-2/
https://www.hemophilia.org/Newsroom/Medical-News/SIPPET-Study-Results-Published-in-NEJM
http://www.wfh.org/en/page.aspx?pid=769
http://www.pptaglobal.org/regions/north-america/28-news/ppta-news/964-new-study-shows-increased-development-of-inhibitors-using-recombinant-factor-viii
http://www.ehc.eu/sippet-study-conference-abstact-published /

SIPPET study results reactions

Raising expectation on complete results and in some cases calling for action


The NEW ENGLAND JOURNAL of MEDICINE

Hemophilia Therapy — Navigating Speed Bumps on the Innovation Highway

Donna M. DiMichele, MD (From the Division of Blood Diseases, National Heart, Lung, and Blood Institute, National Institutes of Health, Bethesda, MD.)

Editorial: *"These data must now be integrated globally into the multifactorial decision-making processes underlying product selection for at-risk children with severe hemophilia A"*

http://www.nejm.org/doi/full/10.1056/NEJMe1603419

SIPPET study results reactions

Raising expectation on complete results and in some cases calling for action

thebmj

Andrea Messori
HTA Unit, ESTAR Toscana
Sabrina Trippoli, Claudio Marinai
Regional Health Service
50100 Firenze

- *"**For every 10 patients who are treated with rFVIII as opposed to pdFVIII, one patient is expected to develop high-titre inhibitors**"*
- *"SIPPET findings have important clinical implications, but also the **economic consequences** deserve to be considered".*
- *"…EUR 338,770 can represent the median lifetime increase in cost per patient that can be attributed to the development of inhibitors".*
- *"… if one focuses the analysis only on the economic aspects, using recombinant Factor VIII as opposed to plasma-derived products implies an increase in the expenditure per patient of about USD 38,000 or EUR 33,877"*

http://www.bmj.com/content/350/bmj.h870/rr

SIPPET study results reactions

Raising expectation on complete results and in some cases calling for action

NEJM Journal Watch

David Green, MD, PhD (Professor of Medicine Emeritus, Division of Hematology/Oncology, Department of Medicine, Feinberg School of Medicine of Northwestern University; and associate editor, NEJM Journal Watch, Oncology and Hematology)

Comment: "*The results of this trial confirm previous smaller, less-robust studies… The rFVIII used in this trial lacked VWF; whether that explains the difference in inhibitor frequency in uncertain. Although recombinant products may pose less risk for transmission of infection, their greater propensity for inhibitor development will decrease enthusiasm for their use*"

http://www.jwatch.org/na41347/2016/05/25/inhibitor-development-hemophilia

SIPPET study results reactions

Challenging view


EDITORIAL

The SIPPET study: what impact will it have on haemophilia care?

Cedric Hermans (Head Division of Haematology Haemostasis and Thrombosis Unit, Haemophilia Clinic, St-Luc University Hospital Belgium. President of EAHAD)

*"**Adoption and use of pdFVIII** will probably be heterogeneous, showing marked variability between countries and centers and **will be influenced by several objective and subjective factors** such as acceptance and confidence of pdFVIII, availability and level of infectious safety of pdFVIII concentrates"*

J Haem Pract 2016; 3(1):1-3. doi: 10.17225/jhp00071

GRIFOLS

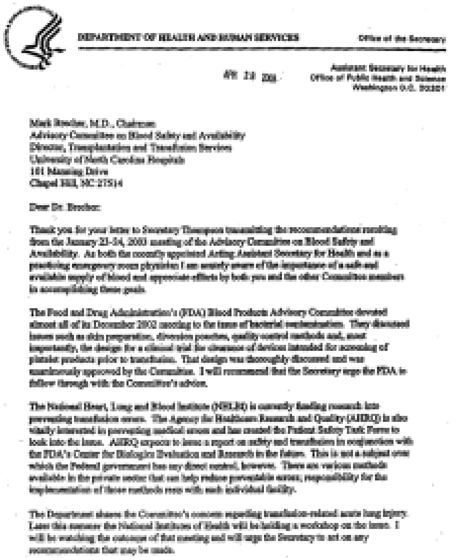
Safety and effectiveness - a regulatory perspective

- "…an evidence based review of the effectiveness of recombinant factor versus native or monoclonal factor . . . found no studies that showed a definite advantage of one over the other."

  (Surgeon General Letter Regarding Hemophilia Products, 2003)

- FDA (Dr. N. Jain): "FDA actually considers the plasma derived products to be safe and effective at the present time"

  (2013 HDDS FDA CBER Workshop on FVIII inhibitors. Page 186)


DEPARTMENT OF HEALTH AND HUMAN SERVICES — Office of the Secretary

Assistant Secretary for Health
Office of Public Health and Science
Washington D.C. 20201

Mark Brecher, M.D., Chairman
Advisory Committee on Blood Safety and Availability
Director, Transplantation and Transfusion Services
University of North Carolina Hospitals
101 Manning Drive
Chapel Hill, NC 27514

Dear Dr. Brecher:

Thank you for your letter to Secretary Thompson transmitting the recommendations resulting from the January 23-24, 2003 meeting of the Advisory Committee on Blood Safety and Availability. As both the recently appointed Acting Assistant Secretary for Health and as a practicing emergency room physician I am acutely aware of the importance of a safe and available supply of blood and appreciate efforts by both you and the other Committee members in accomplishing these goals.

The Food and Drug Administration's (FDA) Blood Products Advisory Committee devoted almost all of its December 2002 meeting to the issue of bacterial contamination. They discussed issues such as skin preparation, diversion pouches, quality control methods and, most importantly, the design for a clinical trial for clearance of devices intended for screening of platelet products prior to transfusion. That design was thoroughly discussed and was unanimously approved by the Committee. I will recommend that the Secretary urge the FDA to follow through with the Committee's advice.

The National Heart, Lung and Blood Institute (NHLBI) is currently funding research into preventing transfusion errors. The Agency for Healthcare Research and Quality (AHRQ) is also vitally interested in preventing medical errors and has created the Patient Safety Task Force to look into the issue. AHRQ expects to issue a report on safety and transfusion in conjunction with the FDA's Center for Biologics Evaluation and Research in the future. This is not a subject over which the Federal government has any direct control, however. There are various methods available in the private sector that can help reduce preventable errors; responsibility for the implementation of these methods rests with each individual facility.

The Department shares the Committee's concern regarding transfusion-related acute lung injury. Later this summer the National Institutes of Health will be holding a workshop on the issue. I will be watching the outcome of that meeting and will urge the Secretary to act on any recommendations that may be made.

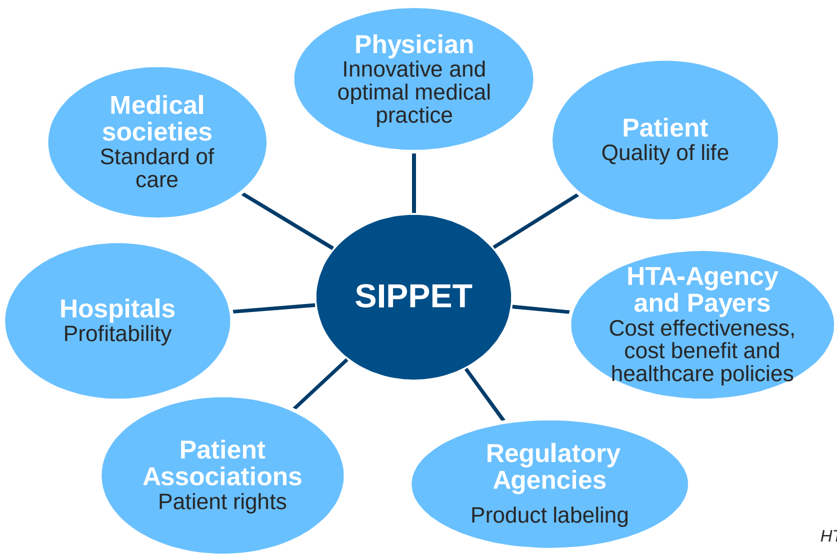
GRIFOLS

Supply of pd-therapies will not be a limitation treating PUPs

- If countries where rFVIII is the current standard of care for PUPs, a decision to change and the hypothetical increase in demand for pdFVIII/VWF will not be a challenge from Grifols' perspective
- Theoretical exercise: If all new severe PUPs in the EU, North America, and Australia were treated with pdFVIII/VWF, increased demand at year 3 would require an **additional supply of 8%** above 2014 Grifols sales*

** Assumptions:*
- *# of severe PUPs/year = 336*
- *Prophylaxis dose: 40IU/kg x 3/week*

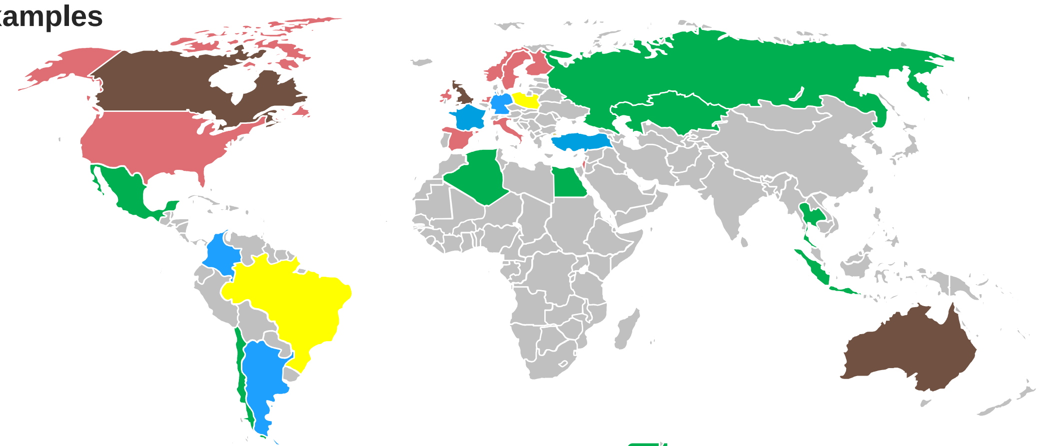
SIPPET, a global study impacting all stakeholders



HTA: Health technology agency

SIPPET, a global study for a global impact

Some examples



Guidelines recommending rFVIII for PUPs

Tender markets with guidelines recommending rFVIII for PUPs

No guidelines recommending rFVIII for PUPs

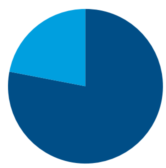
Tender market mostly/only pdFVIII

Tender market with rFVIII + pdFVIII usage

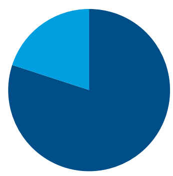
SIPPET, the evidence that empowers the future of the FVIII/VWF

- SIPPET results expected to impact current roles of different hemophilia A therapies (rFVIII and pdFVIII/VWF), however both product categories are needed to cover patients' needs
- Currently rFVIII captures ~80%* of the total FVIII market in U.S. and EU:

EU



U.S.



* PPTA data

- U.S. is Grifols fastest growing market: Today Alphanate® is number one FVIII/VWF brand for treating patients with inhibitors

SIPPET, a key study for Grifols pdFVIII/VWF - I

- Grifols has always believed in the benefits of natural pdFVIII/VWF complex
- **Several Grifols R & D investigational projects** have focused in demonstrating the benefits of the **natural pdFVIII/VWF complex** related to immunogenicity

2001

Haemophilia

Influence of von Willebrand factor on the reactivity of human factor VIII inhibitors with factor VIII

M. Gensana, C. Altisent, J. A. Aznar, F. Casaña, F. Hernández, J. I. Jorquera, M. Magallón, M. Massot, L. Puig

First published: 12 July 2001

DOI: 10.1111/j.1365-2516.2001.00526.x

2011

Haemophilia

LETTERS TO THE EDITORS

Incomplete tyrosine 1680 sulphation in recombinant FVIII concentrates

S. GRANCHA, R. NAVAJAS, C. MARAÑÓN, A. PARADELA, J. P. ALBAR, J. I. JORQUERA

First published: 7 February 2011

DOI: 10.1111/j.1365-2516.2010.02404.x

Cited by: 13 articles

2014 & 2015

Haemophilia

Native plasma-derived FVIII/VWF complex has lower sensitivity to FVIII inhibitors than the combination of isolated FVIII and VWF proteins. Impact on Bethesda assay titration of FVIII inhibitors

M. I. Bravo, B. Da Rocha-Souto, S. Grancha, J. I. Jorquera

First published: 25 August 2014

SIPPET, a key study for Grifols pdFVIII/VWF - II

- SIPPET confirms the R & D hypothesis of the VWF protective role
- SIPPET provides strong clinical evidence that product choice has implications in the management of PUPs
- SIPPET offers an opportunity to increase competitiveness and reputation of pdFVIII/VWF products

SIPPET study - Takeaways

- Development of inhibitors is currently the major complication of hemophilia A therapy
- SIPPET, the only randomized clinical trial evaluating inhibitor development
- rFVIII was associated with an 87% higher incidence of inhibitors than pdFVIII
- The results of this randomized study have implications in the choice of product for management of PUPs
- SIPPET offers an opportunity to increase competitiveness and reputation of pdFVIII/VWF products
- SIPPET confirms the promising results of our natural pdFVIII/VWF products from our investigational research
- Grifols, more than 20 years providing hemophilia therapies with the highest levels of safety

Bioscience manufacturing capacities

Víctor Grífols Deu

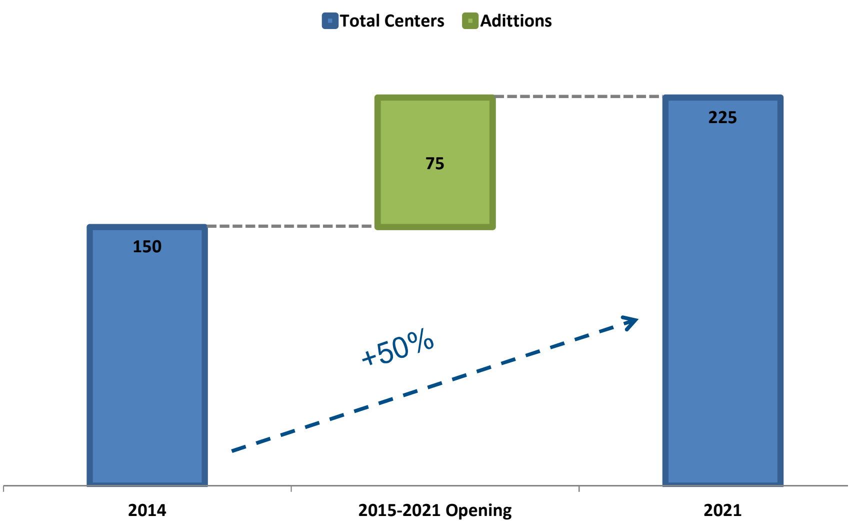
Bioscience strategic & tactic pillars

- Ensure equilibrium in **installed capacities** of plasma procurement, plasma fractionation and protein purification
- **Latent capacity** is needed to support sustained growth of the business
- Full manufacturing **flexibility** for all plasma fractions
- Balance the **plasma use** of at least “3 proteins” (1+1+1/2+1/2) in terms of sales to optimize income per liter

GRIFOLS

Plasma center opening to support Bioscience growing demand

- Beginning last year, an aggressive expansion plan to open 75 new facilities was announced, which will position Grifols to have a network of 225 donor centers in the U.S. by 2021
- Recently Grifols has acquired 49% of IBBI and has an option for the remaining 51% by 2019
- IBBI has 23 plasma donor centers, 8 blood centers and 1 laboratory



GRIFOLS

IBBI does not change the expansion plan

- Beginning last year, an aggressive expansion plan to open 75 new facilities was announced, which will position Grifols to have a network of 225 donor centers in the U.S. by 2021
- Recently Grifols has acquired 49% of IBBI and has an option for the remaining 51% by 2019
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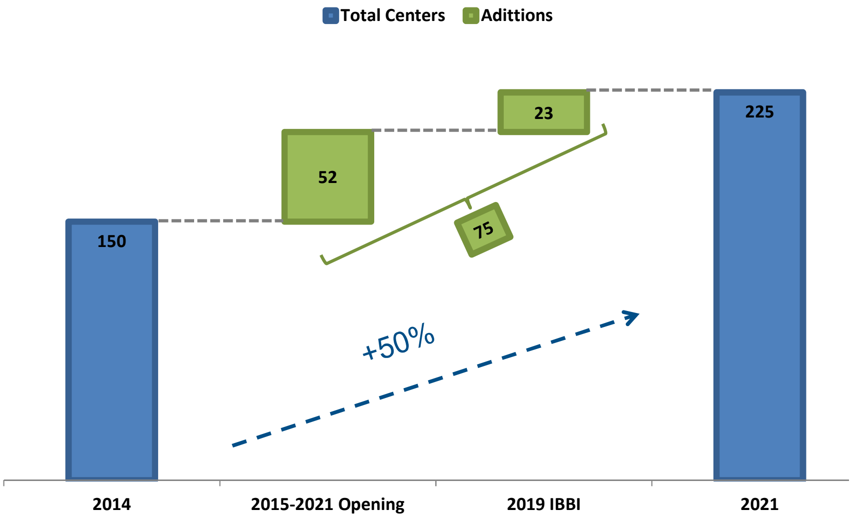
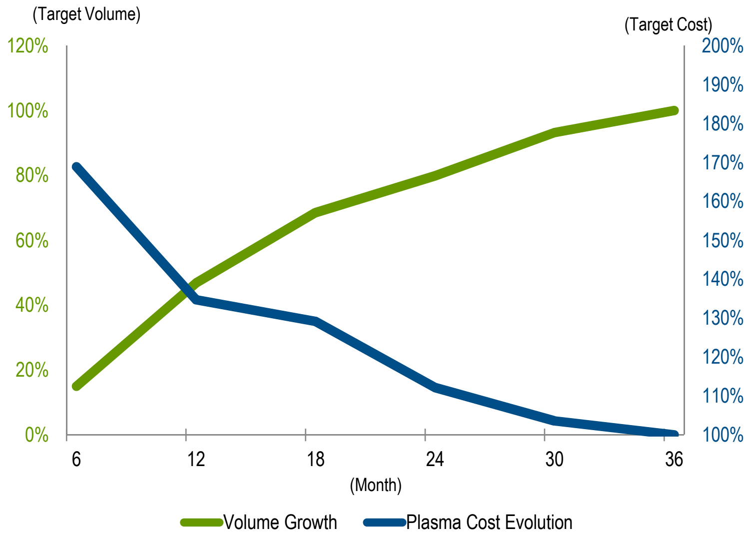


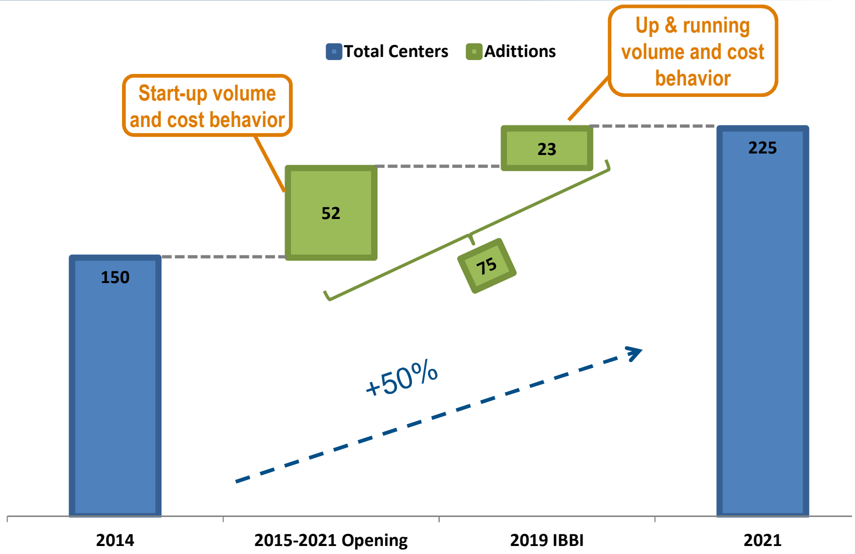
New donor center behavior in start-up mode

- Up to 1 year to obtain the FDA license.
- Need careful balancing of quality operation and collection volume increase
- Are necessary up to 3 years from a new center to achieve average collection volume and cost per liter of existing centers



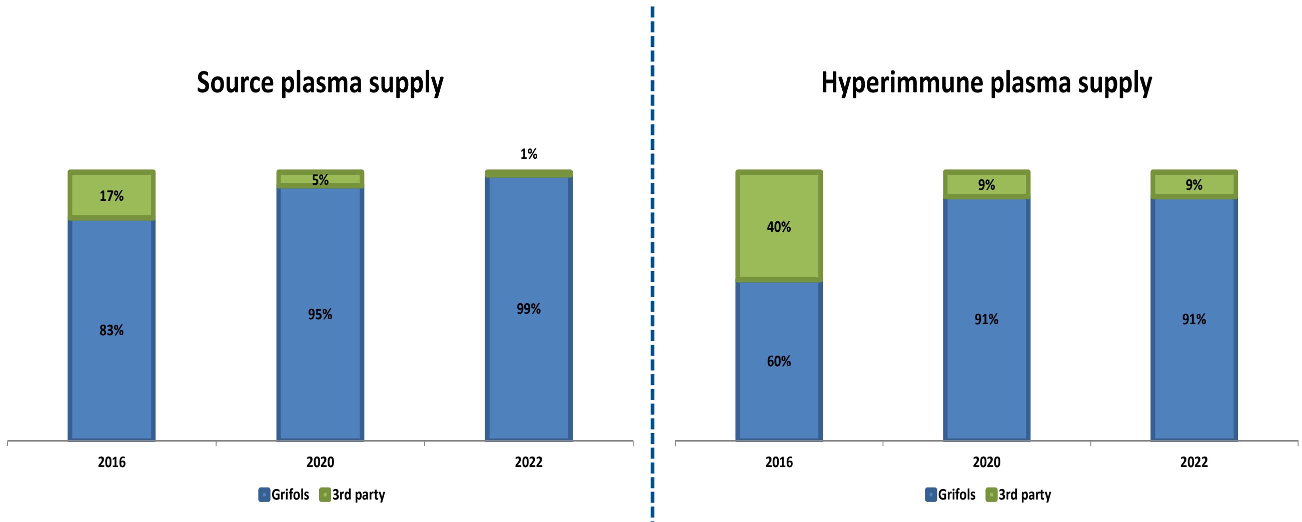
So, IBBI will convey…

- 23 plasma donor centers that grant:
  - A secured vertical integrated plasma volume
  - At the same time this volume will be at a cruise speed cost from "day 1"
- 1 donor testing laboratory
- 8 blood collection centers



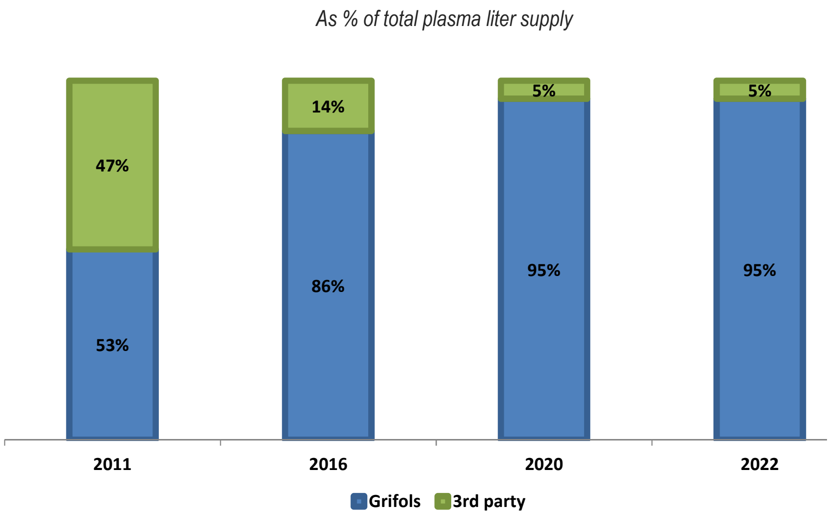
Targeting self-sufficiency for our plasma supply

As % of total plasma liter supply



Plasma testing as well towards vertical integration model

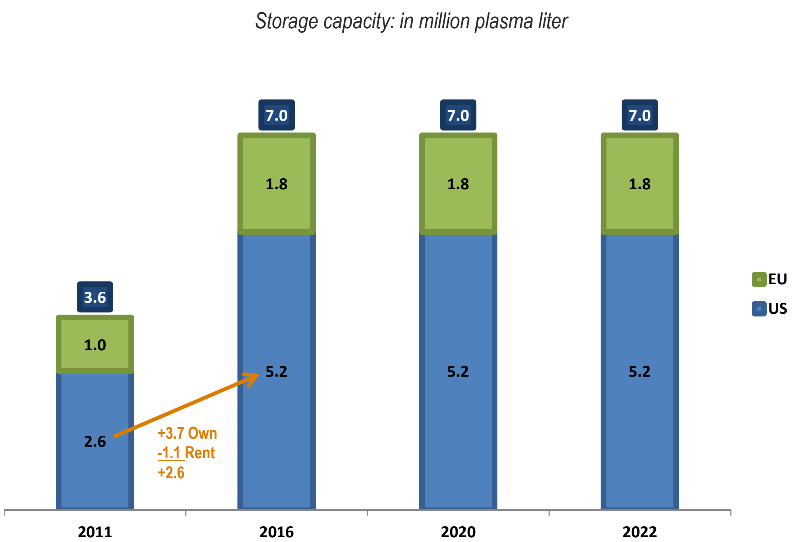
- Grifols currently has 2 laboratories in Texas:
  - San Marcos opened in 2012
  - Scheduled an expansion of Austin to be operative in 2019
- IBBI has its own laboratory in Memphis



GRIFOLS

Plasma warehousing capacity in line with expansion plan

- 2 logistics and plasma warehousing centers have been already constructed:
  - Clayton complex with a capacity for 3.7 million liters
  - Dublin complex with a capacity for 800 thousand liters
- Both facilities will be fully operational by the end of 2016



GRIFOLS

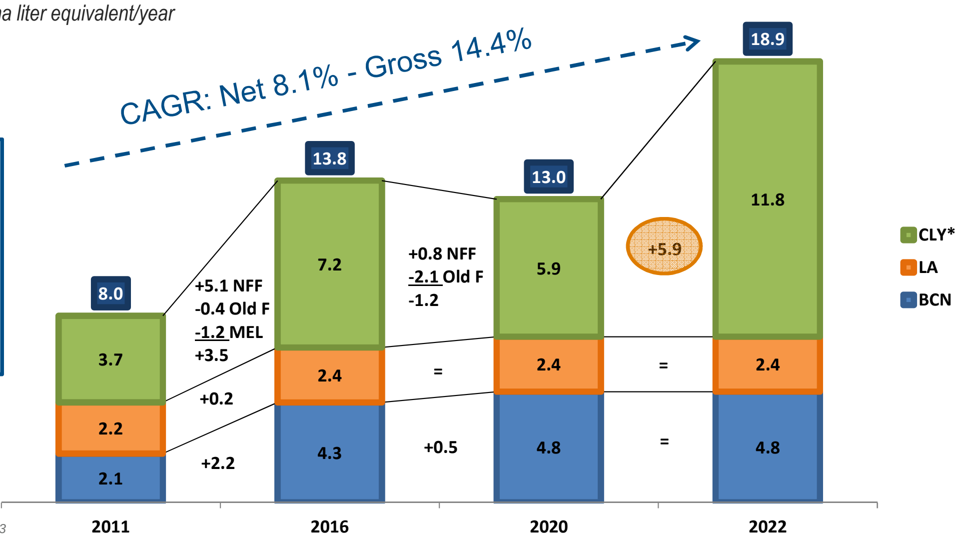
Bioscience manufacturing capacities strategic & tactic pillars

- Ensure equilibrium in **installed capacities** of plasma procurement, plasma fractionation and protein purification
- **Latent capacity** is needed to support sustained growth of the business
- Full manufacturing **flexibility** for all plasma fractions
- Balance the **plasma use** of at least “3 proteins” (1+1+1/2+1/2) in terms of sales to optimize income per liter

Fractionation capacity planned to meet growing demand

Installed capacity by sites: in million plasma liter equivalent/year

Given the long time to execute, validate and get approvals is key to decide well in advance where, when, and for how much capacity a facility is built.



** Includes Melville frac. plant transferred to Kedrion in July 2013*

New fractionation plant that will double* CLY capacity by 2022

** Not considering the Old frac.*

- Site: Clayton
- CAPEX: USD 90 million
- Timeline: From Q1 2016 through Q1 2022
- Capacity: 5.9 million liters of plasma
- Technical aspects: Will be a three floor facility (4,500m^2) containing:
  - 1st: Paste separation, cold boxes, RM & Prod. I/O, HVAC, tanks glycol pumps, electrical cabinets
  - 2nd: ABOs, reactors, gowning area
  - 3rd: RM warehouse, buffer prep., technical area

Bioscience manufacturing capacities strategic & tactic pillars

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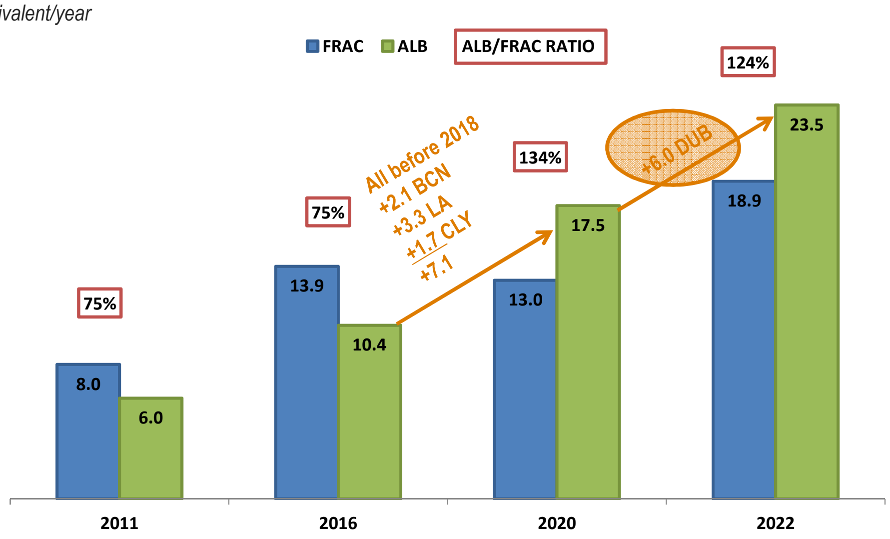
Albumin purification installed capacity leading the expansion

Installed capacity: in million plasma liter equivalent/year

Once decided the fractionation capacity expansion, simultaneously same decision is taken for protein purification



GRIFOLS

New albumin plant fully dedicated to flexible bags

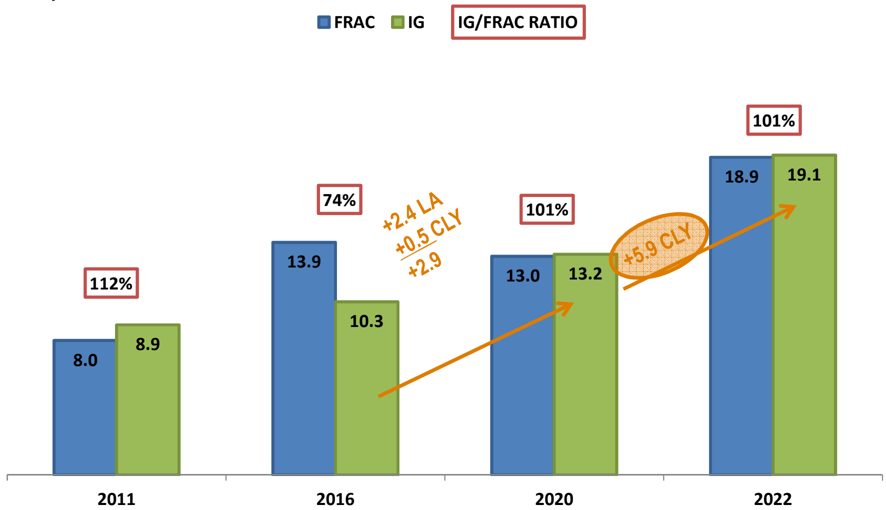
- Site: Dublin
- CAPEX: USD 85 million
- Timeline: From Q1 2016 through Q1 2021
- Capacity: 6.0 million PLE
- Format: Flexible bags
- Technical aspects: Will be a three floor facility (17,500 m^2), containing:
  - 1st : Warehouse, aseptic filling, purification and pasteurization areas, quarantine
  - 2nd: In-process control lab, gowning area
  - 3rd: QC lab, tech. area, offices, cafeteria

GRIFOLS

Immunoglobulin purif. capacity growing in line with fractionation

Installed capacity: in million plasma liter equivalent/year

Once decided the fractionation capacity expansion, simultaneously same decision is taken for protein purification



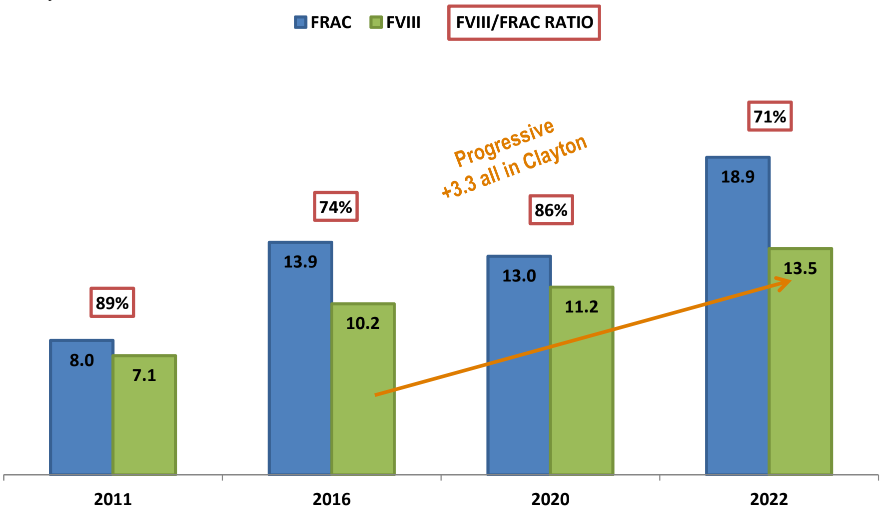
New Gamunex® plant able to process all II+III from new CLY frac.

- Site: Clayton
- CAPEX: USD 120 million
- Timeline: From Q1 2016 through Q1 2022
- Capacity: 5.9 million PLE
- Format: Vials
- Technical aspects: Will be a three floor facility, containing:
  - 1st: Liquid aseptic filling, NVC & VC
  - 2nd: Buffer prep., technical area
  - 3rd: Hyperimmunes area

Factor VIII purification capacity adequately increasing

Installed capacity: in million plasma liter equivalent/year

Once decided the fractionation capacity expansion, simultaneously same decision is taken for protein purification

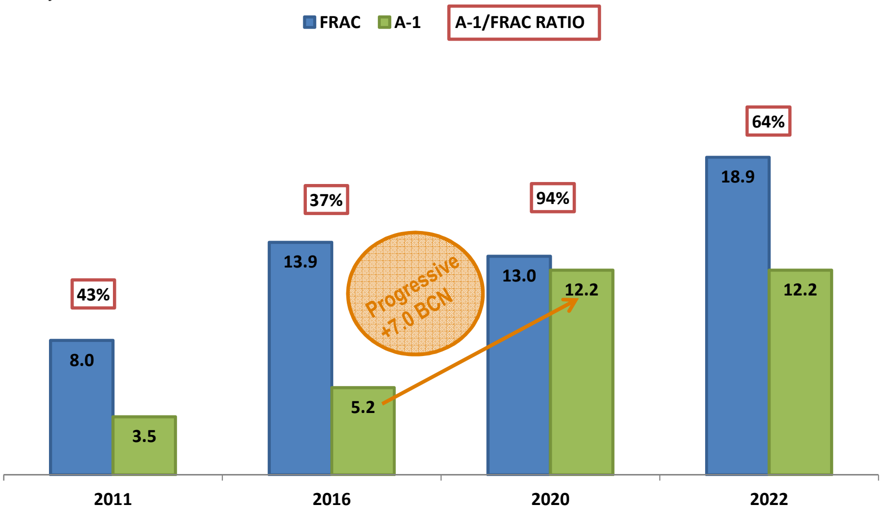


GRIFOLS

Alpha-1 purification capacity multiplied by ~2.5x in 4 years time

Installed capacity: in million plasma liter equivalent/year

Once decided the fractionation capacity expansion, simultaneously same decision is taken for protein purification



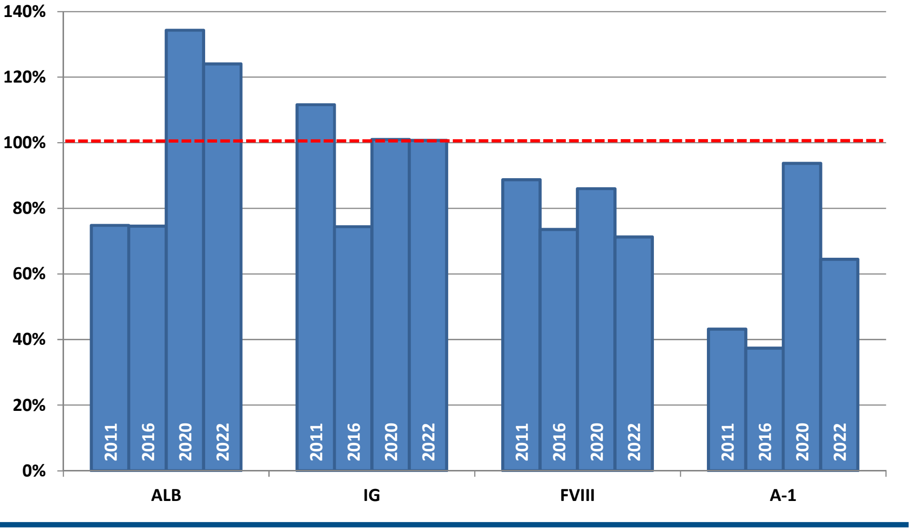
GRIFOLS

The Prolastin®-C plant in Europe

- Site: Barcelona
- CAPEX: USD 65 million
- Timeline: From Q3 2014 through Q3 2017
- Capacity: 4.3 million PLE
- Format: Vials
- Technical aspects: Will be a three floor facility (7,250 m^2), containing:
  - 1st: Aseptic processing, VC purification, vial washing, prep and nano filtration
  - 2nd: NVC purification, VC purification
  - 3rd: VC PEG buffer prep., electrical 6 tech. areas, office

Protein purification installed capacity: Aligned with fractionation

- Summary by protein
  - In red, fractionation installed capacity as target (frac./frac. ratio)
  - In blue, protein/frac. ratio



Bioscience manufacturing capacities strategic & tactic pillars

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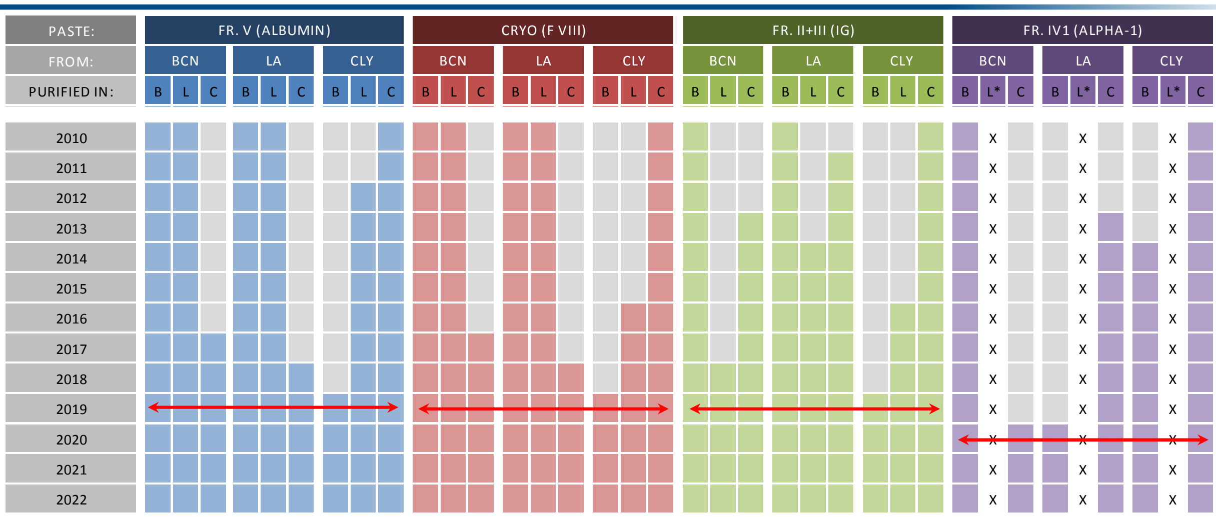
Paste cross-licensing map: Manufacturing flexibility



Licensed In process X: Not needed

Desired cross-licensing achieved

* No Alpha-1 purification facility in LA

Bioscience manufacturing capacities strategic & tactic pillars

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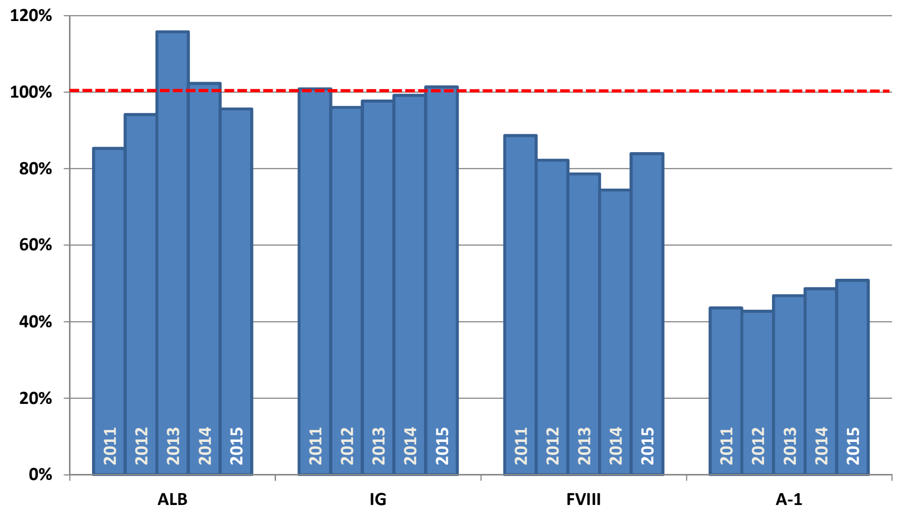
Protein sale evolution: Focus on plasma utilization balance

- Summary by protein
  - In red, actual fractionation as target (frac./frac. ratio)
  - In blue, protein/frac. Ratio

At least "3 proteins" to be sold at similar level in PLE, which will determine the level of fractionation each year



Bioscience manufacturing capacities strategic & tactic pillars

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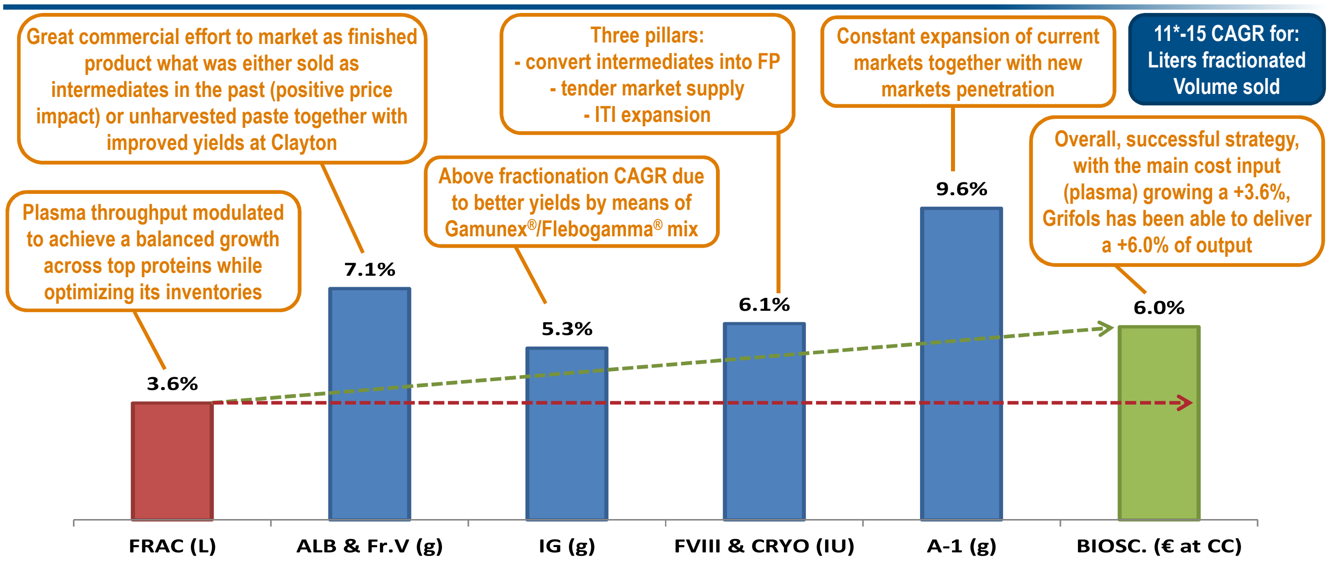
Plasma economics lever…five years later

** Proforma Jan-May data for Talecris*



Bioscience manufacturing capacities: Takeaways

- After five years of Talecris acquisition, the company has successfully operated with inventories, manufacturing capabilities (capacity-flexibility) and commercial strategies in order to deliver more output than input
- Grifols continues to strengthen its capacity leadership with a new industrial investment wave in place until 2022 for plasma procurement-fractionation-purification expansions, that will ensure our ability to meet the demand of plasma derived products until 2028-2030
- All these investments, as usual, are designed and executed by Grifols Engineering. Its wealth of experience gives Grifols a clear competitive advantage, in execution and approval time, investment cost, running cost and Grifols unique manufacturing processes
- The goal is to continue delivering a sustainable and profitable growth based on plasma utilization balance

Hospital Division

Peter Allen

Hospital Division legacy is basis for U.S. expansion

- Grifols strong legacy business in Spain
- Grifols poised for penetration in U.S. market
- Opportunistic expansion in ROW/LATAM
- Hospital Division is strategic to Bioscience business
- Methodical pursuit of a successful strategy

Grifols maintains a strong position and reputation in Spain

Strong Legacy Business - Spain

- Broad portfolio:
  - IV therapy base
  - Medical device
  - Pharmatech
  - Clinical nutrition
- Advanced Hospital pharmacies
- Good “backyard” customer base; learning, trialing
- Manufacturing and engineering advantages

Grifols poised for penetration in U.S. market

The U.S. market drivers align with Grifols strengths

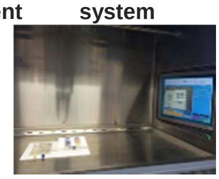
- Novel Pharmatech portfolio - alignment of trends
  - Regulatory specific
  - Personalized medicine individualized
  - Accountability care organization outcomes

  automation, process and compliance
- Opportunity for end to end compounding portfolio: control, efficiency, data

Compliant sterile cleanrooms

Secure high density inventory management

IV workflow management system



Gri-Fill sterile compounder

Kiro® Oncology

Sterile disposables

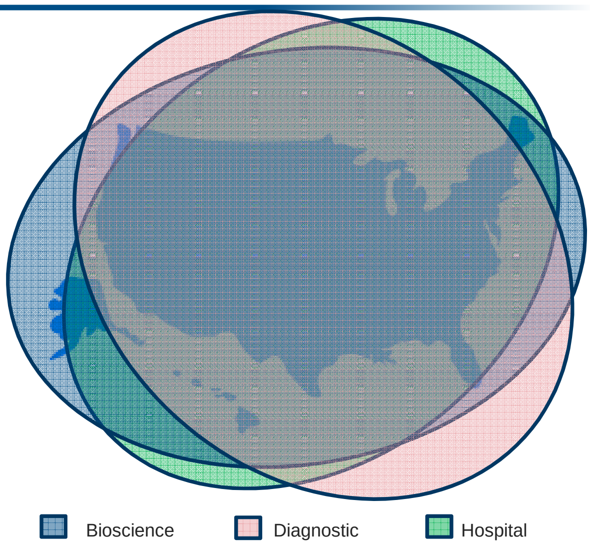
Robust Oncology technology is first product of Kiro® platform

The U.S. market drivers align with Grifols strengths

Grifols poised for penetration in U.S. market

- Leverage Bioscience and Diagnostic brands and Grifols Engineering strength
- Capability for strategic acquisitions

Opportunistic expansion in ROW/LATAM



Hospital Div. portfolio & Grifols Engineering creates opportunities

Hospital Division is strategic to Bioscience business

Grifols technology in plastics and IV fluids and Grifols Engineering capabilities offer strategic value to our Bioscience business

- New flexible container for biological products
  - Product differentiation vs other competitors
  - Albumin in initial release
- Saline production advantages to Grifols plasma centers
  - Provides secured supply and cost containment
  - Opportunity to market LVP's* in the U.S.
- Diluents for Grifols Bioscience lyophilized plasma proteins
  - Provides long-term secured supply stability
  - Volume benefits

** Large Volume Parenterals*

Strategic considerations inform future U.S. focus

Methodical pursuit of a successful strategy

- Current market position
  - Spain
  - United States
  - ROW/LATAM
- Customer/Technology advising the future
- Gap assessment
- Revised strategy - emphasis in U.S. market

Hospital Division - Takeaways

- Strong legacy base
- Good portfolio, well-timed for U.S. market
- Strategic benefits to Bioscience by Grifols Engineering
- Worldwide pursuit of organic and non-organic growth opportunities

Diagnostic Division

Carsten Schroeder

We are the global leader in transfusion medicine

We are building a portfolio in Specialty Diagnostics

The Diagnostic Division is a global organization

AT-A-GLANCE

- 1,100+ full-time employees supporting Diagnostic success
- Integrated from assay/ instrumentation development through commercialization
- FDA, GMP & CE Licenses

Our mission is to…

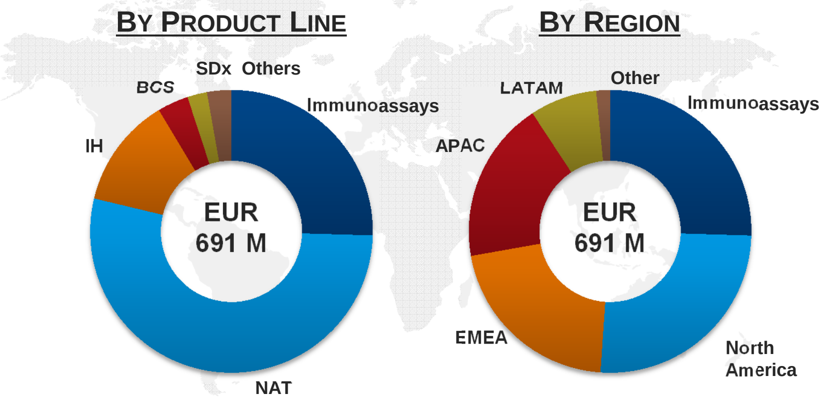
Build a global Diagnostic company focused on select, high value markets providing innovative solutions to:

- Ensure a safe blood and plasma supply
- Detect human diseases
- Monitor therapies

Diagnostic had EUR 691 M in sales in 2015

NAT, Immunoassays and Immunohematology are our core businesses

PEOPLE	160 sales and 50 marketing people globally
DIRECT vs. DISTRIBUTORS	Sales in +85 countries of which 30 direct
2015 SALES	Well-balanced geographically

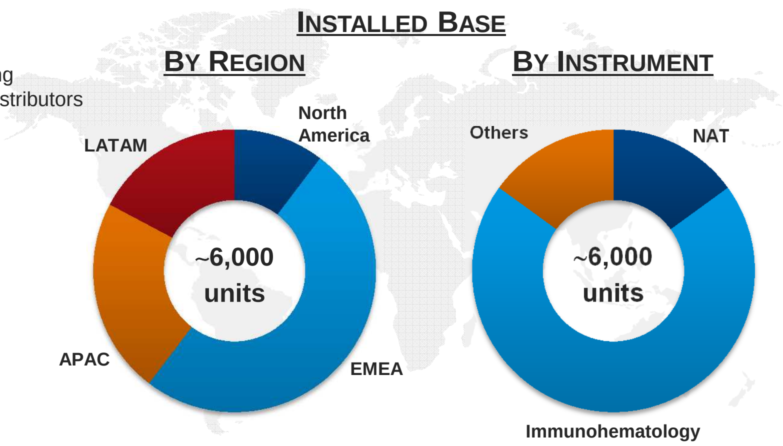


* NAT = Nucleic Acid Testing; Immunoassays = Antigens + Joint Business; IH = Immunohematology; BCS = Blood Collection Systems; SDx = Specialty Diagnostics; Others = Hemostasis, Pathogen Inactivation, Blood Group Genotyping and Special Revenue

Service is a differentiating factor in our go to market strategy

We have an installed base of ~6,000 instruments worldwide

PEOPLE	+250 Global service & Training associates support to +110 distributors
GLOBAL SERVICE	Global presence +85 countries - 30 direct
FUTURE PROJECTS	ServiceMax software rollout worldwide

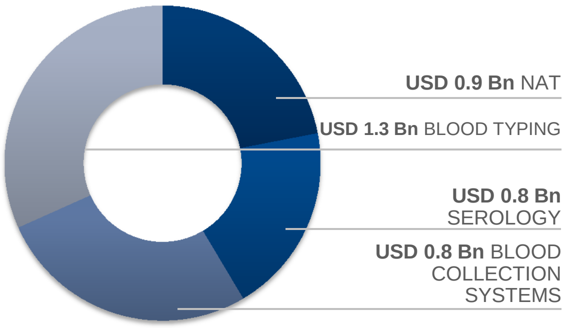


Transfusion Medicine represents 95% of our revenues

We serve blood banks, hospital based transfusion services and plasma fractionators

Transfusion Medicine*

USD ~4 billion market potential



* Does not include plasma collection
Source: 2014 Markets reports

NAT	Grifols is global leader in NAT with 55% market share in adopted markets ▪ 79% in U.S. and 68% in APAC ▪ Approx. 24 % market remains un-adopted
Blood Typing	9% market share globally, growing double-digit ▪ Growing in the U.S. ▪ Strong position in China, Mexico, France & Spain
Serology	Our HCV/HIV antigens are present in 50-80% of immunoassays of Abbott, Siemens and OCD depending on segment & geography
Blood Collection Systems	Strong position in LATAM and Spain

Two key long-term partnerships in NAT and Immunoassays

Immunohematology is a vertically integrated business

NAT - Donor Screening

Revenue share agreement (until 2025)

GRIFOLS
- HCV & HIV patents
- Product commercialization, technical service, support & training
- Regulatory activities outside of U.S.

HOLOGIC®
- Product development & manufacturing
- Technology (TMA) patent
- Regulatory activities in the U.S.

Immunoassays

Profit share agreement (until 2039)

GRIFOLS
- HCV & HIV patents
- Antigen research, manufacturing & supply
- Assay research support

Ortho Clinical Diagnostics
- Assay development & manufacturing
- Instrument development & manufacturing
- Product commercialization

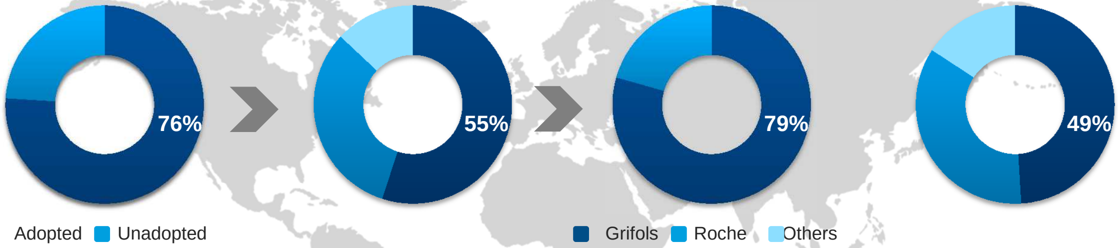
Immunohematology

Vertically integrated business. We are wholly responsible for development, manufacturing (instruments, assays, red blood cells and antisera), sales and service

We are the global leader in NAT Blood Donor Screening

Despite market challenge, there is significant long-term growth potential

GLOBAL MARKET SPLIT (~88 M DONATIONS)* | **GLOBAL SHARE OF ADOPTED (~67 M DONATIONS)** | **UNITED STATES (~13.5 M DONATIONS)** | **REST OF THE WORLD (~53.5 M DONATIONS)**



Future growth drivers
- Geographic expansion into non-adopted countries
- Plasma fractionators (in addition to Grifols) will be addressed with new Procleix Ultrio Elite & Panther in large pool sizes
- Emerging pathogens: Zika & Babesia

Market challenges
- Declining number of blood donations in developed countries due to blood management programs

** Does not include plasma donation*
Source: Q4 2015 Internal Data

Complete portfolio of NAT Instruments and Assays

We are working to develop new assays for emerging pathogens

Procleix NAT Solutions
By Hologic and Grifols

Our Procleix assay menu includes:
- Procleix Ultrio
- Procleix Ultrio Plus
- Procleix Ultrio Elite
- Procleix WNV
- Procleix HEV
- Procleix Parvo/HAV
- Procleix Dengue Virus

Not all assay are available in all territories

IND* in preparation for:
- Procleix Zika Virus
- Procleix Babesia

** IND = Investigational New Device*

Automation will strengthen our NAT portfolio

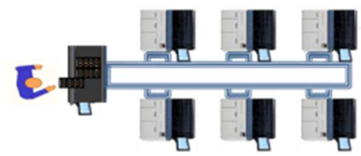
Next Generation Middleware will help to simplify laboratory workflow

Procleix Panther AR
- AR = Automation Ready
- Networks analyzers, to think and act as one analyzer with operational dashboard, ability to connect to standardized laboratory track systems

Procleix Panther AR Workcell
- Customized track system that routes samples tubes for testing to multiple Panther systems with minimal human interaction

Next Generation Middleware
- Modular, flexible middleware to enhance laboratory operational efficiency

Panther AR Track Compatible



Panther AR Workcell

Networked Panther AR, with Dashboard Display

World wide market leader in hep/retro immunoassays

Opportunities to expand customer base and product portfolio

We supply HCV and HIV antigens to the top 3 immunoassay players

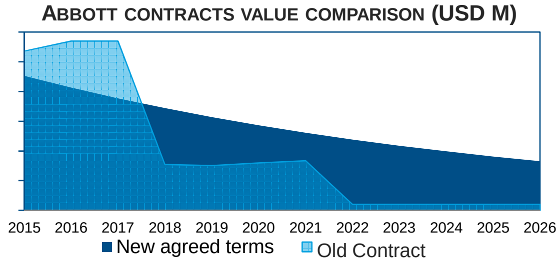
Ortho Clinical Diagnostics

SIEMENS Abbott A Promise for Life

Future growth drivers
- New HIV Combo for OCD's VITROS platform
- Expand customer base for antigens
- Expand portfolio of antigens

Abbott new contract extension provides long-term benefits:
- Total contract value USD 700 M
- Extend contract to 2026, increasing NPV by USD 200 M

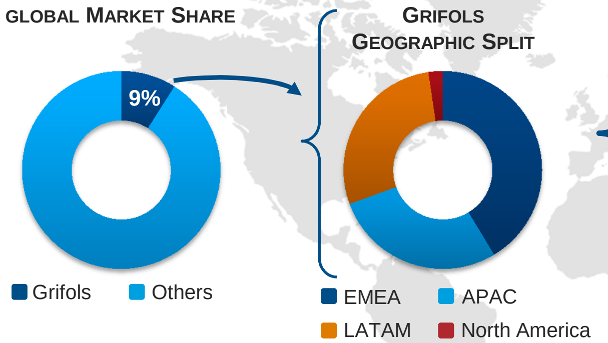
ABBOTT CONTRACTS VALUE COMPARISON (USD M)

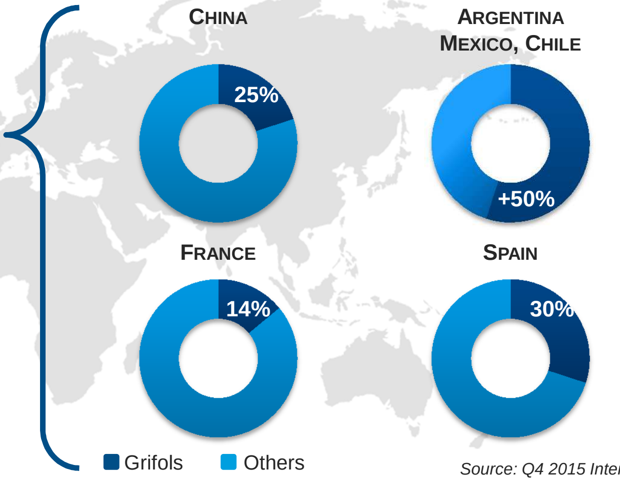


USD 30 million cost reduction in annual manufacturing cost prior to project Horizon
Further savings expected upon completion

Immunohematology is experiencing double digit growth

Penetration in the U.S. market will drive growth in the mid-term





Future growth drivers
- Complete product portfolio
- Market share gain

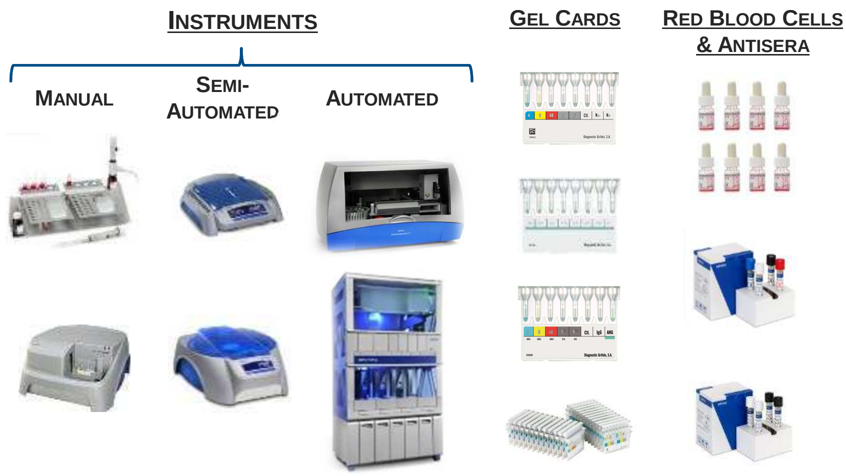
Source: Q4 2015 Internal Data

Complete portfolio of instruments, gel cards, RBC and antisera

Upcoming launch of Eflexis® will further enhance our instrument portfolio

The DGgel® product line consists in manual, semi-automated and automated instruments, gel cards, red blood cells and antisera products

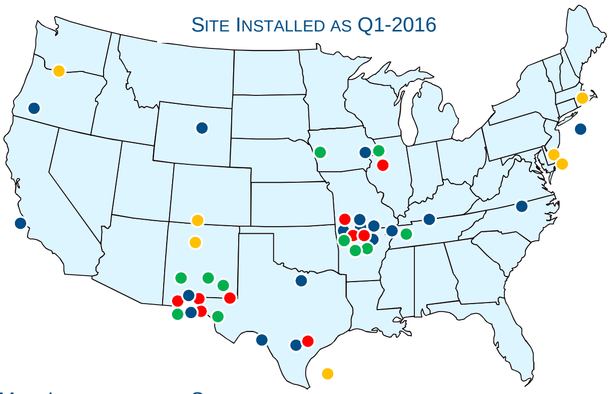
Commercial launch planned for 2017 in Europe



U.S. IH - Significant growth in just one year

Our Investments in Sales, Marketing and Service for market entry are paying off

MARKET OPPORTUNITY	North America is the largest (approx. USD 400 M) and least automated market for Blood Typing Solutions products
OUR GOAL	Our goal is to achieve a >15% market share in the mid-term
SELECTED WINS & DISTRIBUTORS PARTNERS	▪ Reference accounts • OHSU (Oregon Health & Science University), New York Presbyterian ▪ IDN (Independent Delivery Networks): • Tricore, SSM Healthcare ▪ Federal • AttainIT (Distributor) ▪ Small hospitals • McKesson (Distributor)



MAIN INSTRUMENT ON SITE:
●ERYTRA ●WADIANA ●READER ● UNDER CONTRACT (NOT INSTALLED)

Global manufacturing footprint to serve world-wide customers

New capacity being built in the U.S., Spain and Brazil

EMERYVILLE California - U.S.	Manufacture of antigens for diagnostic tests. Expansion: Project Horizon
MURCIA Spain	Production of intravenous serums in flexible packaging and blood collection systems. Under expansion
CURITIBA Brazil	New factory for production of blood collection systems
PARETS DEL VALLES Barcelona - Spain	Instruments and in-vitro diagnostic reagents for immunohematology, autoimmunity and hemostasis
DÜDINGEN Switzerland	Production of tests for the rapid identification of blood type (MDMulticard®); gel-technology test cards (DG GEL®) and Reagent RBC
MELBOURNE Australia	Production of gel-technology test cards (DG GEL®) and red blood cells
DERIO Vizcaya - Spain	Design and manufacture of molecular biology tests and immunoassays

Grifols has acquired 20% of Singulex Inc.

State-of-the-art, innovative technology is key for future growth

- **Ultra-sensitive immunoassay testing**
  - Exclusive worldwide license for Singulex's` proprietary ultra sensitive Single Molecule Counting *SMC™* technology for blood and plasma screening
  - Technology applicable to both transfusion and specialty diagnostics
  - Enable high-value assays using rare biomarkers
  - Reduces time to results for standard assays
  - Amenable to Point of Care, automated IVD, and CLIA
- **Potential areas of application include:**
  - Infectious disease
  - Neurodegenerative
  - Autoimmune
  - Transplantation
  - Oncology

Singulex®

Company Highlights

- **A private company founded in 2003**
- **HQ in the San Francisco Bay Area** *(Alameda, California)*
- **Employees: 250** *(immunoassay expertise)*

SINGULEX SMC™ TECHNOLOGY

We are strengthening our position in Specialty Diagnostics

We are building a portfolio of businesses for future growth

PROMONITOR®
- Continue to expand product portfolio, extending use to other biologics and biosimilars
- Create commercial structure to go direct in five European countries

CLIA U.S.
- Leverage existing CLIA facilities in San Marcos to expand service lab offering for drug monitoring, autoimmune and neurodegenerative diseases

HEMOSTASIS
- Great product line of instruments & reagents
- Actively evaluating global distribution model

AESKU
- Created sales force to introduce autoimmunity product line in the U.S.

PROmonitor

PROMONITOR® ELISA test offer key information about drug bioavailability and immunogenicity in patients prescribed with biological therapy for the treatment of chronic inflammatory diseases and other indications

We are strengthening our position in Specialty Diagnostics

We are building a portfolio of businesses for future growth

PROMONITOR®
- Continue to expand product portfolio, extending use to other biologics and biosimilars
- Create commercial structure to go direct in five European countries

CLIA* U.S.
- Leverage existing CLIA facilities in San Marcos to expand service lab offering for drug monitoring, autoimmune and neurodegenerative diseases

HEMOSTASIS
- Great product line of instruments & reagents
- Actively evaluating global distribution model

AESKU
- Created sales force to introduce autoimmunity product line in the U.S.

GRIFOLS CLIA LAB IS LOCATED IN SAN MARCOS (TX)

Tests currently available
- Familial Hypercholesterolemia (FH)
- Araclon AB assay for AMBAR study
- ApoE assay for Alzheimer prognosis

CLIA = Clinical Laboratory Improvement Amendments

We are strengthening our position in Specialty Diagnostics

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AESKU
- Created sales force to introduce autoimmunity product line in the U.S.

We have a scalable portfolio of hemostasis analyzers and a dedicated portfolio of coagulation reagent

We are strengthening our position in Specialty Diagnostics

We are building a portfolio of businesses for future growth

PROMONITOR®
- Continue to expand product portfolio, extending use to other biologics and biosimilars
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AESKU.GROUP
WE TAKE CARE OF YOUR HEALTH

Helios System is pending FDA approval

We are positioning the business for future growth and profitability

INTEGRATION (2014 - 2015)

TRANSITION (2016 - 2017)

GROWTH (2018 - …)

- Created a global Diagnostic Division, well-balanced geographically and with standardized and globalized management processes
- **NAT, Immunoassays** and **Immunohematology** represent the core businesses today. We invest to:
  - strengthen our current partnership with Hologic and Ortho
  - expand our commercial reach (geographies, products & customers)
  - additional global distribution network
  - increase our manufacturing capabilities
  - enhance our product portfolio to strengthen competitive edge
  - acquire new technologies (SMC™ from Singulex) with broad applicability
- Building a well diversified portfolio of businesses in Specialty Diagnostic
- Leverage leadership position in **Transfusion Medicine** to offer more products to core customer groups and acquisition of new customers (plasma fractionators)
- Grow our existing product lines in **Specialty Diagnostics**
- Explore M&A opportunities

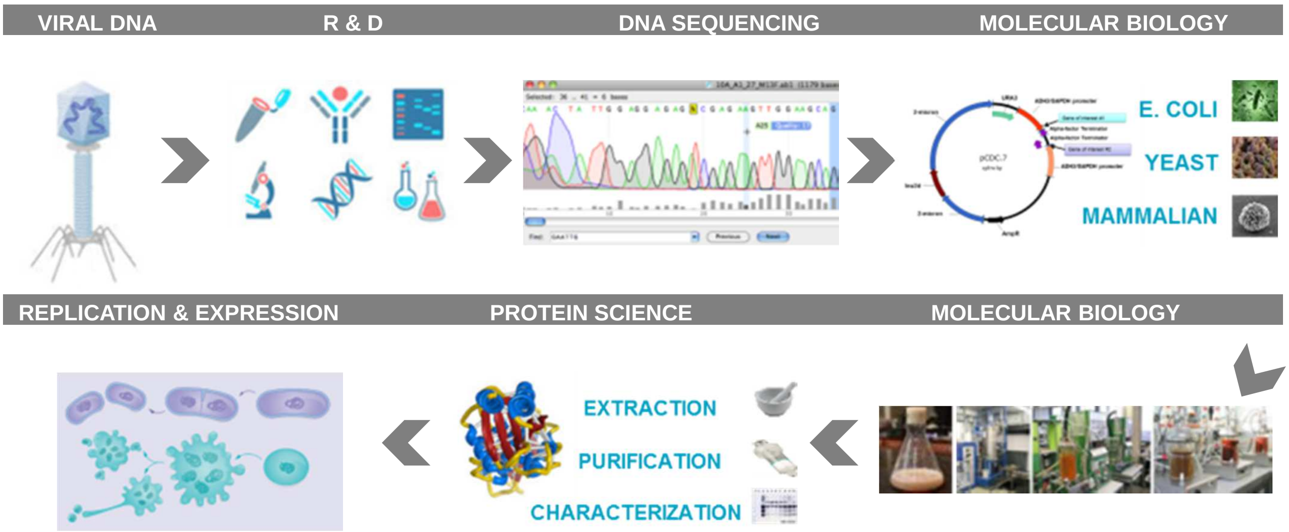
Project Horizon - Grifols Diagnostic Industrial Group Emeryville, California (U.S.)

Oriol Duñach

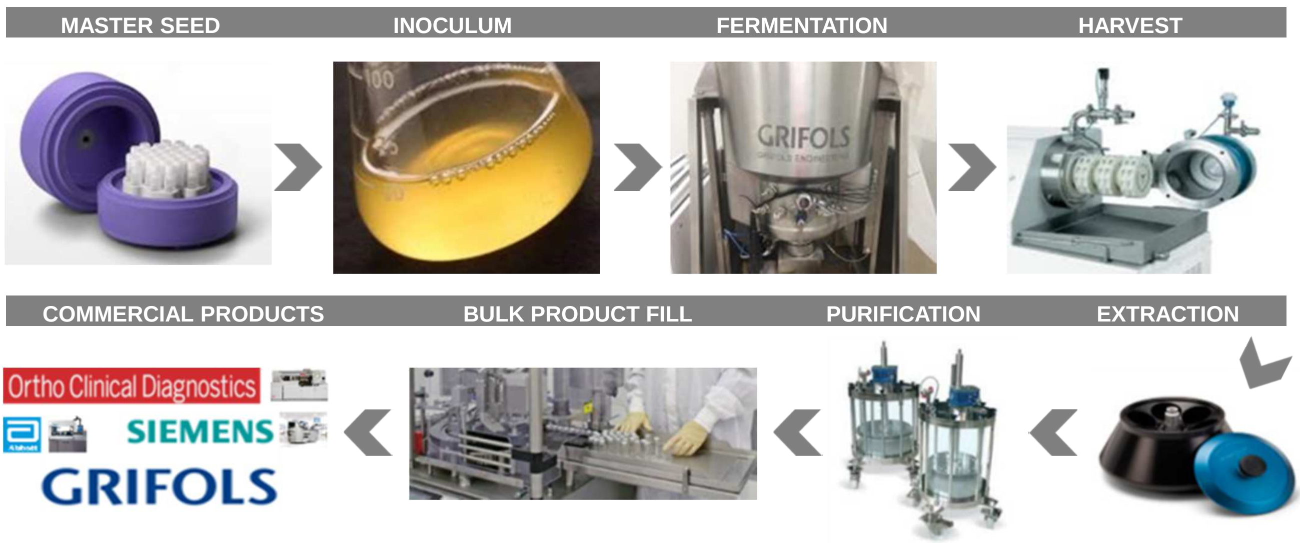
What are Recombinant Antigens (rAg's)?

- Antigen: Any substance that causes the immune system to produce antibodies against it (for instance, virus proteins)
- Recombinant antigen (rAg): Substances (proteins) produced by genetic engineering
- Used in diagnostic testing to detect the presence of antibodies (Ab) against it: rAg + corresponding Ab $\longrightarrow$ Reaction
- The presence of antibodies evidences that the patient has been in contact with the virus

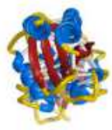
Antigen manufacturing process: seed creation



Antigen manufacturing process: overview



Antigen manufacturing process: key steps

SEEDS	FERMENTATION	PURIFICATION	
			FINAL PRODUCT
R & D	UPSTREAM	DOWNSTREAM	

Main customers

- ABBOTT
- OCD
- SIEMENS
- ORASURE
- New potential customers

Abbott

Ortho Clinical Diagnostics

SIEMENS

OraSure Technologies, Inc.

Project Horizon: project redesign objectives - October 2014

- Leverage Grifols know-how to optimize investment
- State-of-the-art manufacturing facility
- Increase manufacturing process flow efficiency, indirectly increasing also capacity
- Optimize utilization of space in the building
- Consolidate under one roof all manufacturing processes, including material handling and warehouse operations
- Available space for future manufacturing growth

Project Horizon: investing for future growth

Yeast fermentation
E. Coli fermentation

Purification
bulk fill
Tech Services

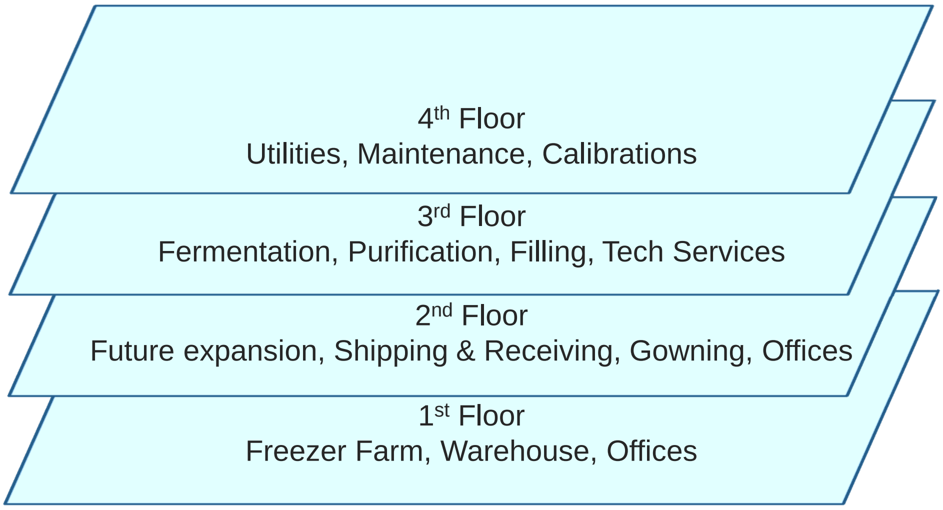
GMP
warehouse

CMF Building

Emeryville site antigen manufacturing

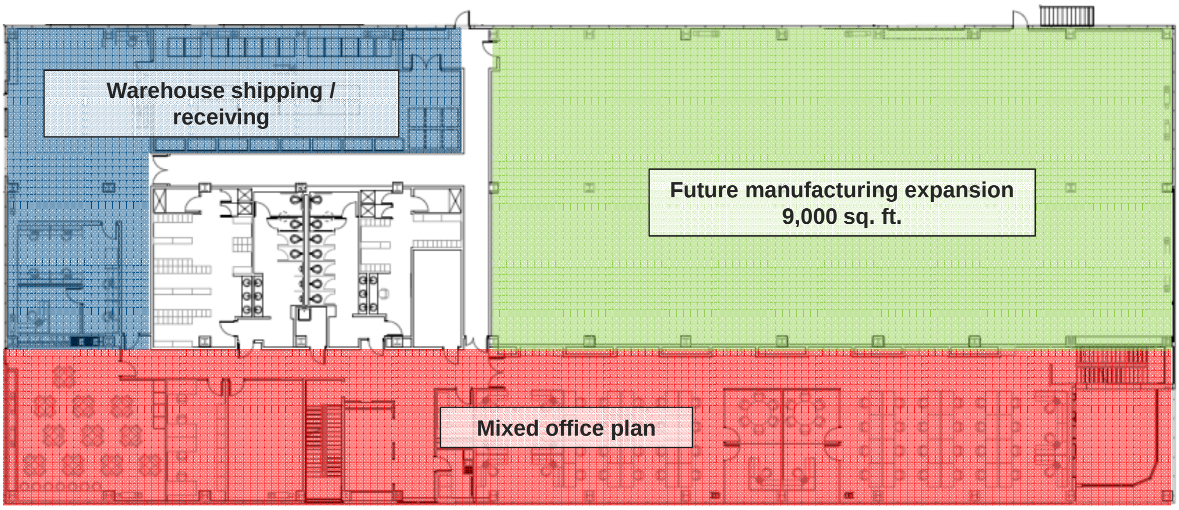
Consolidated manufacturing facility for all bulk antigen products

Project Horizon - reimagining the project: CMF building scope



Horizon - 1st Floor: GMP warehouse & Raw materials inspection

Horizon - 2nd Floor: shipping/receiving, offices & manufacturing



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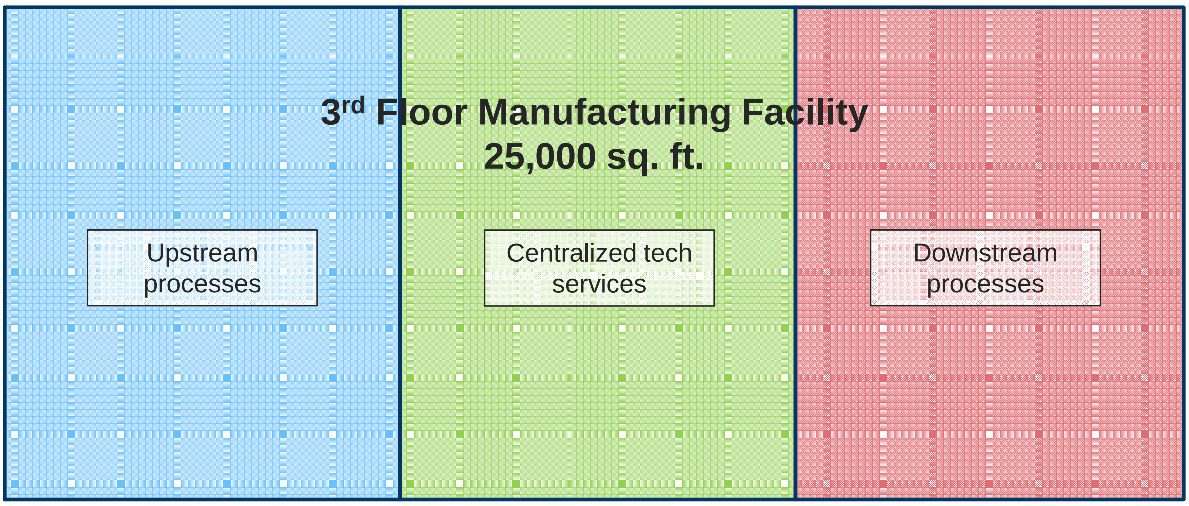
Horizon - 3rd Floor concept: how we optimize the process flow



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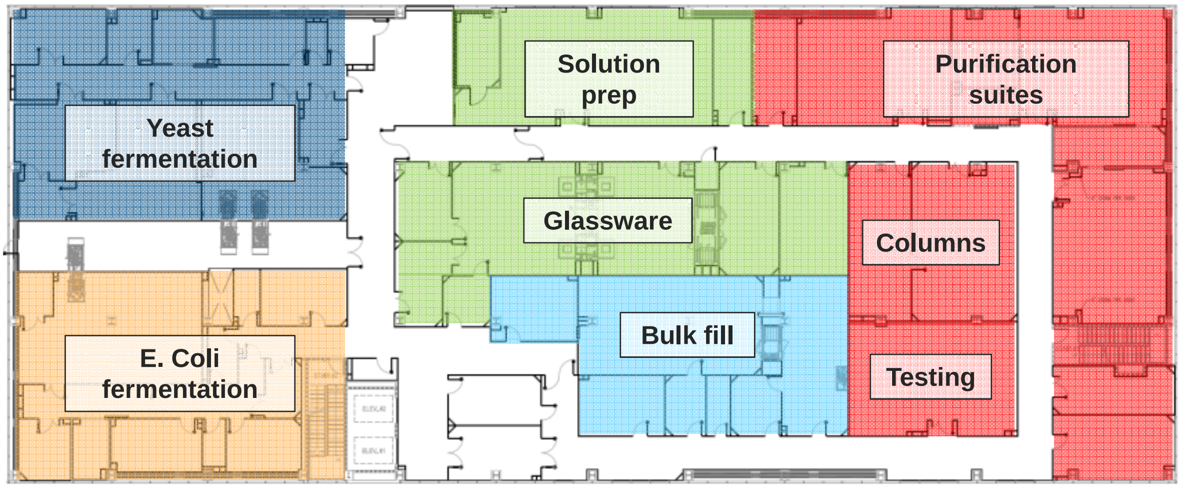
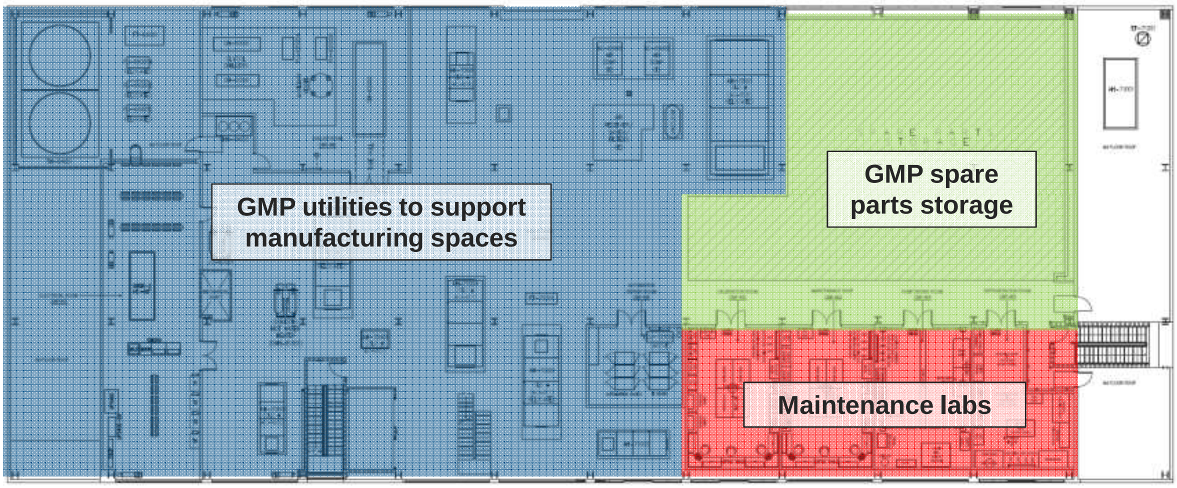
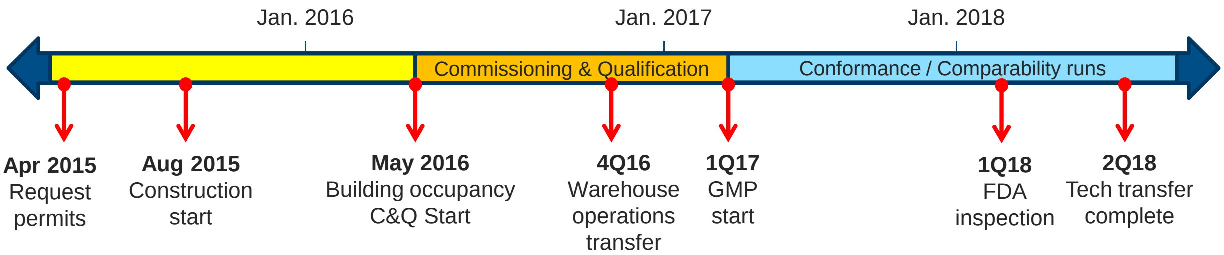
Horizon - 3rd Floor: manufacturing facility



Horizon - 4th Floor: utilities, maintenance labs & spare parts



Project Horizon: Investing for future growth



Project Horizon: Investing for future growth

Project Horizon: Investing for future growth

Project Horizon: Investing for future growth

Project Horizon: Investing for future growth

Project Horizon - Takeaways

- Strategic manufacturing platform investment of approx. USD 80 million
- Manufacturing platform will be able to **support** the **long-term** supply requirements of Abbott contract (2026) and others
- The **increased capacity** allows for the manufacture of new antigens and also to expand the customer base
- The consolidation of all manufacturing operations under one roof and the optimization of the process flow will allow to further **improve yields** in the future

Research + Development + Innovation

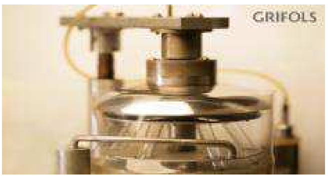
David Bell

New Innovation Organization

Grifols has a long history of transformative innovation - I

…changing the very essence of our industry

- Establishing the core technology of plasmapheresis
- Defining the state of technology through engineering and manufacturing pre-eminence



Grifols remains a recognized leader in innovation redefining the concept of plasma therapeutics and exploring new platforms for growth

Grifols has a long history of transformative innovation - II

Grifols ranked among the world's 100 most innovative companies by Forbes magazine for the third consecutive year

Innovation across all divisions: January 2015 - May 2016

Regulatory submissions 920

Approvals for Biologic products 317

FDA	38
EMA or other European authorities	77
Other regulatory authorities	202

Approvals for Diagnostic products 502

FDA	21
EMA or other European authorities	32
Other regulatory authorities	449

Hospital 12

Approvals for Hospital products by EMA or other European authorities

Innovation across all divisions: January 2015 - May 2016

Studies 35

Studies under the Grifols' Investigator Sponsored Research Program covering 7 varied disease states

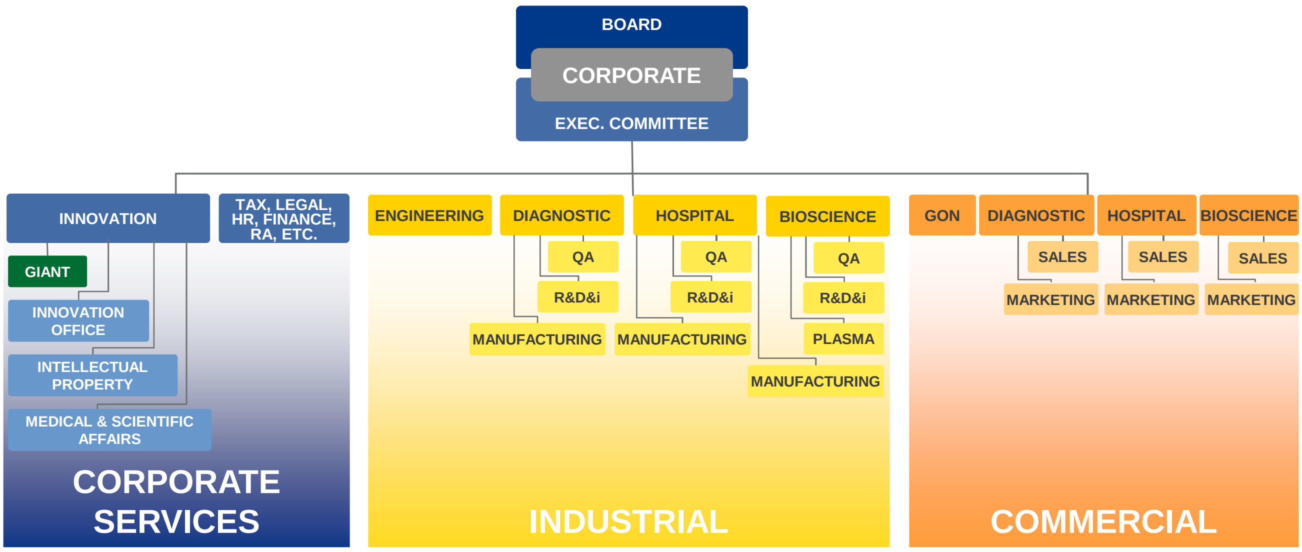
Patents 277

Granted covering 42 distinct inventions

Robust R & D program that is not limited to internal resources

- We have deployed an innovative, productive and functional program within Grifols evaluating and accelerating development and commercialization of innovative therapies, products and services

Strengthening corporate innovation



Robust R & D program that is not limited to internal resources

- We have deployed an innovative, productive and functional program within Grifols evaluating and accelerating development and commercialization of innovative therapies, products and services
- Sourcing innovation through intrinsic capabilities, external investment and collaborative ventures
- Managing innovation. We have developed a business driven approach accelerating new product development including both in-house and external investment through Grifols Innovation and New Technology Limited - **GIANT**
- Monitoring new technologies and assessing their potential to become products, therapies or services
- Monitoring and disseminating scientific and medical information that could impact the company. Identifying opportunities and risks for the business
- Taking advantage of technological/therapeutic trends early

Exploiting the present and exploring the future

- Exploring new opportunities even as we work diligently to exploit existing capabilities
- Exploiting our core, conventional-plasma proteins and ancillary businesses while simultaneously producing a stream of exploratory breakthroughs
- Pursuing incremental innovations; improvements in our existing products and operations that let us operate more efficiently and deliver ever-greater value
- Leveraging and applying technological or process advances to fundamentally change our business
- Advancing disruptive technologies that profoundly alter our portfolio, rendering old products or ways of working obsolete
- Significant investment in plasma therapeutic research

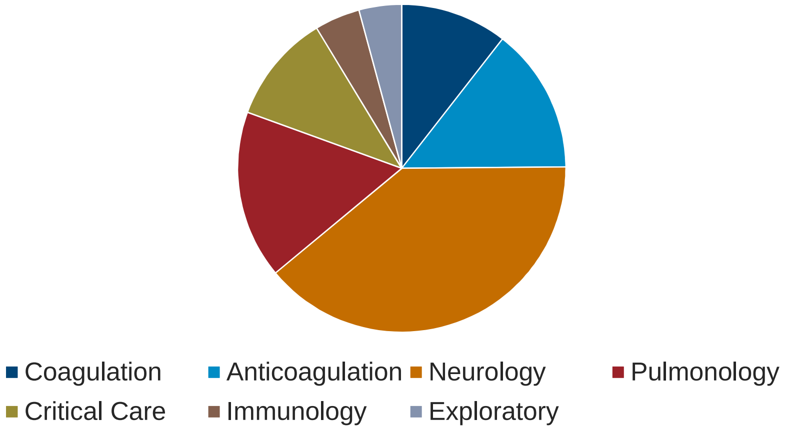
Main R & D Projects on track and continuing…

- Alzheimer's Disease - AMBAR study
- Fibrin Sealant
- Subcutaneous IG
- Alpha-1 Liquid
- Drug delivery systems
- NAT Automation
- Next Generation Sequencing
- Robotics and Pharmacy automation

The Path to Evidence Based Medicine - I

Investigator Sponsored Research

35 separate research studies covering 7 different disease states



The Path to Evidence Based Medicine - II

- Collaborations with over 35 separate academic institutions, including:
  - Stanford University
  - University of Pittsburgh
  - Harvard University
  - Mayo Clinic
  - Hospital Clinic Barcelona
  - Fundación ACE

The Path to Evidence Based Medicine - III

- Specific programs investigating therapeutics for:
  - Diabetes - Alpha-1 Antitrypsin
  - Sickle cell disease - Antithrombin III
  - Lupus - Alpha-1 Antitrypsin
  - Guillain Barré - IVIG
  - Acute myocardial infarction - Alpha-1 Antitrypsin and Antithrombin III
  - COPD - Alpha-1 Antitrypsin and IVIG
  - Liver disease - Albumin and Plasmapheresis
  - Alzheimer - Albumin, IVIG and Plasmapheresis
  - ALS - IVIG and Plasmapheresis

GIANT

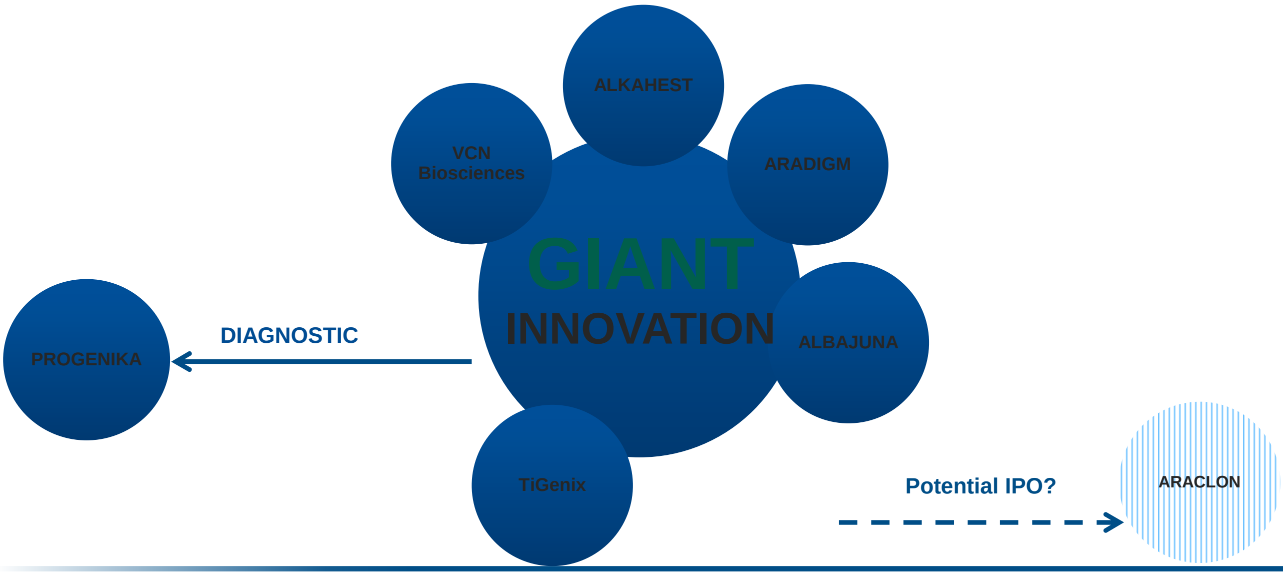
GRIFOLS
INNOVATION
AND NEW
TECHNOLOGIES

Grifols Innovation And New Technologies

- **GIANT** is an organizationally distinct business unit that is tightly integrated at the senior executive level
- **GIANT** brings an interdisciplinary approach to discovering and capitalizing on emerging technology and business, incorporating bridges with Sales/Marketing, Finance, Manufacturing, Legal and Regulatory
- **GIANT** has a distinct operating culture stimulating creativity and necessary risk taking without the requirement to surmount unnecessary obstacles

***Startup Speed and Creativity** coupled with **Corporate Scale and Capabilities** driving the search for innovation adding value to Grifols*

Investments and collaborations



GRIFOLS

Criteria for investment and collaboration

- Transformative or novel business or technology
- Synergistic with our business and core competencies
- Potential to add commercial opportunity and value
- Opportunity for us to contribute to create further value
- Cultural and business fit (people)
- World renowned researchers

Current investment: USD 190 million
Additional funds for strategic investments: USD 200 million

GRIFOLS

Extrinsic Investments - Collaborating for the future

AlbaJuna Therapeutics

EUR 3.75 M equity investment
Two tranches of EUR 3.75 M and EUR 3.5 M bound to milestones (65%)
Preferential right to exploit the patent after Phase II
30% current ownership interest

- Innovative strategy to treat HIV with multi-functional antibodies
- Capacity to interact with several regions of the HIV virus, thus increasing their neutralizing capacity
- Increasing the activity of the natural killer cells responsible for destroying any cells infected by HIV

Extrinsic Investments - Collaborating for the future

AlbaJuna Therapeutics

Grifols Board Members:
Jose Terencio, PhD

Grifols Steering Committee Members:
Sandra Camprubí, PhD
Montserrat Costa, PhD
Núria Jorba, PhD

Key Personnel:
Julián Blanco (Founder), PhD
Jorge Carrillo (Founder), PhD
Ventura Clotet (Founder), MD, PhD

Extrinsic Investments - Collaborating for the future

ARADIGM®

USD 26 M equity investment
USD 65 M funding for Pulmaquin® Phase 3 clinical trials
USD 5 M milestone. Further payments and milestones
35% ownership interest

- Phase 3 development of Pulmaquin® for the treatment of non-cystic fibrosis bronchiectasis
- Pulmaquin® is a dual release formulation composed of a mixture of liposome encapsulated and unencapsulated ciprofloxacin
- Pulmaquin® is being evaluated in two ongoing Phase 3 studies to determine its safety and effectiveness as a once-a-day inhaled formulation for the chronic treatment of patients with non-CF BE who have chronic lung infections with pseudomonas aeruginosa
- **Grifols has global commercial rights**

Extrinsic Investments - Collaborating for the future

ARADIGM®

Grifols Board Members:
David Bell
Lafmin Morgan

Grifols Steering Committee Members:
Lafmin Morgan
Michael Fath
Angela Davis, MD

Key Personnel:
Igor Gonda, PhD
Juergen Froelich, MD

Extrinsic Investments - Collaborating for the future

EUR 4.8 M equity investment
EUR 5 M equity committed at a fixed valuation if Phase I milestones are achieved
68% ownership interest

- Development of new agents for the treatment of solid tumors based on oncolytic adenoviruses
- Orphan drug designation for pancreatic cancer by EMA currently being tested in parallel in two Phase I/(II) clinical trials after intravenous and intratumoral administration

Extrinsic Investments - Collaborating for the future

Grifols Board Members:
Dirk Büscher, PhD
Jose Terencio, PhD

Grifols Steering Committee Members:
Dirk Büscher, PhD
Jose Terencio, PhD

Key Personnel:
Manel Cáscallo (CEO & Founder), PhD
Ramón Alemany (Founder), PhD
Gabriel Capellá (Founder), MD, PhD

Extrinsic Investments - Collaborating for the future

araclon BIOTECH

EUR 32.9 M equity investment
+ Recent capital increase
~75% ownership interest

- Tackling neurodegenerative diseases
  - Diagnostics:
    - Early detection of Alzheimer's disease - ability to differentiate from other dementias
  - Treatment:
    - Alzheimer's - Vaccine against scientifically accepted target
    - Parkinson's - Focus on Neuroprotection and induction of dopaminergic neurons

Extrinsic Investments - Collaborating for the future

araclon BIOTECH

Grifols Board Members:
Dirk Büscher, PhD
Víctor Grífols Deu
Javier Jorba Ribes

Grifols Steering Committee Members:
Dirk Büscher, PhD

Key Personnel:
Jose Manuel Sarasa Barrio, PhD
Pedro Pesini Ruiz, PhD

Extrinsic Investments - Collaborating for the future

ALKAHEST

USD 37.5 M equity investment
USD 12.5 M license fee
Further payments and milestones
~ 45% ownership interest

- Identifying plasma based proteins functioning as “youth” or “aging” factors/triggers
- Developing function-restoring and enhancing therapies derived from plasma
- Proteomic analysis of plasma and plasma fractions occurring at a remarkable rate, accelerating the pathway to therapeutic success
- **Grifols has exclusive rights to commercialize products**

Extrinsic Investments - Collaborating for the future

ALKAHEST

Grifols Board Members:
David Bell
Thomas Glanzmann

Grifols Steering Committee Members:
Todd Willis, PhD
Cesar Alvarez
Tony Paez, MD

Key Personnel:
Karoly Nikolich, PhD
Tony Wyss-Coray, PhD
Joe McCracken
Steven Braithwaite, PhD

Pursuing transformational opportunities

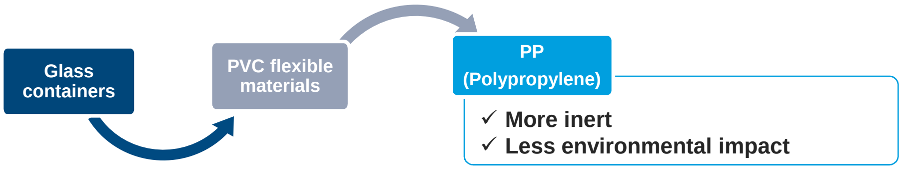
- New indications for existing products in currently untreated disease states and therapeutic rejuvenation
- New plasma proteins identified for the production of novel therapies (plasma derived, recombinant and small molecule)
- Innovation provides opportunities to enhance plasma economics
- Innovation drives sustainability
- Supports "Evidence Based Medicine"

Albumin new container

Carlos Roura

Containers evolution

- Through the years, LVP's (Large Volume Parenterals) have evolved from glass containers to flexible materials like bags due to their advantages



- For plasma products like IVIG or Albumin, bags are not used due to 2 difficult challenges not easy to solve:
  - Container must solve Albumin's high binding capacity as plasticizers may be absorbed by Albumin
    ➡ New plastic technology needed
  - The product does not admit a final sterilization so the filling must be aseptic
    ➡ Need to develop a new filling technology not available in the market

Advantages of bags vs glass

Safety features

- Less breakage and spills
- Can be administered with a non-vented administration set
- Port design helps maintain sterility (no swabbing required for administration)
- Free of latex, PVC, DEHP and DEHA (PP bags)
- Low Aluminum content as the container is aluminum free

Efficiency features

- Easy to administer
- Storable in automated dispensing cabinets
- Lighter than vials
- 2-year at room temperature

Sustainability features - less impact on the environment

- Lower carbon footprint
- Reduced waste volume

Plasma products in flexible container: platform

Bioscience Division

+

Hospital Division knowledge in plastic manufacturing

Grifols Engineering aseptic filling lines expertise

=

Development platform for a liquid biological flexible container

Thanks to our divisions collaboration, Grifols has solved both challenges:

- Container inert bag
- Aseptic filling line for flexible containers

Container main features

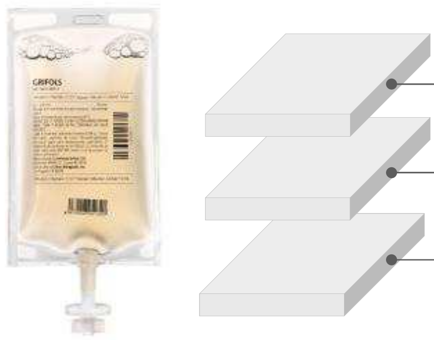
New container

- Consists of a flexible plastic body and a connector with a port through which the bag is filled

- After the aseptic filling the port is welded
- The same port is used to administrate the albumin to the patient
- Empty bags can be sterilized with Gamma radiation and e-Beam (electronic beam)
- Patent in process

Primary bag: exclusive composition

- Grifols has been working in different plastic compounds to select the best possible combination based upon Albumin stability and extractable essays
- This work has made it possible for Grifols to develop a new, three layer coextruded, flexible material with low extractables and leachables



First layer
Container material in direct contact with Albumin
Inert material with very low extractables and leachables

Second layer
Provides an excellent protective layer for oxygen barrier

Third layer
Avoids water steam permeability and provides mechanic resistance to the bag

Overwrapping: aseptic & safer

Grifols has designed an overwrapping with two objectives:

- Improve stability, avoid permeability and extend the expiry date to 2 due to a high oxygen and water steam barrier added
- Assure that when this second bag is open (overwrapping) the outside of the inner bag is aseptic, so it can enter operation rooms

First layer
Resistance "in special thermal resistance "and high barrier to water steam and oxygen

Second layer
Mechanic resistance

Third layer
High barrier to water vapor and oxygen

Fourth layer
The bag can be easily opened by peeling it off

Design of an aseptic filling line

- Grifols Engineering with manufacturing know-how both in form-fill-sealing lines we use in LVP, as well as in aseptic filling lines for glass with GSF® concept (Grifols Sterile Filling), has developed this bags aseptic filling line for plasma products

The bag arrives to the filling machine closed and sterilized → Then the cap is taken off for filling under a laminar flow → The bag is closed again in the same station after the filling process is done

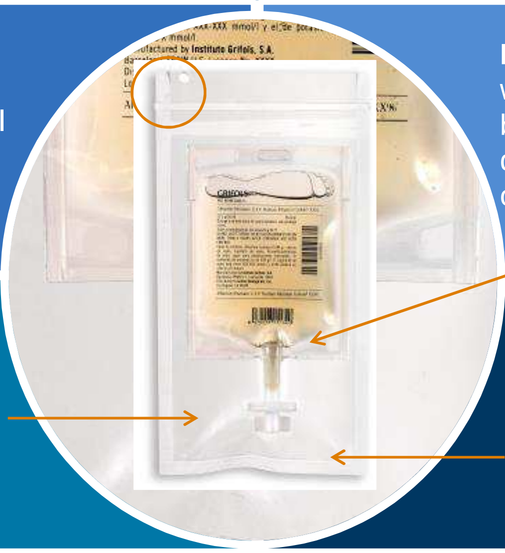
- The system reduces contamination possibilities as the container is closed during most of the time. It is not simply an aseptic filling machine, but a complete concept of filling
- Patented by Grifols (Patent ES2549694A1)

GRIFOLS

Unique competitive advantages

Overwrapping bag
helps maintain the inside bag sterile until its use
No decontamination needed to enter Operation Rooms

New Port
wider design, avoids bubbles accumulation during infusion and optimizes it



Wider base
eliminates the risk of pricking the finger when spiking the bag

Tamper evident
Twist off opening guarantees sterility until the moment of use

GRIFOLS

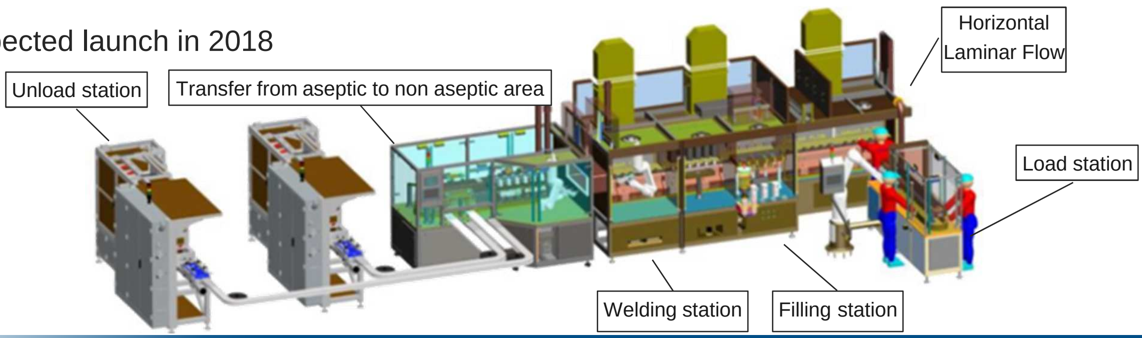
Albumin bag: Grifols vs competitor

- Broader range of concentrations and presentations from launch

Albumin concentration	GRIFOLS	Competitor
5%	50ml, 100ml, 250ml, 500ml	250ml
20% - 25%	50ml, 100ml	50ml, 100ml

First manufacturing line: Los Angeles Site

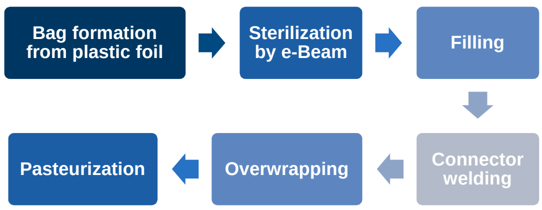
- A first line will be installed in Q3 2016 in our Los Angeles facilities
- Bags will be produced in our Murcia manufacturing plant, sterilized by Gamma radiation and then sent to Los Angeles plant
- Conformance Lots are expected for Q1 2017
- Expected launch in 2018



Albumin bag filling line

Dublin site for Albumin bag

- A new Albumin facility will be built in Ireland with a purification & filling capacity of 130-150 million grams of Albumin
- The filling area will have four automated bag filling lines



- Works will start in December 2016
- First phase with 2 lines is forecasted for mid 2019
- Second phase with 2 machines in early 2021

Albumin new container - Takeaways

- Grifols experience through the years, and our strong intercompany collaboration in all areas has made it possible to develop this platform that takes Grifols to the top of technology
- Grifols provides the market with the most ergonomic and safer flexible container
- With this new development, Grifols stays ahead from most competitors and adapts to the market's latest needs
- IVIG in flexible container is following
- Broader portfolio in the market

Q & A

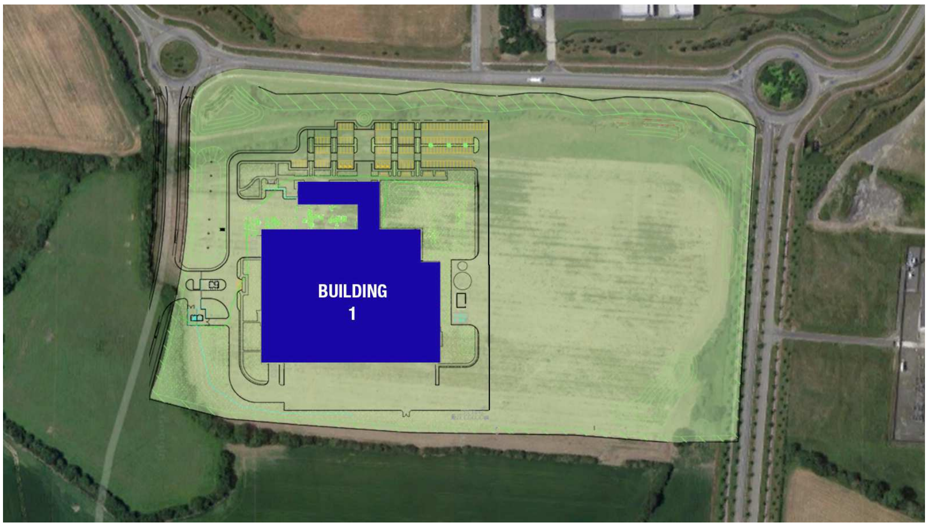
Introduction to the GWWO tour

Andrew O'Connell

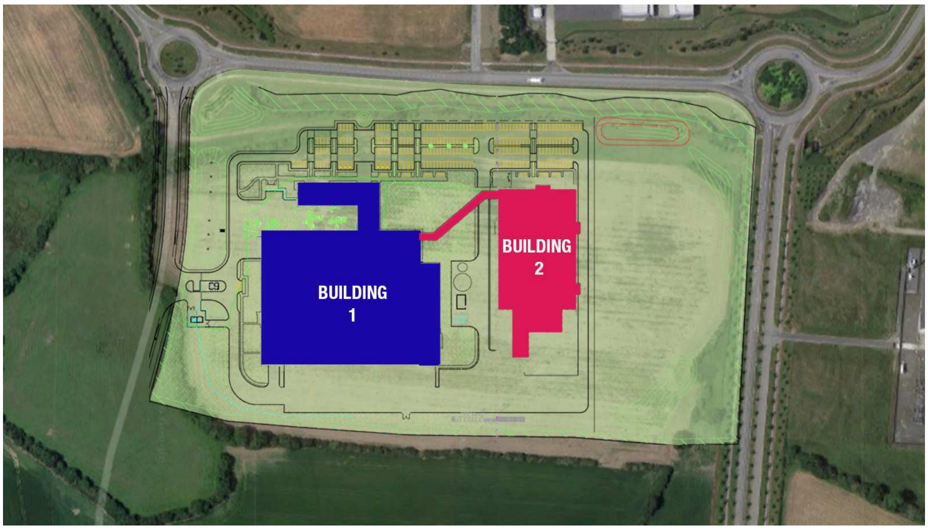
GWWO Dublin site

GWWO Dublin site

GWWO Dublin site



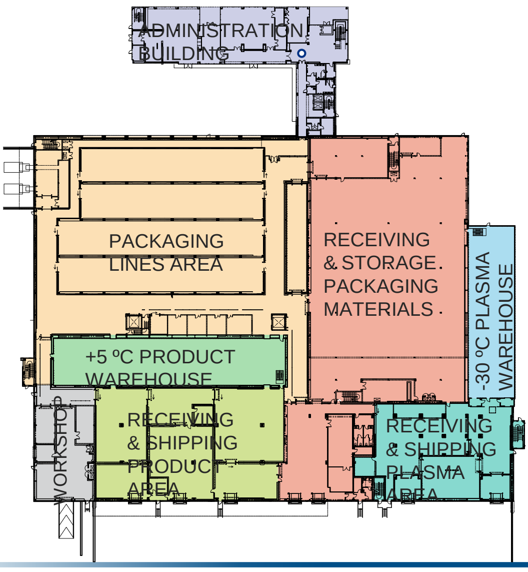
GWWO Dublin site



GWWO Dublin site

How it was built

GWWO Dublin site



GRIFOLS WORLDWIDE OPERATIONS
GLOBAL OPERATIONS PLATFORM
FOR BIOSCIENCE DIVISION

22,000 m² ON **14,000** FLOOR PLATE ON **110,000 m²** LAND LOT

1,150 PALLETS PLASMA AT **-30 ºC**

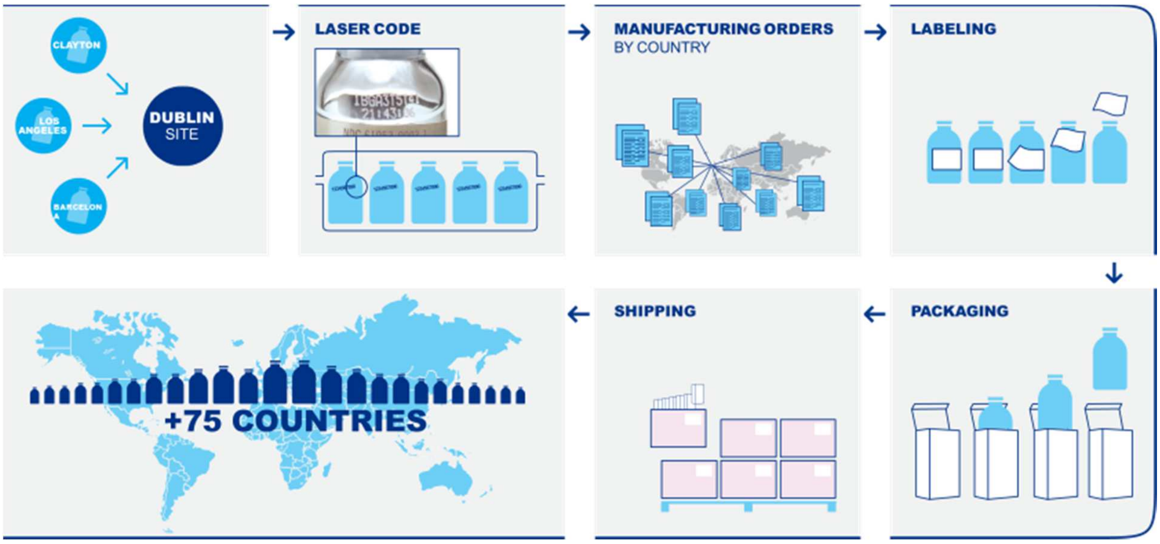
2,950 PALLETS INTERMEDIATE / FINISHED PRODUCT AT +5 ºC

4 PACKAGING LINES

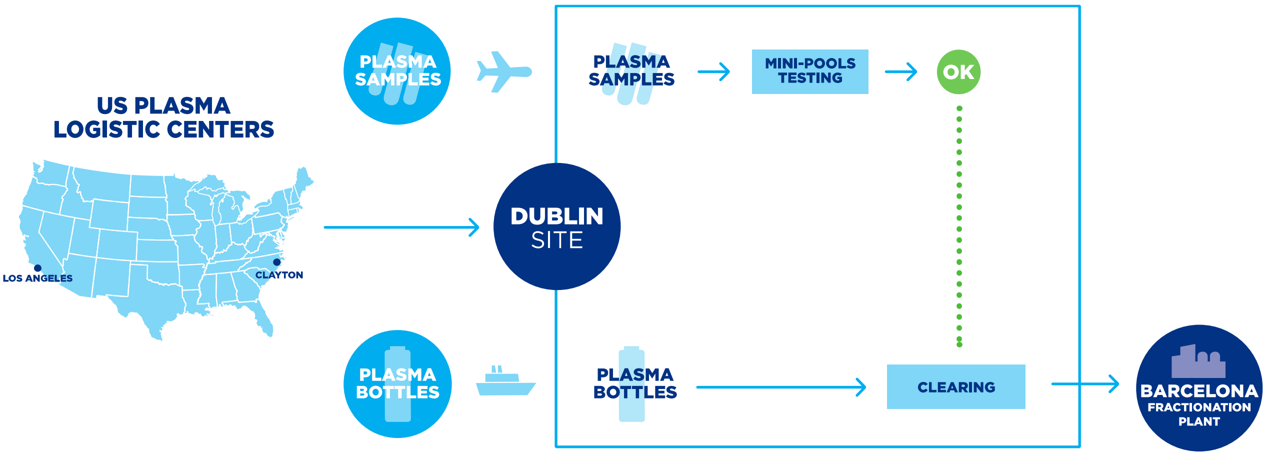
PLASMA TESTING LABORATORY

CORPORATE OFFICES

Product Supply Chain



Plasma logistics



INVESTORS' & ANALYSTS' MEETING - 2016

GRIFOLS

Dublin, 2nd-3rd June 2016

Friday, June 3rd 2016 - Dublin

Time	Topic	Presenter
9:00 - 9:30	*Coffee + Welcome*	
9:30 - 10:15	Grifols Engineering: A competitive advantage	D. Fleta
10:15 - 11:15	Financials	A. Arroyo
11:15 - 11:45	*Coffee break*	
11:45 - 12:15	Emerging Pathogen Project	D. Bell
12:15 - 12:30	Conclusions	T. Glanzmann
12:30 - 13:00	Q&A	
13:00	*Lunch or Transfers to airport*	

Grifols Engineering - A competitive advantage

Daniel Fleta

Grifols Engineering - Competitive advantage

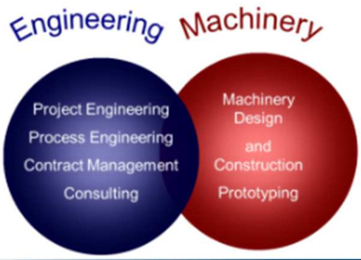
- Grifols Engineering introduction
- Bioscience process equipment and technology developments
  - Plasma Procurement
  - Plasma Fractionation
  - Fill & Finish
- Other divisions project examples
- Grifols Engineering key advantages

Grifols Engineering - Introduction

Developing new technologies and expertise to provide innovative solutions is a core value for Grifols since founding the company

Grifols Engineering offers innovative pharmaceutical engineering, custom and common sense solutions to meet the real needs of our customers

Inheriting this spirit Grifols Engineering S.A. was established in 2001 to provide engineering solutions within the company but also to other pharmaceutical clients



Engineering projects consulting, process engineering, feasibility studies, conceptual and detail design, construction and start-up services

Machinery design and construction include specialized equipment for the fractionation industry, purification and aseptic filling lines

Grifols Engineering - Strengths - I

- Daily and close contact with our production facilities
  - Practical and common sense solutions
  - Continuous feedback of our work for years
  - Looking for Innovation and continuous improvement
- Development and execution of biopharmaceutical process machinery
  - Design and construction of tailor-made solutions for precise applications or specific machines which cannot be found on the market
  - Seamless integration of the process lines with the pharma facilities from the design phase

Grifols Engineering - Strengths - II

- Practical knowledge of the regulatory requirements of the industry
  - Quality expert resources available in the Group
  - Being part of a worldwide multinational Group allows us to have know how of the main regulatory agencies
- Technical support of a great group of professionals
  - Operations
  - R & D
  - Calibrations & Validations

Grifols Engineering - Innovations

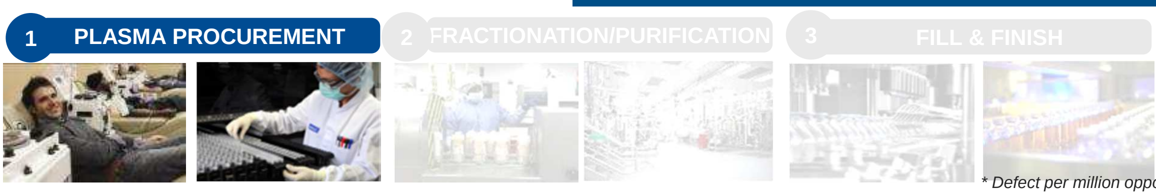
Innovations in plasma collection - Plasma Bottle Sampling PBS®

Typical process and challenges:

- Quality and safety of plasma derived proteins starts and is based on the plasma procurement
- Around 44K plasma donations per day and multiple samples/analysis of each donation. +175 K samples per day and around 44 millions of samples per year…taken manually
- Ergonomics
- Safety for the operator (accidental punctures)

6σ Six Sigma 3.4 DPMO*

It is crucial to ensure the correct traceability of the samples with respect to the donations and to eliminate the risk of a clerical mistake



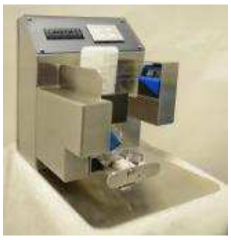
* *Defect per million opportunities*

Innovations in plasma collection - Plasma Bottle Sampling PBS®

- Guarantees plasma sample traceability by allowing taking the sample only if sample tube barcode or identification matches the bottle ID
- Patented system
- Optional sample label printing online
- Network connection to plasma Management Software. Proprietary software suite created for multiple PBS Lite management (GSV). History log and audit trail of sampling activities in a centralized Data Warehouse

PBS® Lite

Barcode matching and sampling



300+ units installed in Grifols donor centers

2 units per center

Innovations in plasma pooling - Typical process and challenges

- Plasma pooling usually involves handling thousands of frozen individual donations into a single batch
- Individual container opening, discharge and thawing processes needs to be fast to minimize loses in product yield
- Opening and emptying individual container to remove the frozen product is a labor intensive, and ergonomically challenging operation
- Open product needs to be handled in Class C environment

Long process + exposed product + labor intensive = Concern

Innovations in plasma pooling - ABO® Automatic Bottle Opener

Automatic Robotic Line that rinses, dries, opens the bottles and automatically discharges the frozen plasma into the thawing vessel(s) featuring:

- Removal of the operators from the exposed product area
- Reduction of the size of the clean room
- No preconditioning required for the frozen donation containers
- Consistency in Process Parameters and Product Quality and Yield
- Minimization of bioburden on the product (CFU)
- Increased line throughput
- Process line automatic cleaning sequence

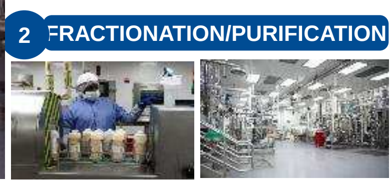
Innovations in plasma pooling - ABO® Automatic Bottle Opener

Loading side

- Automatic Manual Loading
- Skin-Thaw with hot water
- Rinse with fresh WFI/PW

Unloading side

- Automatic Manual Loading
- Air blow to dry bottles
- Cutting station
- Robot empties frozen plasma slugs into chute or vessel
- Detects failure to discharge the bottle by AV and weight
- Empty bottles and lids discarded into waste chute



11 lines installed & in operation

2 lines currently being constructed

7 lines delivered to external customers

Innovations in plasma pooling - PBO® Plasma Bag Opener

The same concept as for bottles has been designed for the alternative plasma container: bags





Vials aseptic filling - GSF® Grifols Sterile Filling

Minimize the risk of microbial and particle contamination during the liquid sterile filling operations

- GSF® is not simply an aseptic filling machine, but rather a complete filling system:
- Component preparation and sterilization
- Aseptic handling
- Aseptic filling
- Environmental control
- Process control
- Container identification
- Applicable to both liquid and freeze dried sterile products

Innovations in Diagnostic - Gel cards automatic filling line

Automatic labelling, filling, sealing and packaging line for DG reagent cards featuring 8 microwells

The line is composed by several integrated modules:

- Feeding cards and labelling module. Includes labelling checking with artificial vision
- Filling and buffering module. Using ceramic volumetric feeding pumps with artificial vision filling checking and sealing with aluminum foil just after filling
- Revision and packaging module. Artificial vision to detect SN/precip levels and packaging in holders

8 lines installed & in operation
2 lines currently being constructed

Innovations in Diagnostic - Antigen production bioreactors

Automatic bioreactors for cell growth (Eukaryotic and Prokaryotic cell cultures)

Usable working volumes from 100 to 1000 L

- Media sterilization
- Automatic and closed addition of media, reagents and inoculum
- Full CIP and SIP capabilities for vessel and individually addition/transfer lines
- Modular skid construction and segregation of elements between clean areas and technical spaces
- Automation system fully parametrizable for multiple antigen production sequences



Production Expansion - Factory for blood collection bags in Brazil

Production plant with a capacity of 2 million of kits/year expandable in the future to 4 million of kits/year

- Located in Curitiba (Paraná, Brazil)
- Constructed in a land plot of 43,400 m^2
- Allocates production plant, QC labs, RM and FP warehouse, Central Utilities Building and office space
- Expands the current capacities in Murcia Plant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Modular construction of a plasmapheresis center

Design and construction, on an expedite basis, of a prefabricated and fully fitted plasmapheresis center and testing lab to be deployed in western Africa as emergency response to 2014 Ebola Outbreak

- The building was constructed following a modular approach in order to be transported by road in precarious conditions. Total construction time was 3 months
- It includes 4 plasmapheresis beds, serology testing lab, plasma treatment with MB for direct infusion, freezer farm, offices/administration and warehousing
- The modular building can be further expanded or replicated in a short period of time if necessary



GRIFOLS

External customers - Recombinant vaccines

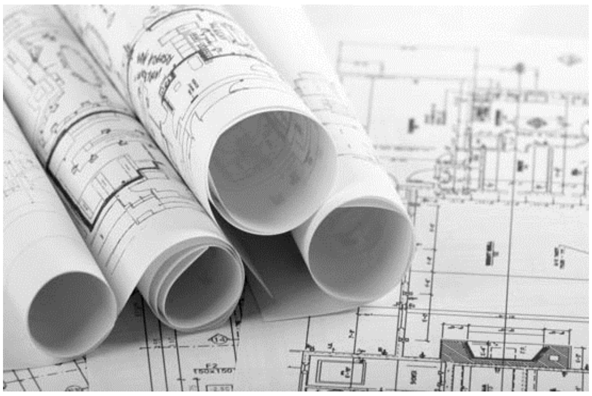
Turn key project of a green field recombinant vaccines manufacturing site

- It includes manufacturing areas, QC labs, Offices, R & D facilities, Central Utilities Building and RM/FP Warehouse
- Two story 3,500 m^2 building built in a 10,000 m^2 land plot
- 24 months execution time from ground breaking to regulatory authorities submission

Grifols Engineering - Key competitive advantage

Focus and mission of the engineering company

Grifols Engineering - Key competitive advantage



External Engineering Companies

Grifols Engineering - Key competitive advantage

Grifols Engineering

Grifols Engineering - Takeaways

- Focus and mission of engineering companies
- Proprietary technology development. Defining new state-of-the-art
- Flexibility and quick response in front of the capital investment priorities of the Group
- Closer control of the projects (quality, schedule and investment)
- Capital Investment Expenditure optimization. Typically yielding total investment costs 60% lower than average market standards
- Shorter project delivery timeframes. We know best what we need and how to get it done

Grifols Engineering - Takeaways

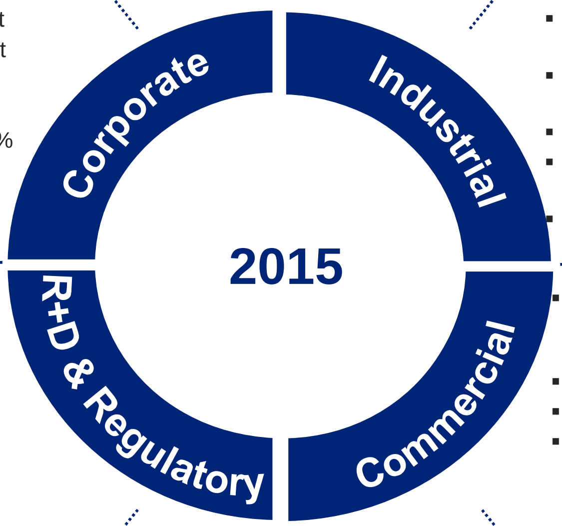
- Specialized know-how retention and transmission within the organization
- Leveraging capabilities, experiences and expertise existing in different areas of the Group through a common technical partner. i.e.: aseptic filling of bags for biological products
- Having our own engineering company delivering both internal and external engineering and machinery delivery services is a singularity in the plasma derivatives industry
- Third party engineering is a profitable business and strengthens the leadership of Grifols in this industry

Financials

Alfredo Arroyo

2015 Grifols highlights

2015 Grifols highlights - Significant progress



Corporate
- 75th Anniversary of commitment
- Succession plan announcement
- Stock split executed
- Rating upgraded
- 2015 dividends: EUR 0.31;+13%

Industrial
- First lot of Gamunex® from Clayton NFF commercialized
- Clayton site obtained FDA approval for Albutein®
- Strategic plan: 75 new centers in 6 years
- Opening of the Bioscience global operations facility in Ireland
- Diagnostic new facility in Emeryville on track

R+D & Regulatory
- AMBAR: intermediate results support its continuation
- Hemophilia SIPPET results: enhance the use of pdFVIII
- Acquisition of 47% of Alkahest
- EMA approval for Gamunex®C
- FDA license for Kiro® Robotics

Commercial
- New agreement with Abbott for the production of antigens: USD 700 M through 2026
- Launch of immunohematology in U.S.
- Australian IVIG tender
- New direct commercial presence: France, India, Taiwan and Indonesia

2015 Financial targets achievement

		2015
Corporate Finance →	TSR*	+26.0%
	EPS growth	+13.0%
	Unlevered FCF % NR	15.2%
	Leverage ratio	3.19x(2.92x at cc)
	Liquidity	+USD 1.7bn
Business Performance →	Recurrent Sales growth at cc	+3.5%
	EBITDA	EUR 1,162.6 M
	EBITDA Margin	29.5%
	EBIT	EUR 970.4 M
	EBIT Margin	24.7%

(*) Class A: +33.9%; Class B: +13.1%; ADR: +1.5%

2015 Recurrent* Net Revenue by Division

In million EUR except %

	Actual 2014	%	Actual 2015	%	% growth	% growth at c.c.
Bioscience	**2,513.5**	*74.9%*	**3,032.1**	*77.1%*	*20.6%*	*4.8%*
Diagnostic	**620.0**	*18.5%*	**691.5**	*17.6%*	*11.5%*	*-0.9%*
Hospital	**94.8**	*2.8%*	**96.2**	*2.4%*	*1.5%*	*-0.2%*
TOTAL	***3,228.3***	***96.2%***	***3,819.8***	***97.1%***	***18.3%***	***3.5%***

- Solid growth driven by volume across main plasma-derived products
- The demand for Grifols' plasma proteins continued its upward trend during 2015. The company is preparing to continue supporting its organic growth
- Diagnostic sales impacted by the NAT competitive environment and the new Abbott contract, which, with a total value of USD 700 M, improved terms and extends the supply of antigens until 2026, raising recurring sales for this business line

** Excluding raw materials, royalties and others*

2015 Recurrent* Net Revenue by Region

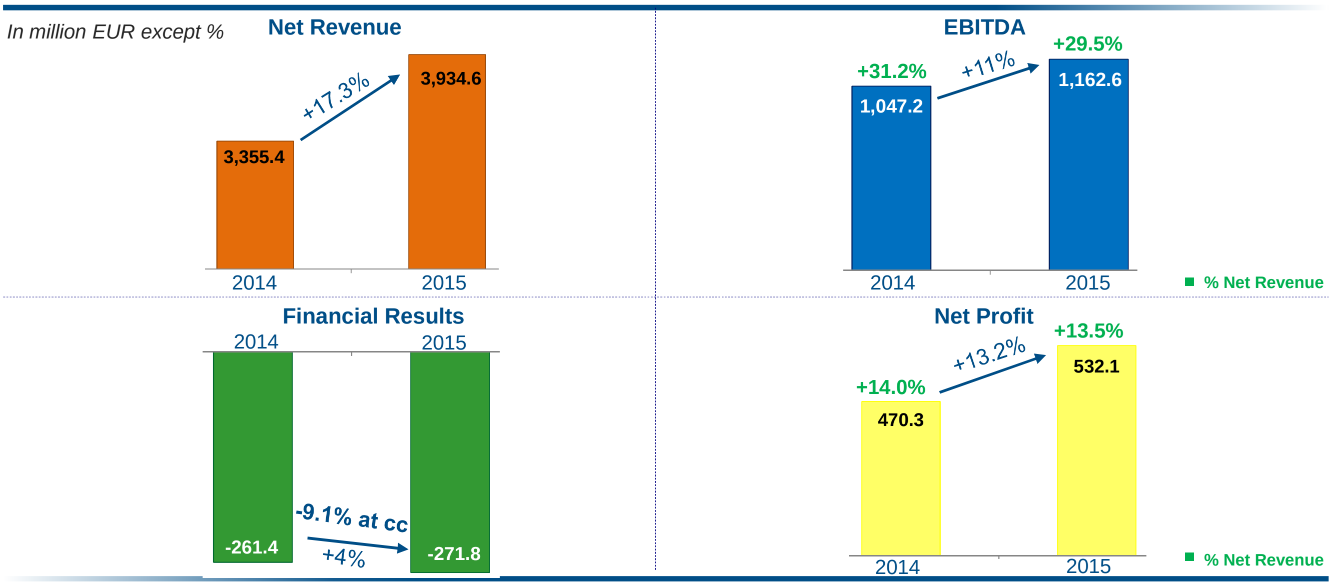
In million EUR except %

	Actual 2014	%	Actual 2015	%	% growth	% growth at c.c.
USA + CANADA	**2,042.7**	*60.9%*	**2,505.8**	*63.7%*	*22.7%*	*2.8%*
EU	**662.8**	*19.8%*	**662.9**	*16.8%*	*0.0%*	*-1.7%*
ROW	**522.8**	*15.5%*	**651.1**	*16.6%*	*24.5%*	*12.8%*
TOTAL	***3,228.3***	***96.2%***	***3,819.8***	***97.1%***	***18.3%***	***3.5%***

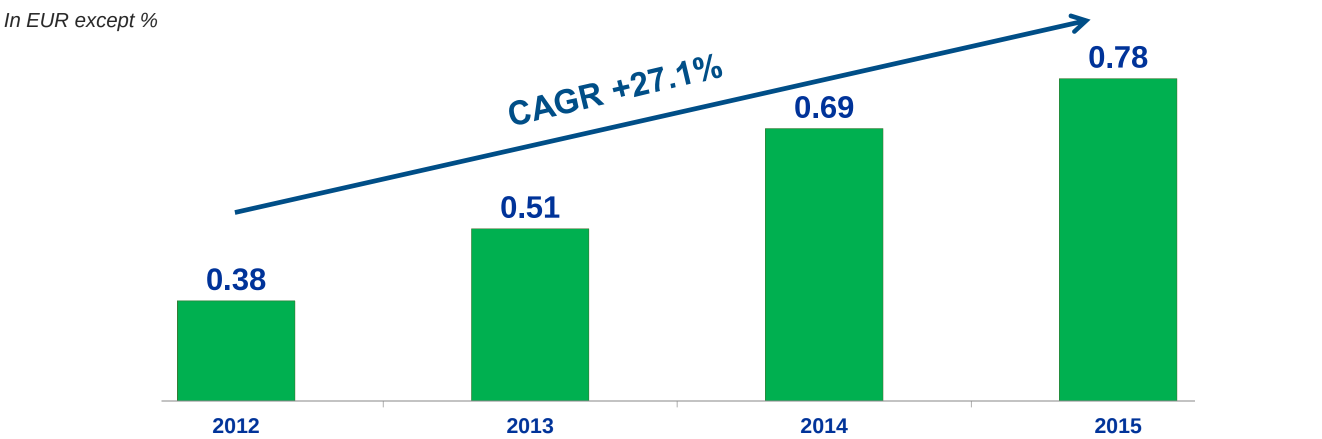
- Steady focus on international activity
- The commercial efforts in U.S. and Canada significantly strengthened Bioscience Division across all proteins
- ROW was driven by growth in China and Asia-Pacific; growth in Latin America, led by countries such as Brazil and Chile; and gradual penetration in Turkey and the Middle East

** Excluding raw materials, royalties and others*

2015 Performance - Solid growth

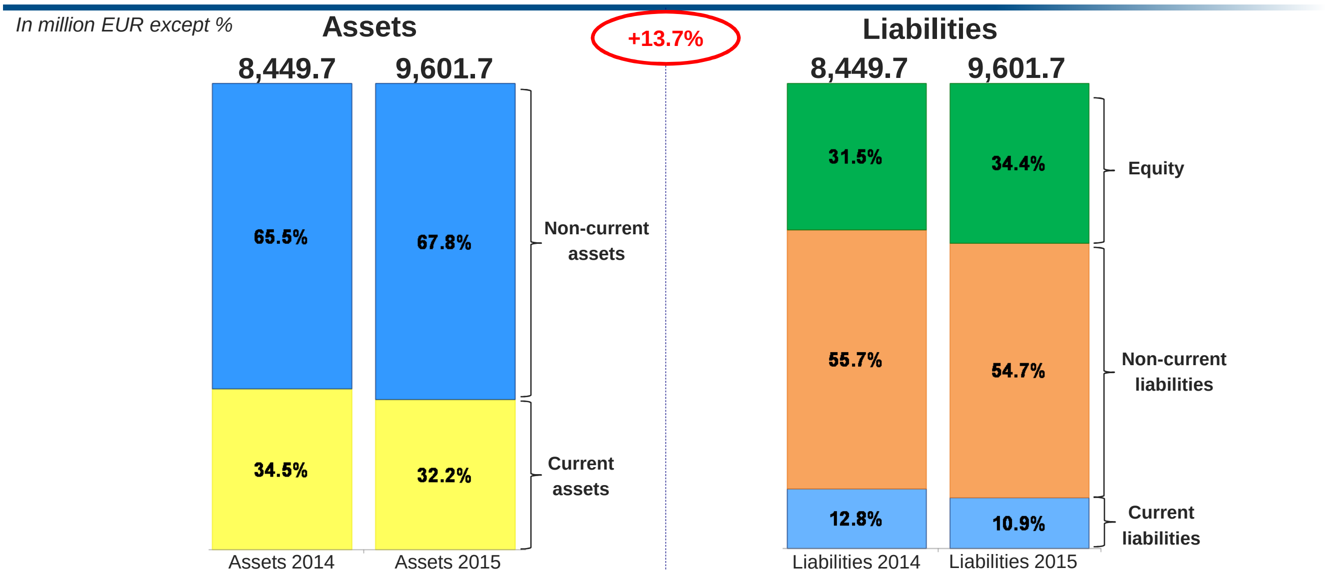


Reported EPS growth



- EPS growth driven by strong underlying business
- EPS remains resilient, growing and profitable
- EPS growth ahead of sales growth, with CAGR of +10.7%

Robust Balance Sheet



Q1 2016 Performance

Q1 2016 Recurrent* Net Revenue by Division

In million EUR except %

	Actual Q1 2015	%	Actual Q1 2016	%	% growth	% growth at c.c.
Bioscience	**681.0**	*75.0%*	**755.0**	*78.7%*	*10.9%*	*6.3%*
Diagnostic	**172.6**	*19.0%*	**161.0**	*16.8%*	*-6.7%*	*-9.9%*
Hospital	**23.3**	*2.5%*	**22.8**	*2.4%*	*-1.8%*	*-1.2%*
TOTAL	***876.9***	***96.5%***	***938.8***	***97.9%***	***7.1%***	***2.9%***

- The demand for plasma proteins continued its upward trend, with growth in the main proteins and a notable contribution from sales of alpha-1 antitrypsin and albumin
- The company maintained the leadership position of its IVIG at global level
- The Diagnostic sales comparative included 2015 significant shipments related to contract signed in Japan and also impacted by the new and extended contract with Abbott

** Excluding raw materials, royalties and others*

Q1 2016 Recurrent* Net Revenue by Region

In million EUR except %

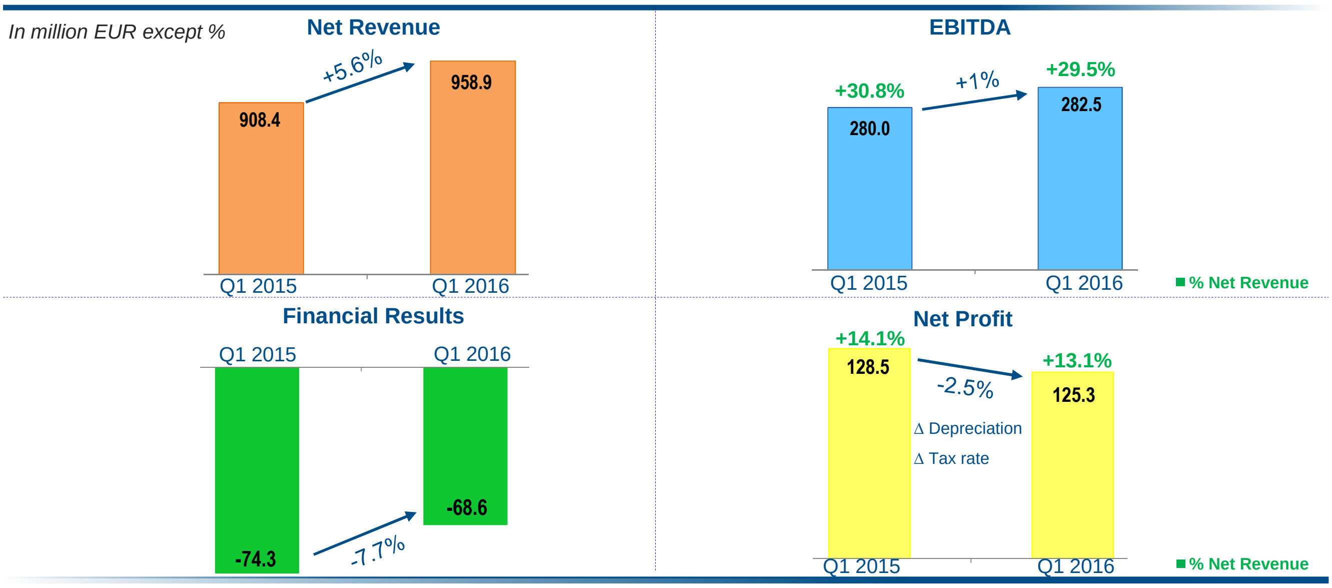
	Actual Q1 2015	%	Actual Q1 2016	%	% growth	% growth at c.c.
USA + CANADA	**567.1**	*62.4%*	**618.6**	*64.5%*	*9.1%*	*2.6%*
EU	**171.0**	*18.8%*	**159.8**	*16.7%*	*-6.5%*	*-6.6%*
ROW	**138.8**	*15.3%*	**160.4**	*16.7%*	*15.6%*	*15.8%*
TOTAL	***876.9***	***96.5%***	***938.8***	***97.9%***	***7.1%***	***2.9%***

- Sales of plasma products remained positive in U.S. & Canada. Lower number of blood transfusions restricted revenue growth in the area of transfusion medicine using NAT technology
- Global expansion is one of the company's main strategic pillars, and the Asia-Pacific region continues to be a priority due to its high growth potential

** Excluding raw materials, royalties and others*

Q1 2016 Performance - Bioscience Division driving growth

In million EUR except %



Q1 2016 Cash Flow

In million EUR

Sources		Uses	
- Operating Cash Flow	203.3	- CAPEX+Intangible	(62.3)
- Working Capital Increase	(115.0)	- Interest	(30.0)
- Net Operating Cash Flow	88.3	- Gross debt decrease	(24.4)
- Cash Beginning Balance	1,142.5	- Acquisitions	(28.7)
- Cash Ending Balance	1,007.6	- FX and Others	(77.8)
- Cash Decrease	134.9		
Total	223.2	Total	(223.2)

Enhancing fundamentals to continue delivering growth

Enhanced growth and profitability opportunities

Bioscience

- Effectively drive organic growth by accelerating the rate of diagnosis and treatments
- Accelerate R & D for new products to increase revenue per liter. Investment in line with current trend
- Drive revenue and gross margin growth through delivery of innovation within new plasma products and new formulations of existing products
- Manufacturing and Plasma cost optimization through scale and efficiency

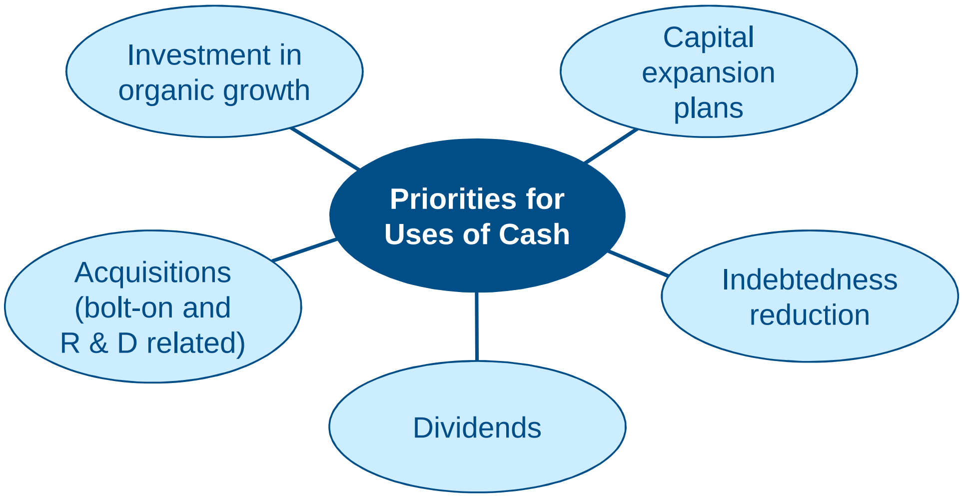
Diagnostic

- Focus commercial efforts on selected product lines and countries driving growth and margins
- Leverage existing line of businesses while improving margins across the whole product portfolio
- Leverage manufacturing capacity in the U.S. (Emeryville) and Spain
- New technologies to develop high value product portfolio

Hospital

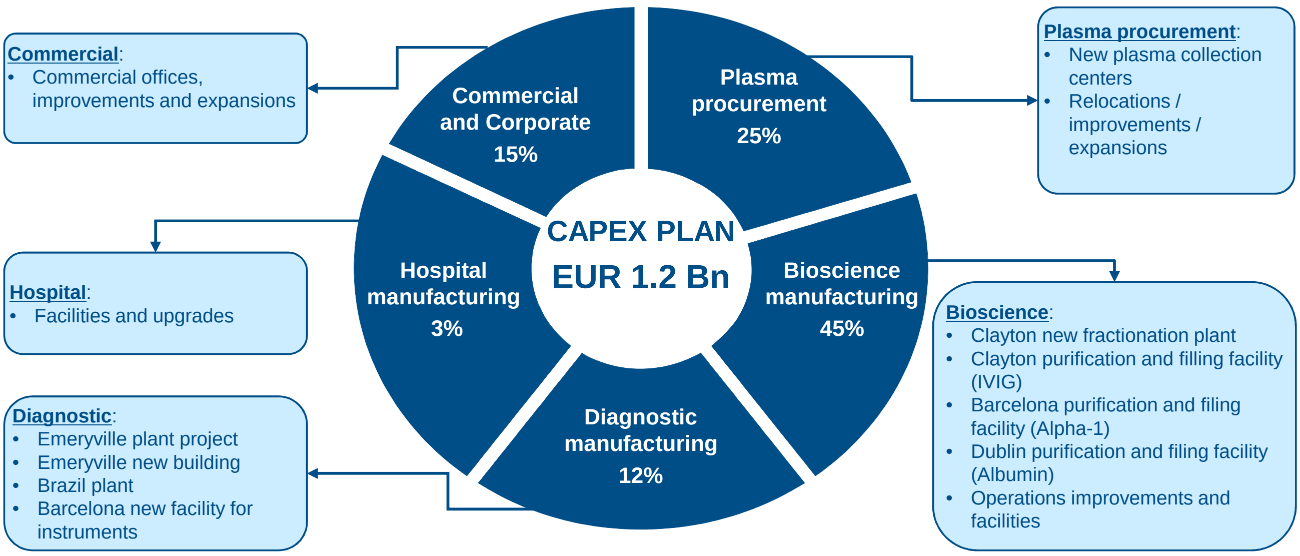
- Increase scale and profitability
- Accelerate penetration in overseas markets with focus in U.S.
- Optimize current manufacturing site profitability
- Leverage existing portfolio while adding new products

Capital allocation - Deploying capital effectively



GRIFOLS

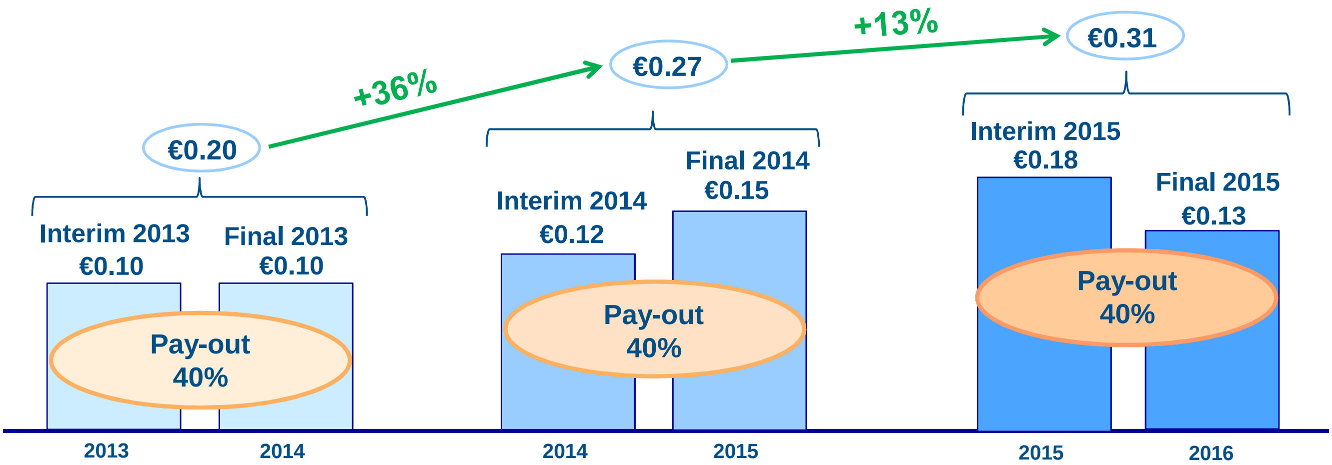
Capex plan 2016-2020



GRIFOLS

Shareholders returns

Significant shareholders returns



For comparison purposes DPS adjusted considering 2016 split

Financials Takeaways

Financial - Takeaways

- **Bioscience Division:** continued execution and momentum, **expecting strong sustainable growth. Opportunities to enhance margins** from new products and new indications
- **Diagnostic Division:** focus on **growth of selected countries and product lines while improving margins**
- Working capital and Balance Sheet optimization to **maximize cash flow generation**
- **Continuous investment** in CAPEX, R & D and Sales and Marketing **to improve EBITDA margin**
- Effective tax rate within the existing range based on country profit mix
- **Expected FX neutral impact** during 2016
- **Constant shareholders reward** through dividends:
  - 40% pay-out
  - Two payments per year (interim/final)

Emerging Pathogen Project

David Bell

Convalescent Plasma Collection, Immunoglobulin Manufacturing and Emerging Pathogens

Project goals

- To provide necessary infrastructure and to demonstrate the ability to promptly respond to outbreaks of deadly pathogens through the use of convalescent plasma and plasma proteins, including IVIG
- To provide a sustainable plasmapheresis plasma collection center with pathogen testing, viral inactivation treatment and storage capabilities for use and operation by local health care professionals after training and initial establishment by Grifols

Immunologic value of IVIG

History of frontline use to treat infection

Evidence based, patient proven

Human Immune Globulin has demonstrated efficacy in treating infection through the inclusion of neutralizing antibodies obtained from convalescent or immunized donors with potential to treat…

- Ebola
- Dengue
- Chikungunya
- Legionairres
- Lassa
- Zika
- Other emerging pathogens

Collection of convalescent plasma

Grifols has designed and built a self contained, modular plasmapheresis unit for the collection of convalescent plasma

- Automated plasmapheresis (4 bed expandable modular units)
- Plasma testing laboratory
- Methylene blue treatment of plasma for direct transfusion
- Freezers for storage of convalescent plasma for transfusion or further manufacture into immunoglobulin
- Ability to deploy to multiple sites
- Training of local healthcare providers for long-term sustainability

Convalescent plasma modular unit

Convalescent plasma modular unit

Convalescent plasma modular unit

Convalescent plasma modular unit

Convalescent plasma modular unit

Processing of convalescent plasma

Grifols has designed and built a self-contained modular fractionation and purification unit for the processing of convalescent plasma into immunoglobulin

- Located in Grifols' Clayton, North Carolina facility
  - Validated and operational
  - Contiguous to the largest capacity, most technologically advanced, FDA licensed fractionation and immunoglobulin processing facility in North America
  - Full compliment of highly skilled and trained personnel
- Fractionation and purification into immunoglobulin from 50 liter plasma pools, using the Gamunex®-C licensed purification process

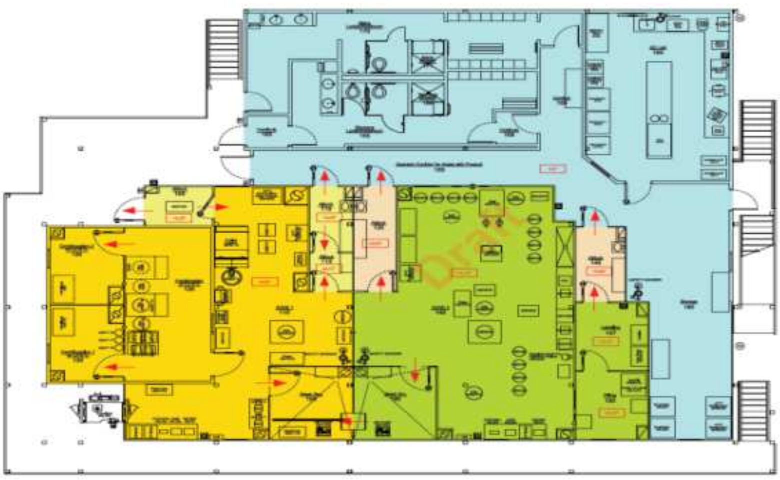
Processing of convalescent plasma

Modular fractionation and purification unit for the processing of convalescent plasma into hyperimmune immunoglobulin

- Fully GMP compliant – isolated from other manufacturing operations
- Utilizes Grifill® proprietary licensed filling technology for small scale aseptic filling of sterile parenteral solutions
- "Import for export" convalescent plasma brought to U.S. for immunoglobulin manufacture pursuant to specifications of Liberian MoH and returned for exclusive use as directed by Liberian authorities

Hyperimmune IVIG production plant

Zones, Classification and overpressures design



AREA CLASSIFICATION LEGEND

SYMBOL	EU GRADE	ZONE	≥0.5 MICRON PARTICLES/CU.FT. AT REST	≥0.5 MICRON PARTICLES/CU.FT. IN OPERATION
	A	N/A	100	100
	B	N/A	100	10.000
	C	ZONE 1	10.000	100.000
	C	ZONE 2	10.000	100.000
	D	ZONE 1	100.000	100.000 *
	D	ZONE 2	100.000	100.000 *
	E	CLEAN MANUFACTURING		
	F	CLEAN SUPPORT		
	UNCLASSIFIED			
	FUTURE – NOT USED FOR PRODUCTION			
	AIR LOCK/GOWN/TRANSITION			
	UNDER CONSTRUCTION			

* = THE EU DOES NOT DEFINE REQUIRED PARTICULATE COUNTS FOR GRADE D IN OPERATION. GRIFOLS TEST TO A 100.000 REQUIREMENT.

Hyperimmune IVIG production plant

Facility construction

Hyperimmune IVIG production plant

Facility construction

Processing of convalescent plasma

Future steps

- Clinical trial to determine the efficacy of IVIG processed from convalescent donors as a surrogate to demonstrating generally the efficacy in using IVIG produced from plasma containing neutralizing antibodies for prophylaxis and therapy in emerging viruses (future outbreaks) - Based upon collaboration with Liberian Ministry of Health

- Ability to deploy plasmapheresis center to areas at risk for emerging pathogens to obtain convalescent plasma for transfusion or processing into IVIG

- Collaborating with USAMRIID and WHO to provide response to new outbreaks of deadly pathogens

Convalescent plasma unit in Liberia

Convalescent plasma unit in Liberia

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Conclusions

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Q & A

GRIFOLS

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