AMPARO®

COVID19 Global Pandemic:
The problem with vaccines

The creation of vaccines and treatments for COVID-19 is a challenge for the scientific community due to its high virulence and transmissibility, characteristics of the new coronavirus, whose genome is highly polymorphic, with about 233 variations. (Sorbonne Université, INSERM, Institut Pierre Louis d'Epidémiologie et de Santé Publique (iPLESP), AP-HP, Hôpital Pitié Salpêtrière, Service de Maladie Infectieuses et Tropicales, Paris, France)

In addition, immunological memory after the first contact with a virus, such as COVID-19 varies in relation to the immunity time, and may fail to protect the patient.

COUNTRY	CASES	DEATHS			
World	**66,950,646**	**1,533,297**	France	2,290,891	**54,804**
United States	14,757,000	**282,299**	Italy	1,728,878	**60,078**
India	9,677,203	**140,573**	United Kingdom	1,723,242	**61,245**
Brazil	6,603,540	**176,941**	Spain	1,684,647	**46,252**
Russia	2,439,163	**42,675**	Argentina	1,463,110	**39,770**

Source: Center for Systems Science and Engineering at Johns Hopkins University, Data as of Dec. 6, 2020.

“WHO Chief Warns Vaccine Won’t End Covid-19 Pandemic As Moderna, Pfizer Announce Early Successes”

Forbes

“It Will Take More Than a Vaccine to Beat COVID-19”

The New Yorker

“Are New COVID-19 Treatments More Important Than a Vaccine?”

Medscape

“We need Covid-19 treatments as well as vaccines – and they have to work for everyone”

Wellcome.org

“Will covid-19 vaccines save lives? Current trials aren’t designed to tell us”

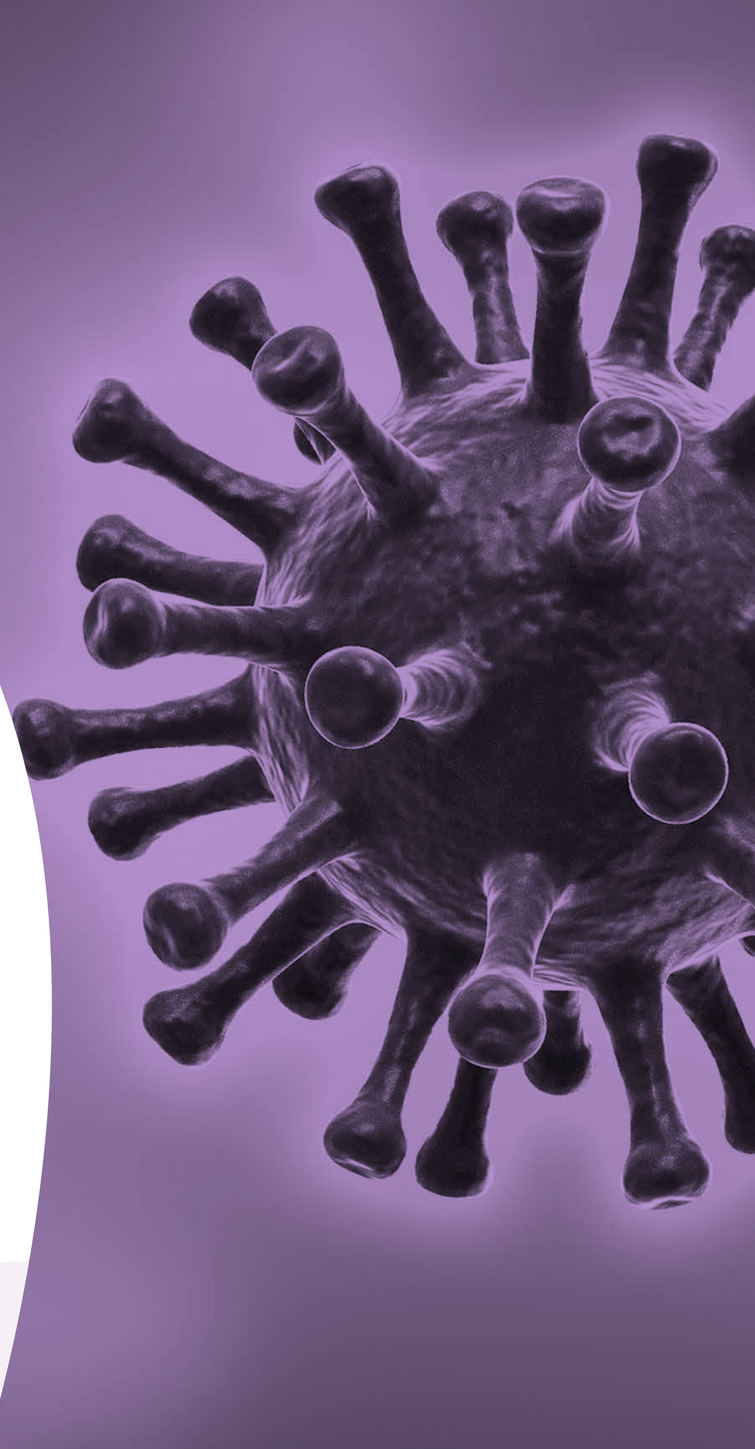
Peter Doshi, Associate Editor at BMJ 2020

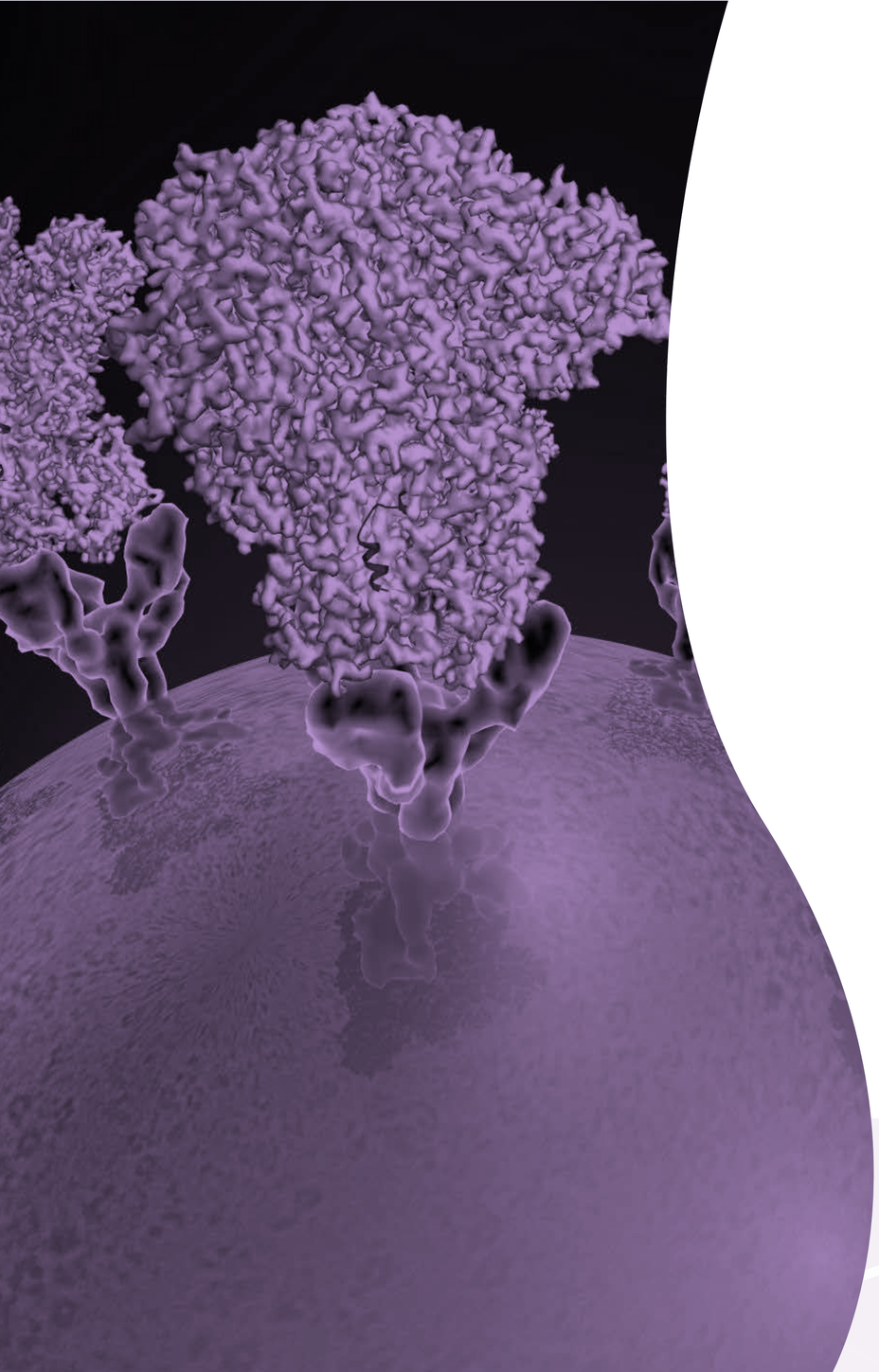
“Beware of Fraudulent Coronavirus Tests, Vaccines and Treatments”

FDA

The Challenge

The challenge is to offer the population, and especially the frontline health workers, extra protection against the novel coronavirus and its strains, also avoiding the potentiation of any cytokine storm. The path to follow, then, would be oriented in the direction of the development of a synthetic molecule that would be a replication of a molecule of our innate immune system with proven and effective antiviral capacity, and, mainly, bypassing any fatal hyperinflammatory biological response the path proposed.





MBL: A new beginning

Since 1998 a staff of Brazilian scientists from University of Pernambuco, Brazil, have been studying a human serum protein with antiviral properties called Mannose-Binding Lectin (MBL), demonstrating its high potential of use in clinical medicine. Such studies present the high capacity of this molecule to fight several respiratory viruses, including Influenza and even SARS-CoV-1 (predecessor of SARS-CoV-2, the COVID-19 virus).

AMPARO®: An Innovative approach

AMPARO® is an innovative approach that will interrupt the binding of viral particles to the target tissue or cell by interference before or after the viral adhesion process. Biocompatible nanoparticles functionalized with a recombinant human mannose-binding lectin (rhMBL) assume a nanostructured platform (AMPARO) capable of binding to various microorganisms with greater avidity, avoiding over-stimulation of the immune response.

The proposal

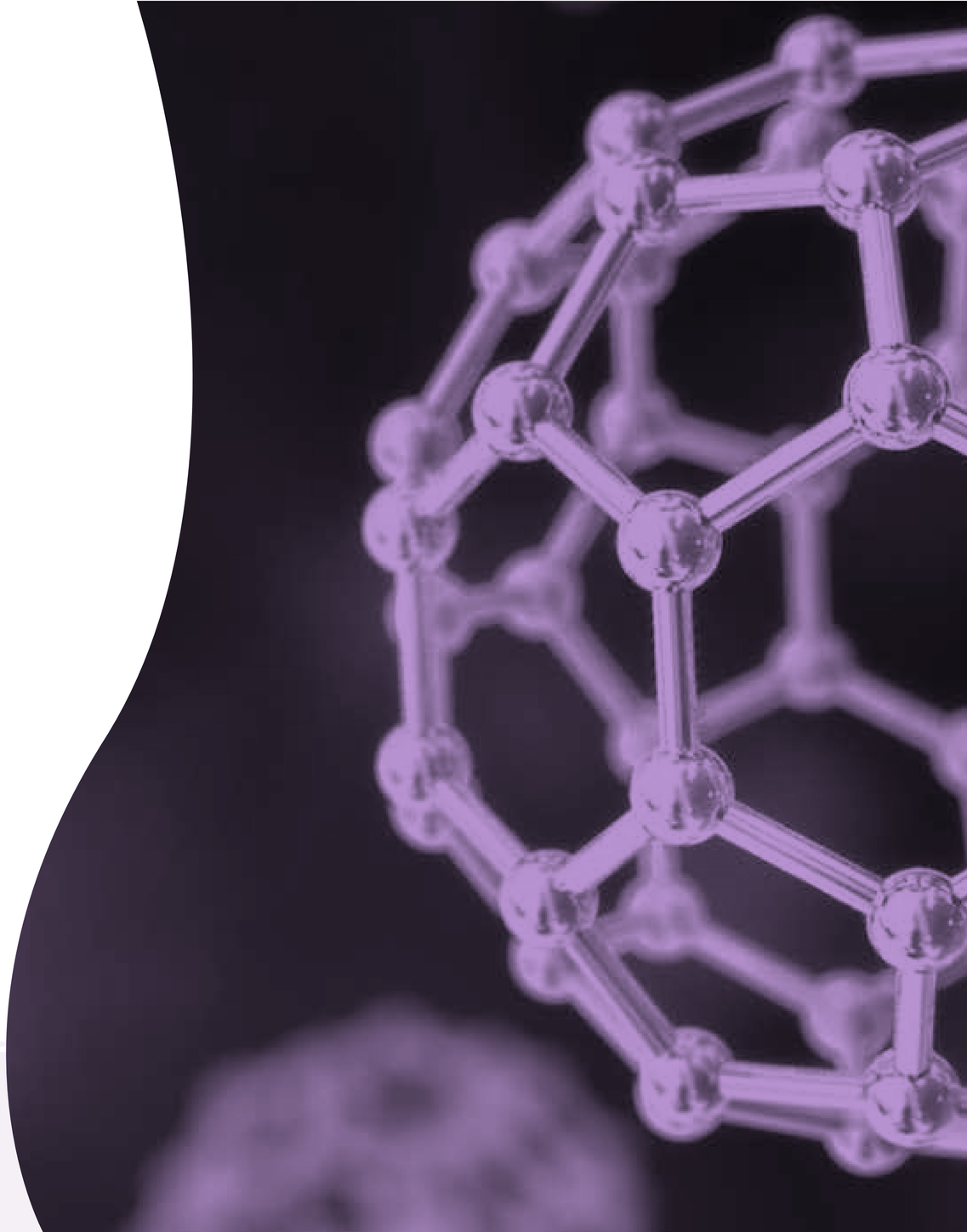
The medication will use nanotechnology for smart drug release and will be administered by aerosol, with the support of a spacer, enabling direct contact of the molecule with the virus right at the upper airways. Thus, synthetic MBL would scan the virus through medication, giving the body time to restore itself to its normal homeostasis. Since it will act right at the upper airways, a noticeable reduction of contamination by bioaerosol (suspended microorganisms in the air) with virus particles, including SARS-CoV-2, is expected. Therefore, preventive MBL therapy can reduce the rates of environmental contamination.

What Technology is behind AMPARO®?

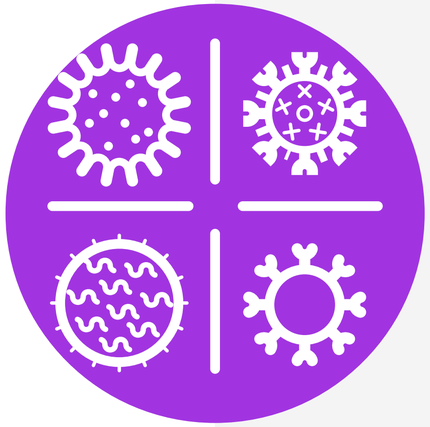
MBL is a plasma protein constituent of the immune system with roles in the human body protection against several infections caused by viruses, bacteria and parasites. One of the main roles of MBL is scavenge cellular debris avoiding overstimulation of the immune system. The actual use of MBL as a purified product from human plasma presents two problems, instability and the adverse effect of super stimulation of the immune response, which limits its use in clinical context.

Technology

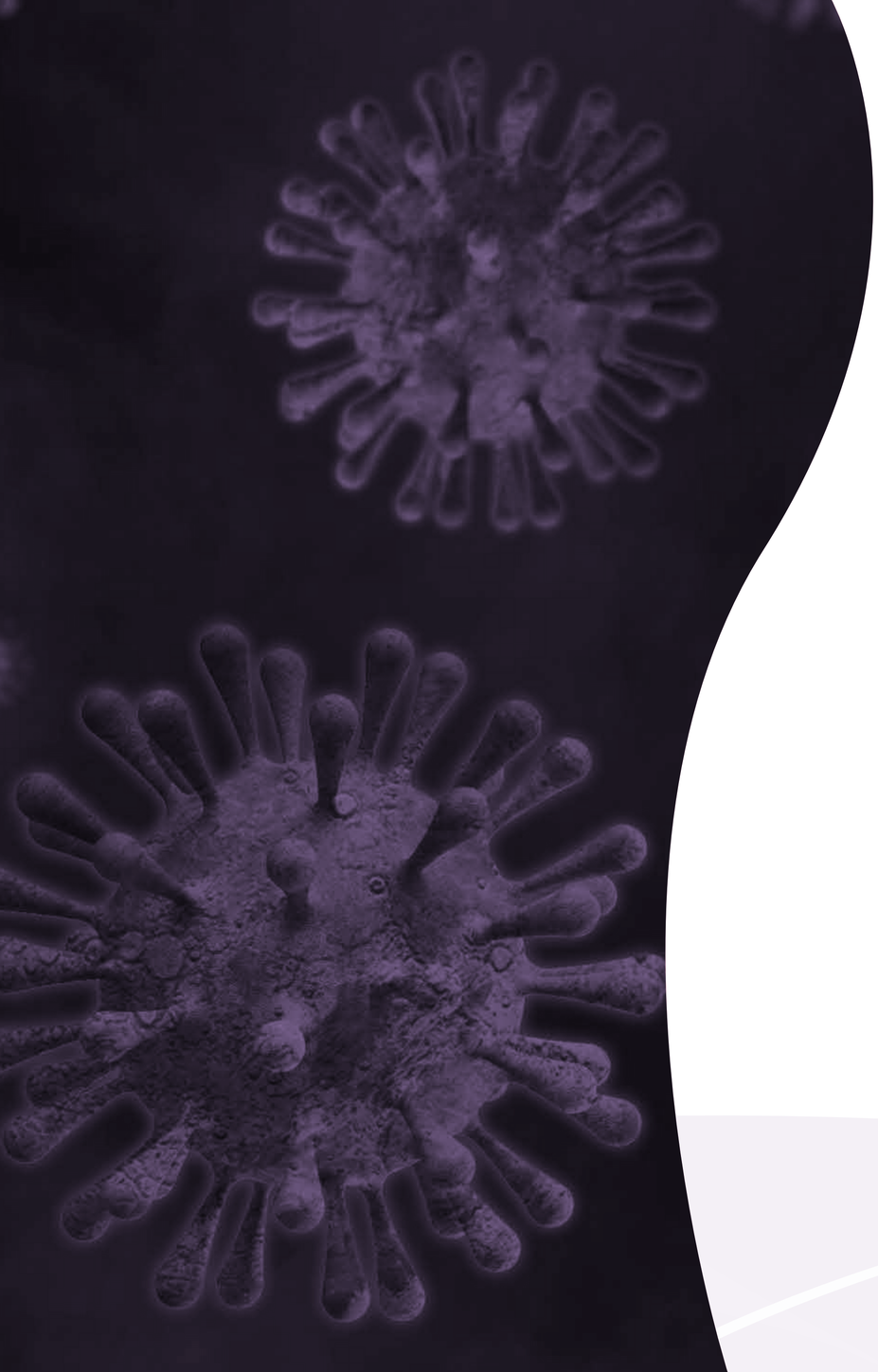
The AMPARO formulation is composed of a synthetic rhMBL that does not activate the complement pathway avoiding the adverse effects. Stability of the AMPARO formulation is furthered by being combined with a (FDA approved) PLGA nanoparticle with a high rate of biodegradability, biocompatibility that is also totally programable for timed medicine release.



Broad-spectrum antimicrobial effect



Disease caused by virus, bacteria or dysfunctions of the immune system generally involves a common and unique system, the complement system (CompS). The activation of the CompS may prevent or exacerbate injury during biological process of infectious or physiological origin. Therefore, AMPARO would be the best approach to solve this task.



1 | Acute viral infection

Acute viral infection leads to the inflammation of the airways with consequent respiratory distress related to the activation of complement against viruses. Although, the complement is important line of defense, the uncontrolled activation may result in severe disease progression. Then, AMPARO will bind to the virus arresting the virus ligands of the lectin complement pathway and simultaneously inhibiting the lectin pathway and inactivating the virus.

- **SARS-CoV-1 and SARS-CoV-2[1]**
- **Influenza[2]**
- **Respiratory Syncytial Virus (RSV)[3]**

2 | Bacterial etiology

Staphylococcus aureus is a Gram-positive bacterial pathogen that is recognized by serum antibodies and a variety of pattern recognition molecules, including mannose-binding lectin (MBL). S. aureus has acquired resistance to the majority of clinically used antibiotics; methicillin-resistant S. aureus strains (MRSAs) show multiple drug resistance and have spread through hospitals and communities all over the world; and an effective vaccine has not yet been developed.

Pseudomonas aeruginosa and S. aureus are the two most common causes of chronic wound infections and are frequently found together. Evidence suggests that dual P. aeruginosa and S. aureus infections are more virulent and/or result in worse patient outcomes than single infections and both species are notorious for their resistance to antimicrobials [4].

The impact of wound infections on health care is enormous. Infections of the dermis, including burns, surgical-site infections, and nonhealing diabetic foot ulcers, affect approximately 2 million people, cause >200,000 deaths, and account for more than $18 billion in direct medical costs in the United States annually [5].

Of Joseph PB&T Private:

Making groundbreaking R&D solutions possible.

Of Joseph PB&T Private is a wealth management and private equity investment company that provides financial backing and makes investments in the private equity on startups or operating companies through a variety of investment strategies. The company also performs the functions of a family office and provides advisory, financial planning, portfolio management, and other aggregated financial services to related parties and associates. The company's business operations are carried out from independently operated offices located in the Americas and Europe.

For more than 20 years Of Joseph PB&T has invested significant resources on R&D solutions for Cancer, HIV-AIDSs, respiratory and cardiovascular diseases, life extension and looks after an actively managed portfolio of companies (SPV's).

How we do it?

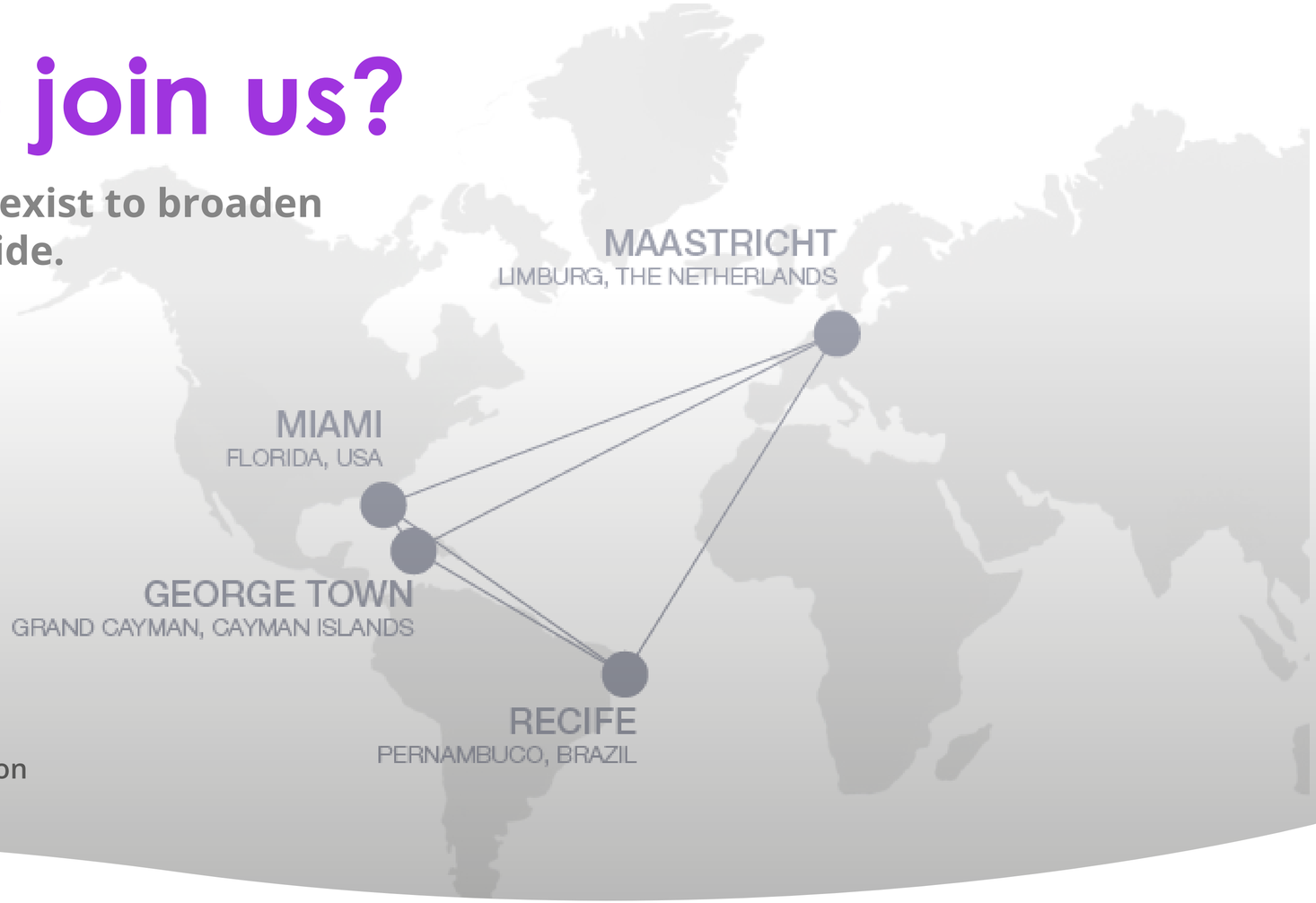
PEIXE ROSA Program | The power of partnership

It’s a network to promote research on life sciences, with the purpose of enabling the onception of innovative products in a duly regulated manner and in conditions to be legally marketed in the pharmaceutical market. Its structuring is based on the construction of strategic partnerships through the local installed capacity of excellent and highly specialized research centers, agencies and public health agencies, in support of the development of tests (such as proofs of concept and clinical trials), in monitoring of regulation and standardization processes, and in the design of a product marketing model with the client pharmaceutical company, enabling their access to the market. Amparo is a Peixe Rosa supported collaborative effort including the following organizations and their affiliates.

Would you like to join us?

Investment and partnership opportunities exist to broaden accreditation and product delivery worldwide.

- Americas
- Asia Pacific
- Europe
- Middle East
- Africa



* Limited opportunity. Please contact us for additional information

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Further reading

[1] Di Maria E, Latini A, Borgiani P, Novelli G. Genetic variants of the human host influencing the coronavirus-associated phenotypes (SARS, MERS and COVID-19): rapid systematic review and field synopsis. Hum Genomics. 2020 Sep 11;14(1):30. doi: 10.1186/s40246-020-00280-6. PMID: 32917282; PMCID: PMC7484929.

[2] Levy ER, Yip WK, Super M, Ferdinands JM, Mistry AJ, Newhams MM, Zhang Y, Su HC, McLaughlin GE, Sapru A, Loftis LL, Weiss SL, Hall MW, Cvijanovich N, Schwarz A, Tarquinio KM, Mourani PM; PALISI PICFLU Investigators, Randolph AG. Evaluation of Mannose Binding Lectin Gene Variants in Pediatric Influenza Virus-Related Critical Illness. Front Immunol. 2019 May 8;10:1005. doi: 10.3389/fimmu.2019.01005. PMID: 31139182; PMCID: PMC6518443.

[3] Ribeiro LZ, Tripp RA, Rossi LM, Palma PV, Yokosawa J, Mantese OC, Oliveira TF, Nepomuceno LL, Queiróz DA. Serum mannose-binding lectin levels are linked with respiratory syncytial virus (RSV) disease. J Clin Immunol. 2008 Mar;28(2):166-73. doi: 10.1007/s10875-007-9141-8. Epub 2007 Oct 20. PMID: 17952574.

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[5] Wolcott RD, Rhoads DD, Bennett ME, Wolcott BM, Gogokhia L, Costerton JW, Dowd SE. 2010. Chronic wounds and the medical biofilm paradigm. J. Wound Care 19:45–46, 48–50, 52–53. 10.12968/jowc.2010.19.2.46966.

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