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A PowerPoint presentation of the Cruzivax project website

Vaccine for Prevention and Treatment of *Trypanosoma cruzi* Infection (CRUZIVAX)

September 2019

Version 1

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This project has received funding from the European Union's Horizon 2020 research and innovation programme

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Project coordinator	Prof. Carlos A. Guzmán, HZI, Germany
EC Project Officer	Patricia Urban Lopez

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A website will be established to present the project, but also contain a secure area for internal project affairs. The website will be updated regularly.

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cruziva(X)

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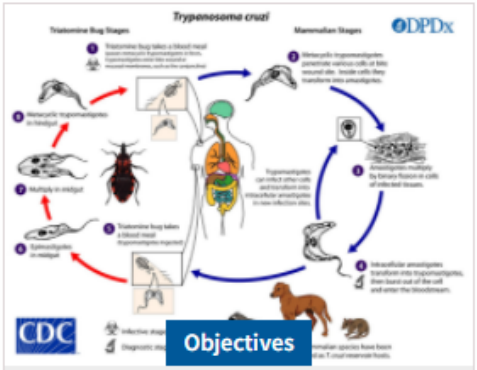
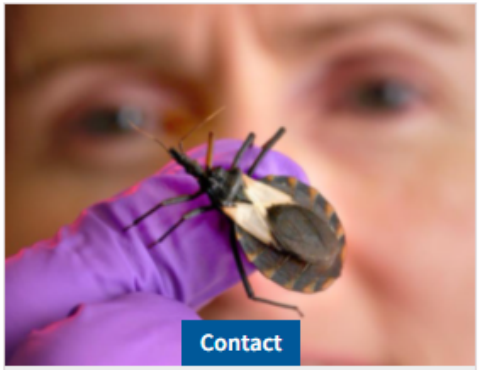


The strategic goal of the CRUZIVAX project.



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Objectives

The strategic goal of the CRUZIVAX project is to develop Traspain as a prophylactic intranasal needle-free vaccine candidate adjuvanted with c-di-AMP against *Trypanosoma cruzi* infection

Chagas is a neglected disease endemic in 21 Latin-American countries caused by *Trypanosoma cruzi*. It is the largest parasitic disease burden in the Americas (>11,000,000 chronic infections) and the first cause of cardiac morbidity in poor rural/suburban areas. It became a worldwide concern as a result of mass migration with reports in 19 non-endemic areas (>1.3 million carriers in EU/USA). Treatment is difficult since acute infections have mild symptoms and remain largely unnoticed evolving to chronicity. Drug therapy is also long, often associated with side effects (10-30% interruption) and only active during early infection. The main objective of CRUZIVAX is to bridge the gap between preclinical and clinical development by performing preclinical and clinical phase 1 studies of a needle-free vaccine against *T. cruzi* with proven efficacy in preclinical models. The vaccine is based on a structure-engineered trivalent chimeric antigen lacking immune decoy sequences and an adjuvant (c-di-AMP) promoting self-limited locally-restricted immune activation stimulating humoral and cellular immunity, which is expected to protect as prophylactic or therapeutic (combined with Benznidazole) vaccine. To achieve this CRUZIVAX will: (i) conduct preclinical studies to assess immunogenicity and efficacy of different vaccine formulations in prophylactic and therapeutic settings, (ii) produce cGMP antigen and adjuvant by cost-efficient manufacturing (facilitated uptake by health systems with limited resources), (iii) perform a preclinical safety assessment of the vaccine, (iv) conduct a phase 1 vaccine clinical trial in healthy volunteers, and (v) carry out a health economics analysis to identify critical target-product profile parameters. The vaccine will strengthen the pipeline of products for Chagas disease, aimed at reducing disease burden and its social and economic impact.

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Consortium

CRUZIVAX is a multinational integrated consortium composed of 3 Universities, 3 publicly-funded Research Institutes and 5 SMEs with access to cutting edge knowledge, technologies and expertise in commercial exploitation. The partners are located in 6 European countries and in Argentina. The partners integrated into the CRUZIVAX consortium have multidisciplinary expertise, resources and technologies enabling to specifically address the requirements of the project, guaranteeing its success chances. Their selection and subsequent inclusion in CRUZIVAX was strictly based on their scientific and/or technical excellence, as well as their excellent track record as "good performers" in previous networks and R&D projects. Indeed, most of the partners within CRUZIVAX have previous collaborations within national and international networks, which further demonstrate their capacity to work together in a productive and synergistic manner. The integration of their complementary competences and resources within CRUZIVAX has created a true added value chain, which will enable to maximise the output. This will enable CRUZIVAX to reach the main strategic goal and specific objectives of the project by successfully addressing all the project tasks and achieving the proposed deliverables.

- Helmholtz Centre for Infection Research (HZI)
- Universidad de Buenos Aires (UBA)
- Universidade Nova de Lisboa (UNL)
- Commissariat à l'Energie Atomique et aux Energies Alternatives (CEA)
- Instituto de Biologia Experimental e Tecnológica (iBET)
- GenIbet Biopharmaceuticals (GenIbet)
- ASA Spezialenzyme GmbH
- ATRC Aurigon Toxicology Center Ltd. (ATRC)
- Center for the Evaluation of Vaccination (CEV)
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Helmholtz Centre for Infection Research (HZI)

HZI HELMHOLTZ Centre for Infection Research

The **Helmholtz Centre for Infection Research (HZI)** in Braunschweig is a publicly funded research centre with more than 800 employees and an annual budget of approximately 90 million Euros as well as an additional approximately 19 million Euros of external funds from national and international support programmes, and industry. The focus of its activities lies on the field of infection. The mission of the HZI is to rise to the societal challenges of infectious diseases by investigating their fundamental pathogenesis mechanisms, with the aim of deriving innovative approaches for their prevention, diagnosis and therapy. The HZI is also member of the German Centre for Infection Research (35 research institutions located at seven sites), being the managing office located at the HZI campus.

Main roles in project

The HZI will be responsible for the overall coordination of the project. The HZI will also contribute to the scientific tasks by providing expertise and technologies in the fields of vaccinology, immunology and adjuvants. More specifically, the HZI will evaluate the immunogenicity of the Traspain-based vaccine against *T. cruzi* in a preclinical setting in the model organism mouse, and evaluate the immunogenicity of the vaccine, in terms of both innate and adaptive immune responses, in the clinical trial vaccinees.

Contact: Prof. Carlos A. Guzmán

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Universidad de Buenos Aires (UBA)

The **Universidad de Buenos Aires (UBA)** is one of the three largest and more important Universities in Latin America. Founded 1821 in the city of Buenos Aires, Argentina, it consists of 13 Faculties, 6 hospitals, 10 museums and is linked to 4 high schools. The project will be conducted in the *Instituto de Estudios de la Inmunidad Humoral Dr. RA Margni* (IDEHU), which is an important Immunology Institute that belongs to UBA and CONICET. It has approximately 35 young and senior researchers, 42 PhD students and 12 technicians. The scientific activities in IDEHU are dedicated to: (i) research, development and validation of vaccines against neglected tropical diseases, including Chagas disease and leishmaniasis; (ii) elucidating the mechanisms of host response to cancer and infection; and (iii) developing integrated technics for detection and diagnostic based in multiplex systems analysed by cytometry and Surface Plasmon Resonance (SPR).

Main roles in project

UBA will be responsible for the experimental work with the mice model and the efficacy of Traspain+CDA vaccine against *T. cruzi* in both prophylactic and therapeutic settings, with and without benznidazol. UBA will also contribute by providing expertise and technologies in the fields of parasite management, vaccinology and immunology, supervising infection in both dogs and non-human primates and will analyse the affinity of antibodies in preclinical and clinical studies by SPR. In addition, UBA will supervise the health-related quality of life associated with Chagas disease and estimation of the potential demand for Traspain-based vaccine in endemic areas of Argentina.

Contact: Prof. Emilio L. Malchiodi

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Universidade Nova de Lisboa (UNL)

DESDE 1902
INSTITUTO DE HIGIENE E
MEDICINA TROPICAL
UNIVERSIDADE NOVA DE LISBOA

The *Instituto de Higiene e Medicina Tropical* (IHMT) founded in 1902 is a unit of the **Universidade Nova de Lisboa (UNL)** and has been at the forefront of research on tropical diseases, often within networks and partnership projects. IHMT-NOVA hosts research and development programs of global health and tropical medicine, tackling neglected and emerging diseases under a multidisciplinary integrated approach ranging from the molecular level to global health systems. The research work is closely linked to 6 MSc (https://www.ihmt.unl.pt/course-type/mestrados/) and 6 PhD (https://www.ihmt.unl.pt/course-type/doutoramentos/) programs. IHMT-NOVA aims to contribute to eliminating extreme poverty, defending the principles of human dignity, equality, and equity, reducing the burden of diseases of poverty and promoting sustainable development.

Main roles in project

IHMT-NOVA is responsible for the preclinical studies performed in *T. cruzi*-dog model. Dogs which are *T. cruzi* hosts can develop Chagas disease when naturally infected. IHMT-NOVA will investigate the safety, immunogenicity, and efficacy of CDA-adjuvanted Traspain as a prophylactic vaccine against Chagas disease in dogs, and the therapeutic effectiveness of Traspain in controlling *T. cruz* infection. Infection progress and immunopathology will be evaluated in vaccinated and treated dogs, including the characterization of innate, humoral, and cellular immune response developed by *T. cruzi*-infected, Traspain immunized, and Traspain treated dogs.

Contact: Prof. Gabriela Santos-Gomes

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Commissariat à l'Energie Atomique et aux Energies Alternatives (CEA)

Commissariat à l'Energie Atomique et aux Energies Alternatives (CEA) employs 15,300 people and is active in three main fields: energy, information and health technologies, defence and national security. The Fundamental Research Directorate is in charge of health research and related technologies and includes the "Institut de Biologie François Jacob", hosting the "Infectious Disease Models for Innovative Therapies" (IDMIT) Department headed by Dr. Roger Le Grand. IDMIT's mission is to provide the academic and industrial scientific community with state-of-the-art expertise, facilities and technologies for pre-clinical studies, particularly through the development of non-human primate models of human infectious diseases and immune disorders.

Main roles in project

CEA will evaluate the immunogenicity and efficacy of the CRUZIVAX candidate vaccine in non-human primates, using immune monitoring as well as cutting-edge mass cytometry (CyTof) and *in vivo* imaging technologies.

Contacts: Dr. Isabelle Mangeot and Dr. Camille Bouillier

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Instituto de Biologia Experimental e Tecnológica (iBET)

iBET
Instituto de Biologia Experimental e Tecnológica

The **Instituto de Biologia Experimental e Tecnológica (iBET)** is a private non-profit institution specialized in biology research and drug discovery/bioprocess development services. As a Biotechnology Research Organization iBET acts as an interface between academic and private institutions while also creating and organizing autonomous knowledge and expertise. iBET works in a broad range of fields that encompass multidisciplinary approaches ranging from basic, technological to clinical and translational research. Our expertise encompasses the development of complex biopharmaceuticals and novel therapies which include vaccines, recombinant proteins and viral vectors for gene therapy, the development of *in vitro* models and methodologies for pre-clinical research and stem cells for cell therapy applications; structural biology for assisted drug design, research and technology development in the area of food and health with a particular emphasis in by-products and waste valorisation technologies; water, environment and energy nexus, and agro-forestry.

Main roles in project

iBET will support the Cruzivax project by providing expertise and technologies in the fields of bioengineering and process/product monitoring and control. Specifically, iBET will be responsible for (i) establishing the analytical techniques for Traspain characterisation, (ii) production of GLP-grade Traspain for preclinical immunogenicity and efficacy studies in dog and NHP animal models as well as for GLP-toxicology studies, and (iii) technology transfer to cGMP production.

Contacts: Prof. Manuel Carrondo & Dr. Antonio Roldao

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GenIbet Biopharmaceuticals (GenIbet)

GenIbet Biopharmaceuticals (GenIbet) is a GMP CDMO offering highly specialized GMP manufacturing and development services to research groups, Biotech and Pharma companies. GenIbet core activity is the manufacture and supply of materials for use in early stage drug development, pre-clinical studies and GMP manufacturing for clinical trials.

GenIbet runs projects within a very broad spectrum, including not only Cell and Gene Therapy products, but also Recombinant proteins, Vaccines, *RNA* and Live Microbial Products.

The GenIbet team has experience with mammalian, avian and insect cells, bacteria & yeasts and Viruses and a proven track record with A549, CAP, CHO, EB66, HEK293, SF9, MDCK, Vero, *E. coli*, *Pichia pastoris*, Baculovirus and Adenoviruses.

Our mission is to manufacture safe and reliable breakthrough products to support worldwide costumers on building the therapies of the future. We offer a unique combination of strict GMP compliance and troubleshooting/problem solving mindset which is crucial for early stage product development and believe on tailor made solutions for each specific product.

Main role in the project

GenIbet will be responsible for the GMP production of a Master Cell Bank (MCB) of *Escherichia coli* BL21 and of the Traspain Drug Substance for a phase 1 clinical trial. The GMP MCB will be used throughout process development and in the production of Traspain for the toxicology and clinical lot. For the clinical lot, a Master Batch Processing Record will be prepared, detailing all steps of the manufacturing process, which will be used in the cGMP production of the clinical batch and will be included for the IND submission.

Contact : Ana Alves

This project has received funding from the European Union's Horizon 2020 research and innovationprogramme under grant agreement No 815418.

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ASA Spezialenzyme GmbH

Business activities at **ASA Spezialenzyme GmbH** are the development and production ofenzymes, microbial mixed cultures and other biotechnological products.The product range covers the fields of application food and feed processing, pharmaceutical enzymes organic synthesis, analytics, biosensors, bioenergy, textile industry and paper industry. Furthermore ASA offers services as contract research and contract manufacturing.Since the foundation in the year 1991, several research projects were carried out in the area ofenzymatic conversion of ingredients for food applications, pharmaceutical purposes and renewable raw materials resulting in new marketable products.

Main roles in project

ASA will be responsible for the production of GLP- and GMP-grade CDA for preclinical and clinical studies. Further tasks are the development of adjuvant formulation and the implementation of stabilitests with CDA and Traspain. Finally a filling facility for liquid forms of adjuvant and vaccine will be set up in order to provide all project partners with the necessary quantities of CDA and vaccine.

Contact: Dr. Arno Cordes

This project has received funding from the European Union's Horizon 2020 research and innovationprogramme under grant agreement No 815418.

ATRC Aurigon Toxicology Center Ltd. (ATRC)

ATRC Aurigon Toxicology Center Ltd. (ATRC) is the research facility of the Aurigon Group, which was established in 2000 as an independent, privately-owned contract research institute dedicated to preclinical services for human and veterinary pharmaceuticals, food and chemicals. ATRC has more than 65 highly educated staff members with experience up to 3 decades in non-clinical research and drug development. ATRC provides a full range of advisory and experimental services in pharmacology, bio-/analytics and toxicology. Ranging from early-phase product efficacy and safety evaluation to regulatory toxicology and late-stage pre-marketing testing, we cover all areas of non-clinical drug development. ATRC operates state-of-the-art GLP- and/or GMP-compliant facilities in Dunakeszi (north border of Budapest) and in Budapest itself.

Main roles in project

ATRC will provide the relevant non-clinical GLP studies and assays for the non-clinical safety evaluation of the selected Traspain vaccine candidate (with and without CDA adjuvant) in the required rodent or non-rodent species, which are needed for the IND/CTA to support the clinical translation. As a final deliverable, a complete non-clinical toxicological evaluation of the different vaccine doses in the selected species will be presented in a study report.

Contact: Dr. Istvan Novak and Sigrid Messemer

This project has received funding from the European Union's Horizon 2020 research and innovationprogramme under grant agreement No 815418.

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Center for the Evaluation of Vaccination (CEV)

Centre for the Evaluation of Vaccination
Vaccine & Infectious Disease Institute
University of Antwerp

The **Center for the Evaluation of Vaccination (CEV)** of the University of Antwerp, headed by Prof. Pierre Van Damme, was founded in 1994. It has until present conducted more than 380 vaccine trials (phase 1-4) with a variety of vaccines and in all age groups. Furthermore, CEV has conducted more than 60 policy research projects related to vaccination. It has published more than 400 peer reviewed papers. The Center has been recognised by the World Health Organization as a *WHO* Collaborating Center for the control and prevention of viral hepatitis and more recently for the control and prevention of infectious diseases. CEV provides state-of-the-art infrastructure for the conduct of vaccine studies. The research mission of CEV is to improve knowledge on all aspects of vaccination and to support vaccination policy making.

Main roles in the project
The Center will provide support to all Phase I clinical trial preparatory activities to assess the safety, reactogenicity, tolerability and immunogenicity of the Traspain-based vaccine against *T. cruzi*. The Center will conduct the Phase I clinical trial including subject recruitment, vaccine administration, assessment of safety and tolerability and biological sampling for immune response. Furthermore, it will provide support for the analysis of clinical parameters and for the clinical study report.

Contact: Prof. Pierre Van Damme

This project has received funding from the European Union's Horizon 2020 research and innovationprogramme under grant agreement No 815418.

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Home > Consortium > Barcelona Institute for Global Health (ISGlobal)

Barcelona Institute for Global Health (ISGlobal)

The **Barcelona Institute for Global Health (ISGlobal)** is a cutting-edge institution with capacity to address global public health challenges through research, translation and education, with 385 members from 31 different countries. ISGlobal has a broad research portfolio in communicable and non-communicable diseases with special attention to environmental health determinants. Research is organized in 9 different programs: Air Pollution and Urban Environment; Chagas, Parasitic and other Imported Diseases; Childhood and Environment; Climate and Health; *Malaria*, *HIV* & TB; Maternal, Child and Reproductive Health; Radiation; NCDs and Environment; Viral and Bacterial Infections. ISGlobal's approach is multidisciplinary, ranging from the molecular to the population level and including disciplines across health sciences, life sciences, environmental, social, economic and climate sciences. ISGlobal is an affiliated institute to the University of Barcelona and to the University Pompeu Fabra.

Main roles in the project

ISGlobal will be responsible for the economic-oriented WPs in this project. The multidisciplinary team is composed by: Elisa Sicuri, Maria Jesús Pinzaso, Celine Aerts (ISGlobal), Paula Sartor (Norwest National University of Argentina), Hector Freilij (Hospital de Niños Ricardo Gutiérrez, Buenos Aires), Emilio Malchiodi (University of Buenos Aires). The team will estimate the potential demand for the CRUZIVAX vaccine candidate and the quality of life associated with Chagas disease in both endemic (Chaco, Argentina) and non-endemic areas (Barcelona, Spain). The team will also estimate life-long cost-of-illness associated with Chagas disease through analysing the use of healthcare resources (and relative costs) of Chagas disease patients in Barcelona. This estimate represents the potential savings to the health system that may arise from the CRUZIVAX Chagas disease vaccine candidate implementation.

Contact: Dr Elisa Sicuri

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Vakzine Projekt Management GmbH (VPM)

Vakzine Projekt Management GmbH

Vakzine Projekt Management GmbH (VPM), founded in 2002, is a privately held company in the field of biomedical research and development. Within the last decade, VPM has been successfully developing promising biopharmaceutical candidates. Additionally, VPM offers tailor-made hands-on services and consultancy to biopharmaceutical enterprises, private funding organizations and research groups, based on their in-depth experience and a strong network of reliable partners. VPM has acted as sponsor or sponsor-representative for more than 15 clinical trials. Since July 2018 Serum Institute of India (SIIPL) is majority shareholder of VPM.

Main roles in project

VPM will support the Cruzivax project with their expertise in translational project management. Furthermore, VPM will be responsible for GxP consulting in the areas chemistry, manufacturing and control (CMC), and non-clinical and clinical development of the Traspain-based vaccine against *T. cruzi*. VPM has extensive experience with the conduct of regulatory/scientific advice meetings with national competent authorities. Therefore, VPM will perform, including the preparation, conduct and follow up, two scientific advice meetings with the national regulatory authority of Belgium. VPM will also act as sponsor (according to ICH E6 (R2) and Directive 2001/20/EC) of the phase 1 clinical trial.

Contact: Dr. Leander Grode

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CRUZIVAX Zenodo Community
On March 27th, 2021 the project established a Zenodo Community for providing open access to the project's results.
https://zenodo.org/communities/cruzivax/
CRUZIVAX 2nd consortium meeting
The project conducted its second consortium meeting on March 3rd, 2021. It was also attended by the project's Scientific Advisory Board. Because of the COVID pandemics, it was necessary to conduct it virtually.
CRUZIVAX kick-off meeting
The consortium conducted its kick-off meeting June 26th-27th, 2019 in Frankfurt, Germany. Along with the partners getting to know each other better, the agenda included an overview of Chagas disease and presentations and discussion of the work to be conducted during the first 18 months.
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Contact

For all enquiries concerning CRUZIVAX please do not hesitate to contact:

Prof. Carlos A. Guzmán (coordinator)
Helmholtz Centre for Infection Research
Inhoffenstr. 7
38124 Braunschweig
Germany

Prof. Emilio Malchiodi (deputy coordinator)
Instituto de Estudios de la Inmunidad Humoral
Facultad de Farmacia y Bioquímica, UBA
Junín 956, 4to P Inmunología
1113 Buenos Aires
Argentina

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Imprint according to the following German regulations: § 6 TDG, § 10 MDStV

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Registration Number: HRB 477

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Silke Tannapfel, Administrative director
(address like above)

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Corporate Governance:

The Helmholtz Centre for Infection Research GmbH submits to the "Public Corporate Governance Code (PCGC)" of the federal government according to the memorandum of association. The Code recommends that the management and the supervisory board reports on the Company's corporate governance (Corporate Governance Report) on an annual basis.

The report refers to the PCGK as constituted on 30th of June 2009. Management and Supervisory Board declare that the recommendations of the Code are being complied essentially and will, deviations are explained in the respective report.

The Management Board and Supervisory Board declare that the Federal Public Corporate Governance Code as amended on 30 June 2009 has been complied with with reasonable deviations from the prescribed recommendations.

- PCGK-Report 2011
- PCGK-Report 2012
- PCGK-Report 2013
- PCGK-Report 2014
- PCGK-Report 2015
- PCGK-Bericht 2016
- PCGK-Bericht 2017

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Bitmotion GmbH, Hanover. Bitmotion is TYPO3 Agency Business Partner and TYPO3 Association GOLD Member.

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Privacy

Data controller contact information
The responsible party pursuant to the European General Data Protection Regulation (GDPR), other national data protection laws of Member States and other provisions of data protection law is:

Helmholtz Centre for Infection Research GmbH
Inhoffenstraße 7
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Website: www.helmholtz-hzi.de

Represented by:
Prof Dirk Heinz (Scientific Director)
Silke Tannapfel (Administrative Director)

2. Data protection officer contact information
Data protection officer
Helmholtz Centre for Infection Research GmbH
Tel.: +49 531 6181 2050
Email: datenschutzbeauftragter@helmholtz-hzi.de

General data processing information

Scope of processing personal data
We process the personal data of our users only to the extent required for providing a functional website as well as our content and services. The processing of our users' personal data on a regular basis only takes place with consent of the user. Exceptions are such cases in which prior consent cannot be obtained for practical reasons and the processing of the data is permitted by legal regulations.

Legal basis for the processing of personal data
If we obtain the consent from the data subject for the processing of personal data, the legal basis is Article 6(1)(a) of the GDPR.

For the processing of personal data that is necessary for the performance of a contract to which the data subject is party, the legal basis is Article 6(1)(b) of the GDPR. This also applies to processing that is required for the implementation of pre-contractual measures.

Insofar as the processing of personal data is necessary for compliance with a legal obligation of our company, the legal basis is Article 6(1)(c) of the GDPR.

In the case that processing personal data is necessary to protect the vital interests of the data subject or another natural person, the legal basis is Article 6(1)(d) of the GDPR.

If processing is necessary for the purpose of a legitimate interest pursued by our company or by a third party, and the interests or fundamental rights and freedoms of the data subject do not override the above interest, then the legal basis for the processing is Article 6(1)(f) of the GDPR.

Data erasure and storage period
The personal data of the data subject is erased or blocked as soon as the purpose of the storage no longer applies. Storage beyond this point may take place if it is required by European or national legislation through Union regulations, laws or other directives with which the controller must comply. The data is also blocked or erased when a storage period prescribed by the aforementioned standards expires, unless further storage of the data is necessary for conclusion or performance of a contract.

Provision of the website and creation of log files

Description and scope of data processing
Upon each visit to our website, our system automatically collects data and information from the system of the visiting computer. The following data is collected:

1. Information about the browser type and version
2. The operating system of the user
3. The Internet service provider of the user
4. The IP address of the user
5. Date and time of access
6. Websites from which the user's system accesses our website
7. Websites accessed by the user's system through our website

The data is also stored in the log files of our system. This data is not stored together with other personal data of the user.

Legal basis for data processing
The legal basis for the temporary storage of the data and log files is Article 6(1)(f) of the GDPR (legitimate interest).

Purpose of data processing
The temporary storage of the IP address by the system is necessary to enable delivery of the website to the user's PC. The IP address of the user must remain stored for the duration of the session.
Storage in the log files is necessary to ensure the functionality of the website. This data is also used to optimise the website and to ensure the security of our information technology systems. The data is not evaluated for marketing purposes in this context.

These purposes also constitute our legitimate interest in data processing pursuant to Article 6(1)(f) of the GDPR.

Storage period
Data is deleted as soon as it is no longer required for achieving the purpose for which it was collected. In the case of data collection for provision of the website, this is done when the respective session ends.

If the data is stored in log files, this is done after seven days at the latest. Extended storage is possible. In this case, the IP addresses of the users are erased or modified so that these cannot be assigned to the client that accessed the site.

Objection and removal option
Collection of the data for provision of the website and the storage of data in log files is mandatory for the operation of the website. Therefore, the user does not have the option of objecting.

Use of cookies

Description and scope of data processing
Our website uses cookies. Cookies are text files that are stored in the Internet browser or by the Internet browser on the user's computer system. If a user accesses a website, a cookie can be stored on the user's operating system. This cookie contains a characteristic string of characters that allows for the clear identification of the browser when the website is accessed again.

We use cookies to make our website more user-friendly. Some elements of our website require the accessing browser to continue to be identified after switching to another page.

The following data is stored in and transmitted by the cookies:

1. Language settings
2. Login information

We also use cookies on our website that enable us to analyse users' surfing behaviour.

The user data collected in this manner is anonymised through technological measures. This ensures that it is no longer possible to assign the data to the user who accessed the site. The data is not stored together with any other personal data of the users.

When visiting our website, users are informed about the use of cookies for analytical purposes and their consent is obtained for the processing of the personal data used in this context. This also includes a reference to this privacy policy.

Legal basis for data processing
The legal basis for the processing of personal data using cookies that are technically necessary is Article 6(1)(f) of the GDPR (legitimate interest).

The legal basis for the processing of personal data using cookies for analytical purposes is the consent of the user pursuant to Article 6(1)(a) of the GDPR.

Purpose of data processing
The purpose of using technically necessary cookies is to simplify the use of websites for users. Some functions of our website cannot be offered without the use of cookies. For these functions, it is necessary that the browser is recognised even after switching pages.

We require cookies for the following applications:

1. Adopting language settings

The user data collected by the technically necessary cookies is not used to create user profiles. The analysis cookies are used for the purpose of improving the quality of our website and its contents. The analysis cookies provide information about how the website is used, allowing us to continually optimise our site.

These purposes also constitute our legitimate interest in processing the personal data pursuant to Article 6(1)(f) of the GDPR.

Storage period, objection and removal option
Cookies are stored on the user's computer and transmitted from there to our website. This means that you, as the user, also have full control over the use of cookies. You can deactivate or restrict the transmission of cookies by changing the settings in your Internet browser. Previously stored cookies can be deleted at any time. This can also take place automatically. If cookies are deactivated for our website, it is possible that the full functionality of the website may not be available.

Web analysis using Google Analytics

Description and scope of data processing
We use Google Analytics to analyse use of our website. The resulting data is used to optimise our website and advertising activities.

Google Analytics is a web analytics service operated and provided by Google Inc. (1600 Amphitheatre Parkway, Mountain View, CA 94043, United States). Google processes data on website usage on our behalf and is contractually bound to take measures to ensure the confidentiality of the processed data.

During your visit to our website the following data, inter alia, is recorded:

1. Pages visited
2. Your behaviour while viewing these pages (for example, clicks, scrolling, length of visit)
3. Your general location (country and city)
4. Your IP address (in shortened form, meaning that no direct assignment is possible)
5. Technical information, such as browser, Internet provider, end device and screen resolution
6. Source of your visit (i.e. the website or advertising medium through which you accessed our website)

This data is transferred to a Google server in the USA. Google complies with the privacy provisions of the EU-US Privacy Shield.

Legal basis for data processing
The legal basis for the processing of the data is Article 6(1)(f) of the GDPR (legitimate interest).

Purpose of data processing
Processing users' personal data enables us to analyse the surfing behaviour of our visitors, and evaluating the data we acquire enables us to gather information regarding the use of the individual components of our website. This helps us to continually improve our website and its user-friendliness. These purposes also constitute our legitimate interest in processing the data pursuant to Article 6(1)(f) of the GDPR. Anonymising the IP address sufficiently takes into account the users' interest in the protection of their personal data.

Storage period
Google Analytics stores cookies in your Internet browser for a period of two years after your last visit. These cookies contain a randomly generated user ID that can be used to recognise you on future visits to the website.

The recorded data is stored together with this randomly generated user ID, which enables the evaluation of anonymous user profiles. This user-related data is automatically deleted after 14 months. Other data remains stored indefinitely in an aggregated form.

Opting out of Google Analytics
If you do not agree with your data being collected, you can prevent this by installing the Google Analytics opt-out browser add-on.

Rights of data subjects

If your personal data is processed, you are a data subject according to the GDPR, and you have the following rights in relation to the controller:

1. Right to access
You may request confirmation from us as to whether or not your personal data is being processed by us. If that is the case, you can ask the controller for the following information:

1. the purposes for which the personal data is processed;
2. the categories of personal data that are being processed;
3. the recipients or categories of recipients to whom the personal data has been or will be disclosed;
4. the envisaged period for which the personal data will be stored, or, if specific information cannot be provided in this regard, the criteria used to determine that period;
5. the existence of the right to request from the controller rectification or erasure of your personal data, the right to restriction of processing of personal data by the controller or the right to object to such processing;
6. the existence of a right to lodge a complaint with a supervisory authority;
7. any available information as to the source of the data, if the personal data is not collected from the data subject;
8. the existence of automated decision-making, including profiling, referred to in Article 22(1) and (4) of the GDPR and, at least in those cases, meaningful information about the logic involved, as well as the significance and envisaged consequences of such processing for the data subject.
9. whether your personal data is transferred to a third country or to an international organisation. Where this is the case, you have the right to be informed of the appropriate safeguards pursuant to Article 46 of the GDPR relating to the transfer.

This right of access may be limited to the extent that this right is likely to render impossible or seriously impair the achievement of research or statistical purposes and such limit is necessary for the fulfilment of the research or statistical purposes.

2. Right to rectification
You have the right to obtain from the controller the rectification and/or completion of inaccurate or incomplete personal data concerning you. The controller must carry out the rectification without delay.

With regard to data processing for scientific, historical or statistical research purposes:

Your right to rectification may be limited to the extent that this right is likely to render impossible or seriously impair the achievement of research or statistical purposes and such limit is necessary for the fulfilment of the research or statistical purposes.

3. Right to restriction of processing

You have the right to obtain from the controller restriction of processing where one of the following applies:

1. if you contest the accuracy of your personal data, for a period enabling the controller to verify the accuracy of the personal data;
2. the processing is unlawful and you oppose the erasure of the personal data and request the restriction of its use instead;
3. the controller no longer needs the personal data for the purposes of the processing, but it is required by you for the establishment, exercise or defence of legal claims; or
4. if you have objected to processing pursuant to Article 21(1) of the GDPR pending the verification whether the legitimate grounds of the controller override yours.

Where processing of your personal data has been restricted, such data shall, with the exception of storage, only be processed with your consent or for the establishment, exercise or defence of legal claims or for the protection of the rights of another natural or legal person or for reasons of important public interest of the Union or of a Member State.

If you have obtained restriction of processing pursuant to the above conditions, you shall be informed by the controller before the restriction of processing is lifted.

With regard to data processing for scientific, historical or statistical research purposes:

Your right to restriction of processing may be limited to the extent that this right is likely to render impossible or seriously impair the achievement of research or statistical purposes and such limit is necessary for the fulfilment of the research or statistical purposes.

4. Right to erasure

Erasure obligation

You have the right to obtain from the controller the erasure of your personal data without undue delay and the controller has the obligation to erase this data without undue delay where one of the following grounds applies:

1. Your personal data is no longer necessary in relation to the purposes for which it was collected or otherwise processed.
2. You withdraw the consent on which the processing is based pursuant to Article 6(1)(a) or Article 9(2)(a) of the GDPR, and where there is no other legal ground for the processing.

3. You object to the processing pursuant to Article 21(1) of the GDPR and there are no overriding legitimate grounds for the processing, or you object to the processing pursuant to Article 21(2) of the GDPR.
4. The personal data has been unlawfully processed.
5. Your personal data has to be erased for compliance with a legal obligation in Union or Member State law to which the controller is subject.
6. Your personal data has been collected in relation to the offer of information society services referred to in Article 8(1) of the GDPR.

Information to third parties

Where the controller has made your personal data public and is obliged pursuant to Article 17(1) of the GDPR to erase the personal data, the controller, taking account of available technology and the cost of implementation, shall take reasonable steps, including technical measures, to inform controllers which are processing the personal data that you as the data subject have requested the erasure by such controllers of any links to, or copy or replication of, those personal data.

Exceptions

The right to erasure shall not apply to the extent that processing is necessary

1. for exercising the right of freedom of expression and information;
2. for compliance with a legal obligation which requires processing by Union or Member State law to which the controller is subject or for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller;
3. for reasons of public interest in the area of public health in accordance with Article 9(2)(h) and (i) as well as Article 9(3) of the GDPR;
4. for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89(1) of the GDPR in so far as the right referred to in paragraph a) is likely to render impossible or seriously impair the achievement of the objectives of that processing; or
5. for the establishment, exercise or defence of legal claims.

5. Right to information

If you have exercised the right to rectification, erasure or restriction of processing towards the controller, the controller shall communicate this rectification or erasure of personal data or restriction of processing to each recipient to whom the personal data has been disclosed, unless this proves impossible or involves disproportionate effort.

You have the right to be informed by the controller about those recipients.

6. Right to data portability

You have the right to receive your personal data that you have provided to a controller in a structured, commonly used and machine-readable format. You also have the right to transmit those data to another controller without hindrance from the controller to which the personal data has been provided, where

1. the processing is based on consent pursuant to Article 6(1)(a) or Article 9(2)(a) of the GDPR
2. the processing is carried out by automated means.

In exercising this right, you have the right to have your personal data transmitted directly from one controller to another, where technically feasible. This shall not adversely affect the rights and freedoms of others. The right to data portability shall not apply to the processing of personal data necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller.

7. Right to object

You have the right to object, on grounds relating to your particular situation, at any time to processing of your personal data based on Article 6(1)(e) or (f) of the GDPR, including profiling based on those provisions.

The controller shall no longer process your personal data, unless the controller demonstrates compelling legitimate grounds for the processing that override your interests, rights and freedoms or for the establishment, exercise or defence of legal claims.

Where your personal data is processed for direct marketing purposes, you have the right to object at any time to processing of your personal data for such marketing, which includes profiling to the extent that it is related to such direct marketing.

If you object to processing for direct marketing purposes, your personal data will no longer be processed for these purposes.

In the context of the use of information society services, and notwithstanding Directive 2002/58/EC, you may exercise your right to object by automated means using technical specifications.

With regard to data processing for scientific, historical or statistical research purposes:
You have the right to object, on grounds relating to your particular situation, to processing of your personal data for scientific or historical research purposes or statistical purposes pursuant to Article 89(1) of the GDPR.

This right to object may be limited to the extent that this right is likely to render impossible or seriously impair the achievement of research or statistical purposes and such limit is necessary for the fulfilment of the research or statistical purposes.

8. Right to withdraw the data protection declaration of consent

You have the right to withdraw your data protection declaration of consent at any time. The withdrawal of consent shall not affect the lawfulness of processing based on consent before its withdrawal.

9. Automated individual decision-making, including profiling

You have the right not to be subject to a decision based solely on automated processing, including profiling, which produces legal effects concerning you or

similarly significantly affects you. This shall not apply if the decision

1. is necessary for entering into, or performance of, a contract between the you and the controller,
2. is authorised by Union or Member State law to which the controller is subject and these laws contain suitable measures to safeguard your rights and freedoms and legitimate interests, or
3. is based on your explicit consent.

However, these decisions shall not be based on special categories of personal data referred to in Article 9(1) of the GDPR, unless Article 9(2)(a) or (g) applies and suitable measures to safeguard your rights and freedoms and legitimate interests are in place. In the cases referred to in points (1) and (3), the controller shall implement suitable measures to safeguard your rights and freedoms and legitimate interests, at least the right to obtain human intervention on the part of the controller, to express your point of view and to contest the decision.

10. Right to lodge a complaint with a supervisory authority

Without prejudice to any other administrative or judicial remedy, you have the right to lodge a complaint with a supervisory authority, in particular in the Member State of your residence, place of work or place of the alleged infringement if you consider that the processing of your personal data infringes the GDPR.

The supervisory authority with which the complaint has been lodged shall inform the complainant on the progress and the outcome of the complaint including the possibility of a judicial remedy pursuant to Article 78 of the GDPR.

The competent supervisory authority of the HZI is:
The Federal Commissioner for Data Protection and Freedom of Information
Husarenstraße 30
53117 Bonn, Germany
Tel.: +49 228 997799-0

HEADQUARTER

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