# Desarrollo de una agenda de investigación en temas prioritarios. El desarrollo tecnológico en torno al Zika.

Taller Regional Andino, Lima Perú,
Junio 26, 2017

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*Knowledge Management, Bioethics and Research*
*Pan American Health Organization*

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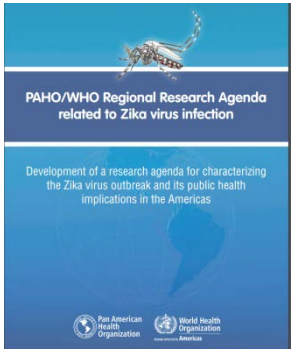
# Agendas de Investigación sobre Zika

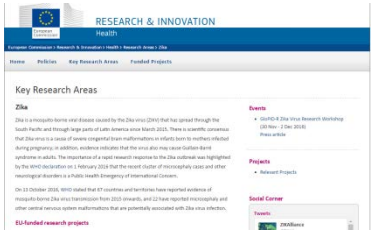









PRIORIDADES DE COOPERACIÓN INTERNACIONAL DEL SECTOR SALUD PARA COMBATIR EL VIRUS DEL ZIKA - **Ministerio de Salud y Protección Social - Colombia**





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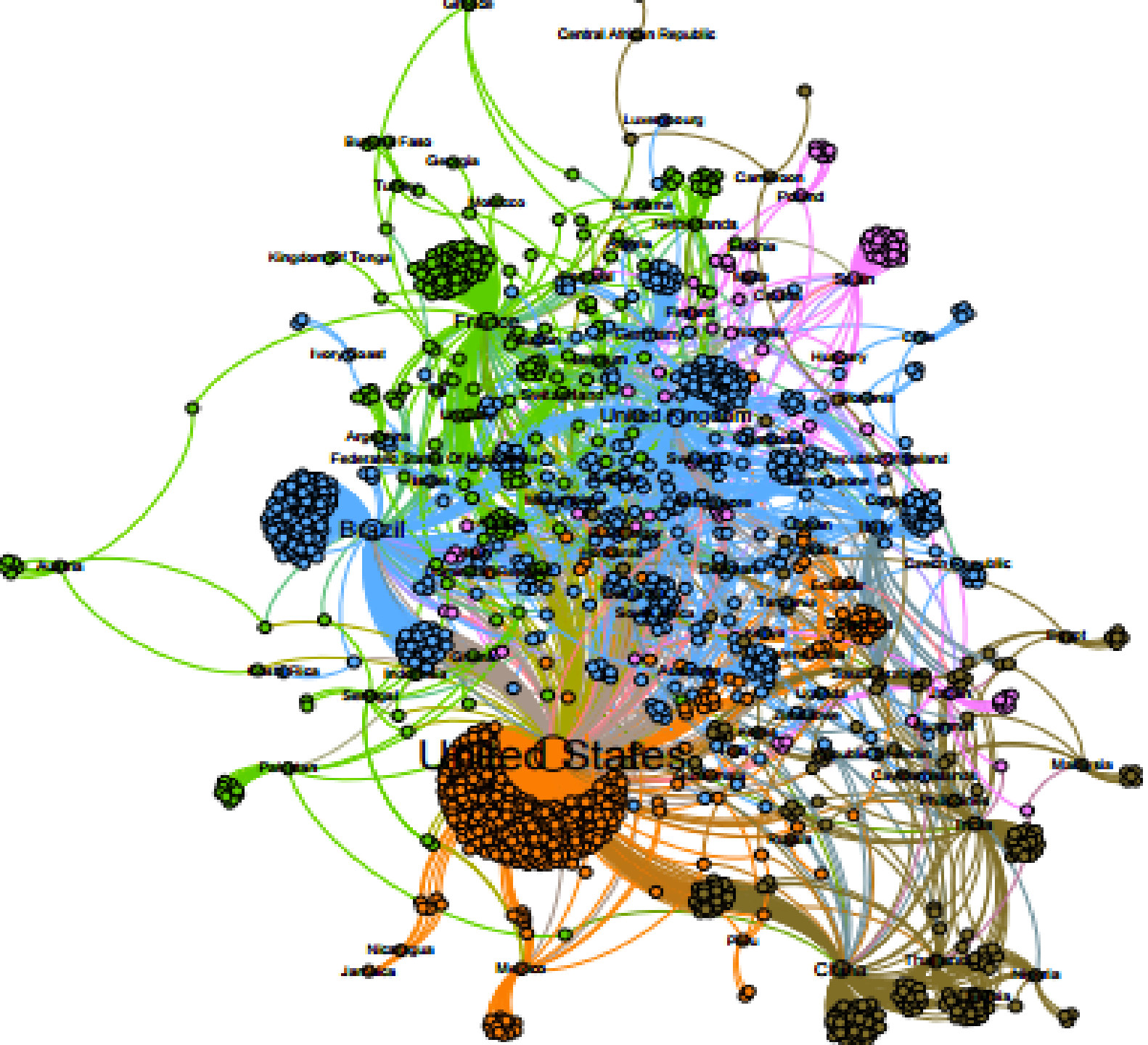


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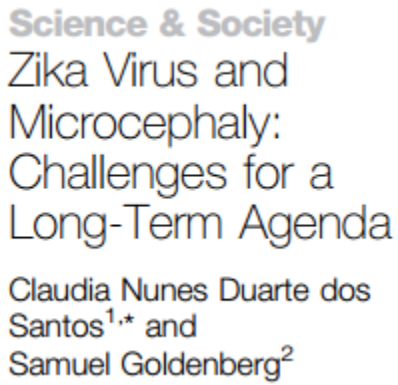
# Evaluación de la implementación de la agenda: identificación de brechas


Science & Society

Zika Virus and Microcephaly: Challenges for a Long-Term Agenda

Claudia Nunes Duarte dos Santos[1,*] and Samuel Goldenberg[2]


Review

Zika in the Americas, year 2: What have we learned? What gaps remain? A report from the Global Virus Network

Matthew T. Aliota[b], Leda Bassit[a, c], Shelton S. Bradrick[a, d], Bryan Cox[a, c], Mariano A. Garcia-Blanco[a, d], Christina Gavegnano[a, c], Thomas C. Friedrich[b, e], Thaddeus G. Golos[e, f, g], Diane E. Griffin[a, h],

Show more


Home » American Journal of Public Health (AJPH) » June 2017

The Zika Virus Outbreak in Brazil: Knowledge Gaps and Challenges for Risk Reduction

Claudia Garcia Serpa Osorio-de-Castro ScD, Elaine Silva Miranda ScD, Carlos Machado de Freitas ScD, Kenneth Rochel de Camargo ScD, and Hilarie Hartel Cranmer MD, MPH


Special Communication

May 2017

Bridging Knowledge Gaps to Understand How Zika Virus Exposure and Infection Affect Child Development

Bill G. Kapogiannis, MD[1]; Nahida Chakhtoura, MD[1]; Rohan Hazra, MD[1]; et al

Author Affiliations

JAMA Pediatr. 2017;171(5):478-485. doi:10.1001/jamapediatrics.2017.0002

Influencia de Zika sobre casos de dengue?

Cross-protective immunity ZIKV - Dengue ?

Zika virus infection elicits protective immunity?

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# Plataforma de protocolos sobre ZIKV

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World Health Organization
Regional Office for the Americas

Zika Research Projects List | Knowledge Translation | Zika website | PAHO

Published primary research studies and protocols


Go back to Research Projects List

**General Category**

- Please Choose -

Reset Search

**Type of publication**

- Please Choose -

Reset Search

## Zika Research Projects List

Filter Search Reset

**Análise genômica e funcional para a compreensão dos efeitos teratogênicos do virus Zika**
2016-3. *Mayana Zatz*
Full text:
http://aplicacao.saude.gov.br/plataformabrasil/login.jsf;jsessionid=E6F7E35A6ECE6D8AD2A4027D45B232DC.server-plataformabrasil-srvjpdf130

**Avaliação da imunidade inata e resposta humoral autoimune na infecção por vírus Zika em pacientes com e sem síndrome Guíllan-Barré (SGB)**
2016-3. *Eloisa Silva Dutra de Oliveira Bonfa*
Full text:
http://aplicacao.saude.gov.br/plataformabrasil/login.jsf;jsessionid=E6F7E35A6ECE6D8AD2A4027D45B232DC.server-plataformabrasil-srvjpdf130

**Zika Resources**

- Missions to support countries
- Events
- Epidemiological Alerts and Updates
- Guidance for reporting ZIKV
- Technical Reports and Guidelines
- Microcephaly
- News
- Countries with local transmission
- Communication Materials
- Resource Mobilization
- WHO website
- Back to Zika page

**PAHO Institutional Repository**

**Information Resources about Zika**
Click here

**Pan American Journal of Public Health / Revista Panamericana de Salud Pública**

**Zika virus**
Information for authors and researchers

**Virtual Health Library**

Search in the VHL Portal.
Click Here

# Caracteristicas de estudios incluidos en la Plataforma de protocols de investigación de OPS n= 264

| A. Classification of protocols by subtopic, N=264* | N (%) |
|---|---|
| Clinical management | 90 (34.09) |
| Disease pathogenesis and consequences of infection | 37 (14.02) |
| Epidemiology | 79 (29.92) |
| Ethical aspects | 3 (1.14) |
| Health systems and services response | 8 (3.03) |
| Public health interventions | 23 (8.71) |
| Research and development of products | 13 (4.92) |
| Virus Vectors and Reservoirs | 11 (4.17) |

| A. Type of study, N=76 | N (%) |
|---|---|
| Basic research | 10 (13.16) |
| Case control | 13 (17.11) |
| Case report | 4 (5.26) |
| Case series | 5 (6.58) |
| Clinical trials | 1 (1.32) |
| Cohort | 32 (42.1) |
| Cross sectional | 8 (10.53) |
| Experimental development | 2 (2.64) |
| Review and cost estimation | 1(1.32) |

| A. Classification of protocols by subtopic, N=264* | N (%) |
|---|---|
| Children | 19 (8.92) |
| Children presenting microcephaly | 61 (28.64) |
| GBS | 17 (7.98) |
| General population | 53 (24.88) |
| Health workers | 5 (2.35) |
| Macaques | 2 (0.94) |
| Men | 5 (2.35) |
| Military and families | 1 (0.47) |
| Placenta | 2 (0.94) |
| Pregnant women | 16 (7.51) |
| Pregnant women and children | 31 (14.55) |
| Women of reproductive age | 1 (0.47) |

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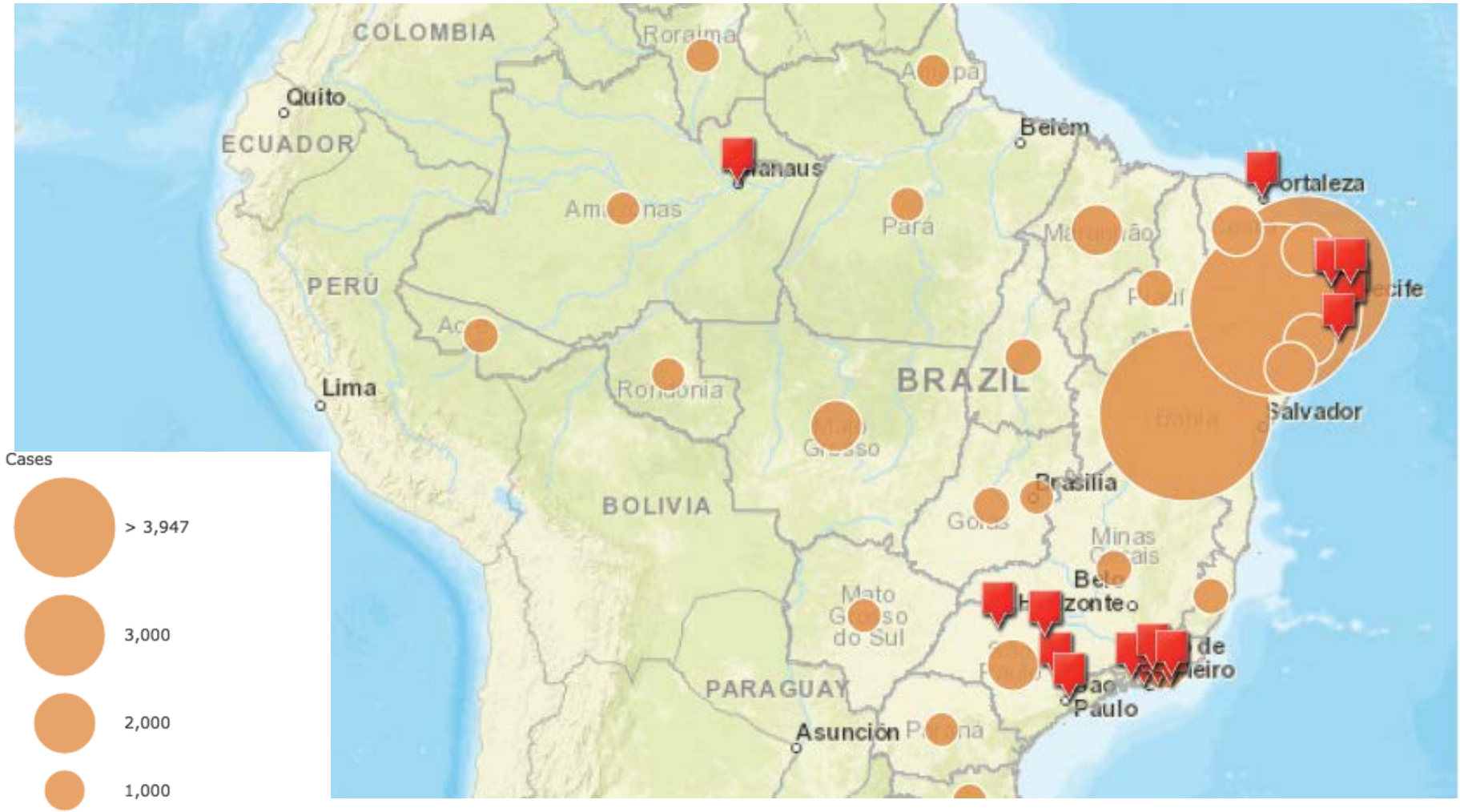
# Estudios de cohorte N=36

| | | | | | |
|---|---|---|---|---|---|
| Children presenting microcephaly (n=2) | Characterize the clinical condition and describe the neurocognitive growth and development | 2 years | HC* ≤ 32 cm born with 37-42 weeks or HC ≤ percentile 3 (2 SD) on Fenton's growth curve and CT findings consistent with congenital CNS infection | Children born with normal HC | Visual/ hearing impairment, Epilepsy<br>Hospitalizations<br>Mortality |
| Pregnant women (n=14) | Estimate the RR for congenital malformations in pregnant women | Birth | Pregnant women presenting rash<br>Asymptomatic cases<br>Zika+ though PCR | Absence of rash<br>No clinical symptoms of ZIKV infection<br>Negative laboratory result for ZIKV | Miscarriage/stillbirth<br>Pregnancy complications<br>Microcephaly and other abnormalities of the central nervous system |
| Pregnant women and their children (n=19) | Estimate the RR for congenital malformations in pregnant women and adverse outcomes in pregnancy, childbirth and babies | 6 weeks-3 years | Pregnant woman with rash and fever<br>Zika+ confirmed by clinical or laboratory<br>High risk pregnant woman without symptoms, pregnant woman with rash and fever, and pregnant women with abortions<br>HIV positive | Pregnant women | Microcephaly<br>Congenital malformations<br>Adverse outcomes in children |
| Arbovirus+ patients (n=1) | Demographic, clinical, biological, virologic, immunologic genetic factors associated with arbovirus infections. | 12 weeks | Suspected of infectious by an arbovirus<br>Acute febrile/ rash illness consistent with arbovirus | - | Adverse outcomes: shock, internal bleeding, failure of one or several organs or systems<br>Changes in quality of life |
| ZIKA+ patients (n=1) | To assess the presence and duration of infectious ZIKV and related markers | 4 weeks | Positive RT-PCR for ZIKV in a serum or urine | - | Incidence rate of ZIKV persistence in semen |

# Cohortes sobre Zika en Brazil



# Six standardized protocol designs for the study of ZIKV

1) Cross-sectional seroprevalence study of ZIKV infection in the general population
2) *Prospective longitudinal cohort study of ZIKV-infected patients to measure the persistence of ZIKV in body fluids*
3) *Prospective longitudinal cohort study of women and newborns exposed to ZIKV during the course of pregnancy*
4) *Prospective longitudinal cohort study of newborns and infants born to mothers exposed to ZIKV during pregnancy*
5) Case-control study to assess potential risk factors related to microcephaly, including ZIKV infection during pregnancy
6) Case-control study to assess potential risk factors related to Guillain-Barre Syndrome (GBS), including ZIKV infection

Pan American Health Organization
Regional Office of the World Health Organization

World Health Organization

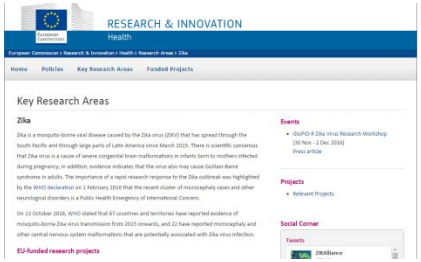
# Financiamiento de la Investigación sobre Zika

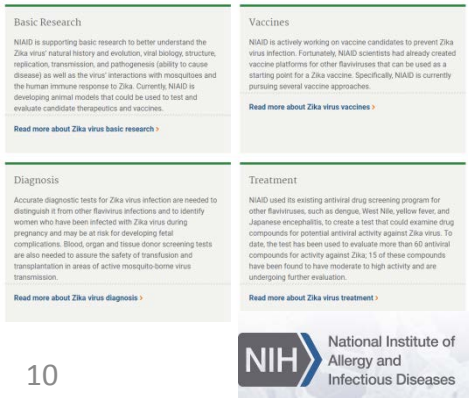
## Zika epidemic fast-tracks research funding in Brazil

*March 02, 2016*

MRC Medical Research Council

FAPESP




NIH National Institute of Allergy and Infectious Diseases

## Who is funding zika published research?


**Methods**:

- A cross sectional study of primary research
- Articles on primary studies investigating Zika virus published from January 2007 to October 2016

**Results**:

- 268 met the inclusion criteria
- 48 countries with Brazil 49/268 (18.3%) and USA 59/268 (22.0%) conducting the majority of the research
- The laboratory study design 80/268 (29.9%); case reports 68/268 (25.4%) and case series 54/268 (20.1%); research involving animals 22/268 (8.2%).
- 60% reported source of funding; 57% public funding:
- 146 funding bodies are represented as the primary financial source of assistance for Zika Virus research. National Institute of Health (NIH) represents 22.6%.

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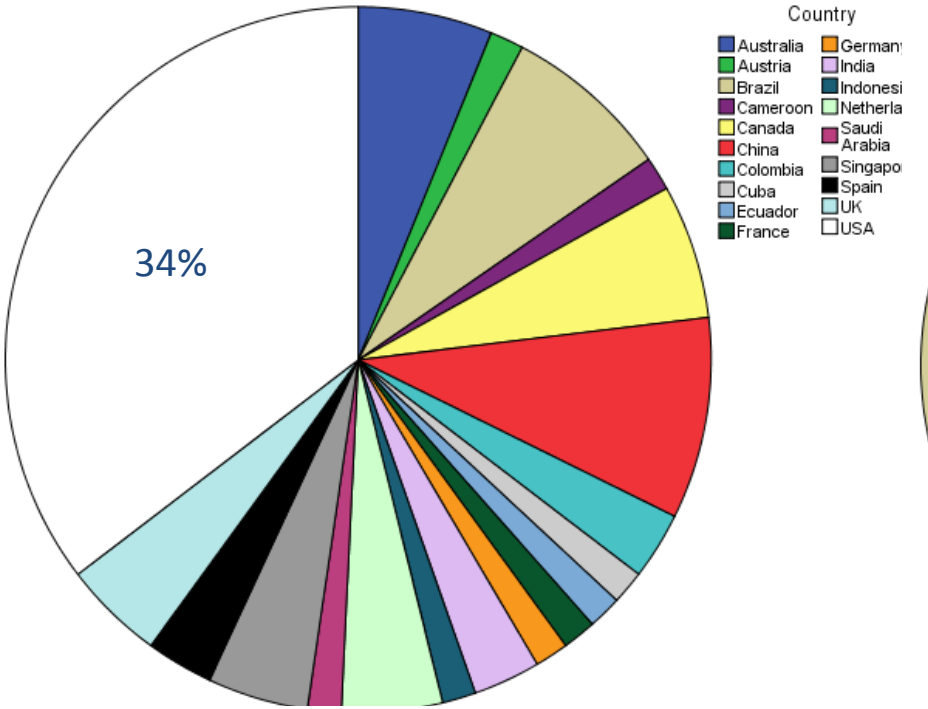
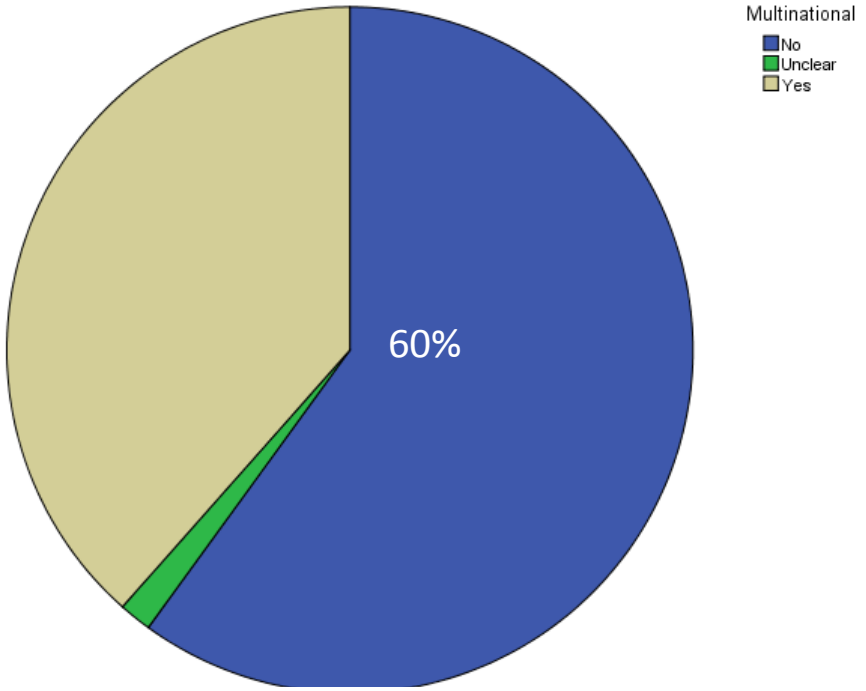
# Publicaciones recientes de estudios primarios sobre zika




N=65 estudios primarios / 167 referencias indexadas recientemente por Pubmed



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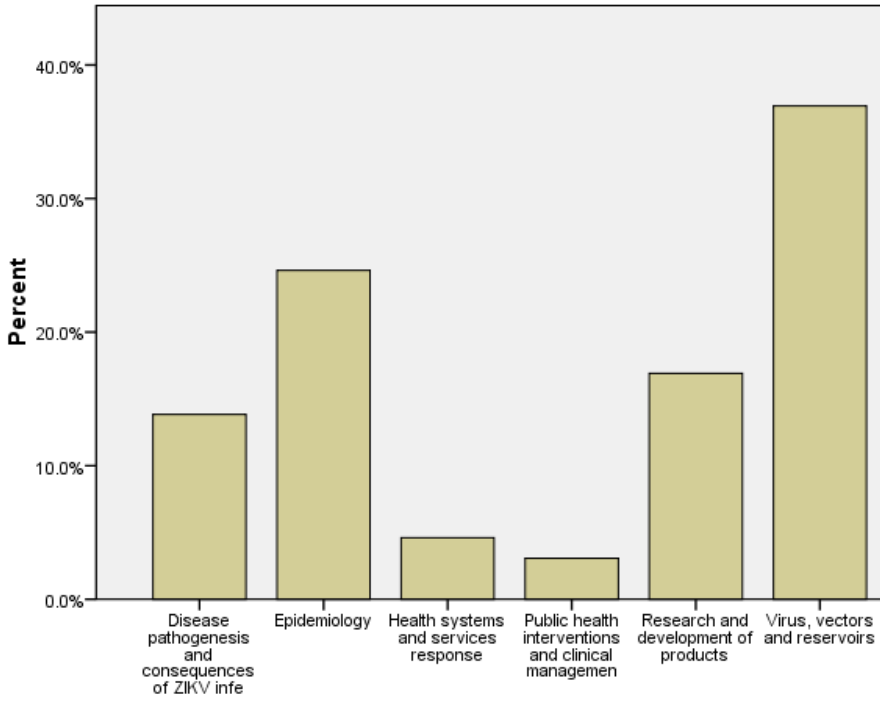
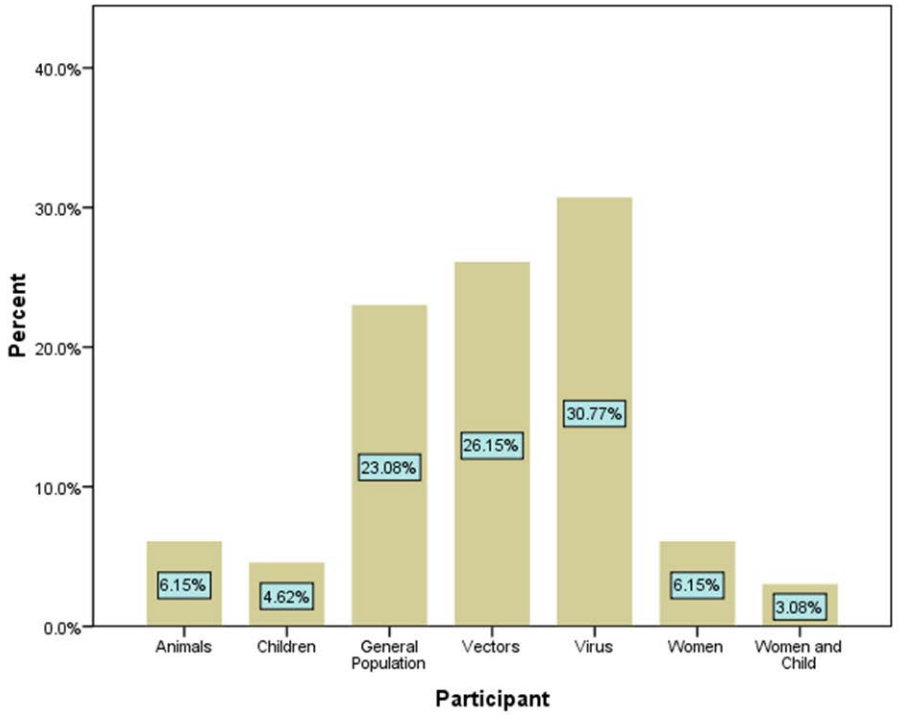
# Publicaciones recientes de estudios primarios sobre zika




N=65 estudios primarios / 167 referencias indexadas recientemente por Pubmed



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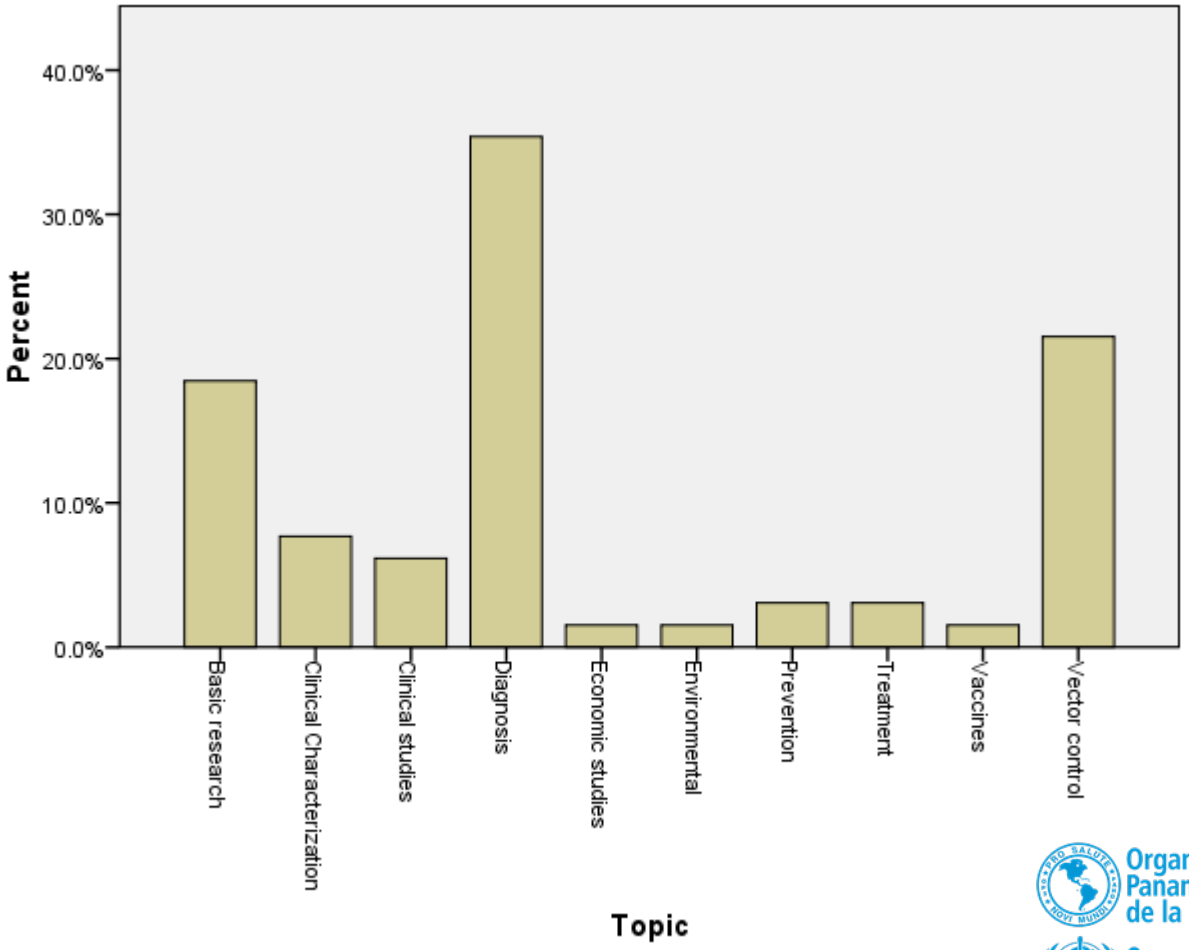
# Publicaciones recientes de estudios primarios sobre zika

Current literature:

- Clinical manifestations and epidemiology of ZIKV
- Isolation and Characterization of ZIKV
- Development of animal models to study ZIKV infection, host immune responses against ZIKV,
- Current state of development of vaccines and therapeutics against ZIKV
- Diagnostics: serological test; nucleic acid amplification tests; imaging
- Vector control

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# Estudios sobre tratamiento:

NIAID utiliza su programa de tamizaje sobre antivirales para evaluar su efectos sobre Zika. Asimismo se evalúan los medicamentos aprobados por la FDA.

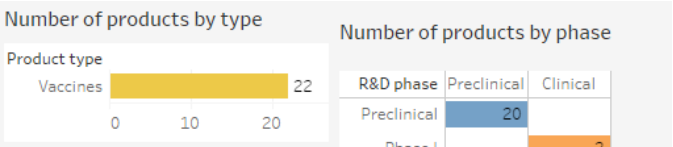
**"Number of NIH compounds and FDA approved drugs such as have shown potent anti-ZIKV activity *in vivo* as well as *in vitro"* :**

"SaliPhe, CID 91632869, NITD, pyrimidine synthesis inhibitors e.g, brequinar, 6-azauridine and finasteride, saliphenylhalamide, gemcitabine, obatoclax, kitasamycinm, lovastatin, 6-azauridine, palonosetron, 5-fluorouracil, emricasan, niclosamide, ten cyclin-dependent kinases specifically PHA-690509, PHA-690509, sofosbuvir, Type I Interferons, mycophenolic acid (MPA), chloroquine, 2'-C-methylated nucleosides, azithromycin, T-1105, 2'-C-methylcytidine (2CMC), CX4430 and GS-5734"

"Accumulating evidence suggest the potent anti-ZIKV activity of number of **monoclonal antibodies**. ZIKV-117 was found to be the most inhibitory antibody that prevented the replication of ZIKV and fetal disease in mice. Moreover, another study demonstrate that **administration of convalescent** serum from a subject recovered from ZIKV in pregnant mice resulted in suppression of ZIKV likewise, adoptive transfer of purified IgG from vaccinated mice triggered passive protection".

Amjad Ali. Advances in research on Zika virus. Asian Pacific Journal of Tropical Medicine 2017; 10 (4) 321–331;

# Ensayos clínicos sobre vacunas:




Number of products by phase

| R&D phase | Preclinical | Clinical |
|---|---|---|
| Preclinical | 20 | |
| Phase I | | 2 |
| Total | 20 | 2 |

## Health products in the pipeline

*by disease, product name, type and phase of development*

| Disease name | Product type | Product name | |
|---|---|---|---|
| Zika virus | Vaccines | Butantan attenuated ZIKV | Preclinical |
| | | Butantan ZIKV | Preclinical |
| | | ChAdOx1-Zk | Preclinical |
| | | Chimerivax-Zika | Preclinical |
| | | GEO-ZM05 | Preclinical |
| | | GLS-5700 | Phase I |
| | | mRNA-1325 | Preclinical |
| | | MV-Zika | Preclinical |
| | | NI.LV-ZIK | Preclinical |
| | | None (preclinical) | Preclinical |
| | | | Preclinical |
| | | | Preclinical |
| | | | Preclinical |
| | | | Preclinical |
| | | Replikins Zika Vaccine and Bock.. | Preclinical |
| | | rZIKV-3'D4delta30 | Preclinical |
| | | rZIKV/D2delta30 | Preclinical |
| | | rZIKV/D4delta30 | Preclinical |
| | | rZIKVdelta30 | Preclinical |
| | | SCV-CHIKV+ZIKV+YF | Preclinical |
| | | VRC ZIKV DNA | Phase I |
| | | VXA-Zikavax | Preclinical |
| | | ZIK-80E | Preclinical |
| | | ZIKA recombinant | Preclinical |
| | | ZIKV PIV | Preclinical |
| | | ZIKVLP | Preclinical |

**Global Observatory on Health R&D**

"Candidate health products (e.g. medicines, vaccines and diagnostics) that are currently under development are reported by disease, product name, type, and phase of development.

Inactivated Whole Organism (with or without Adjuvant)
DNA vaccines
RNA vaccines
Recombinant Viral Vector



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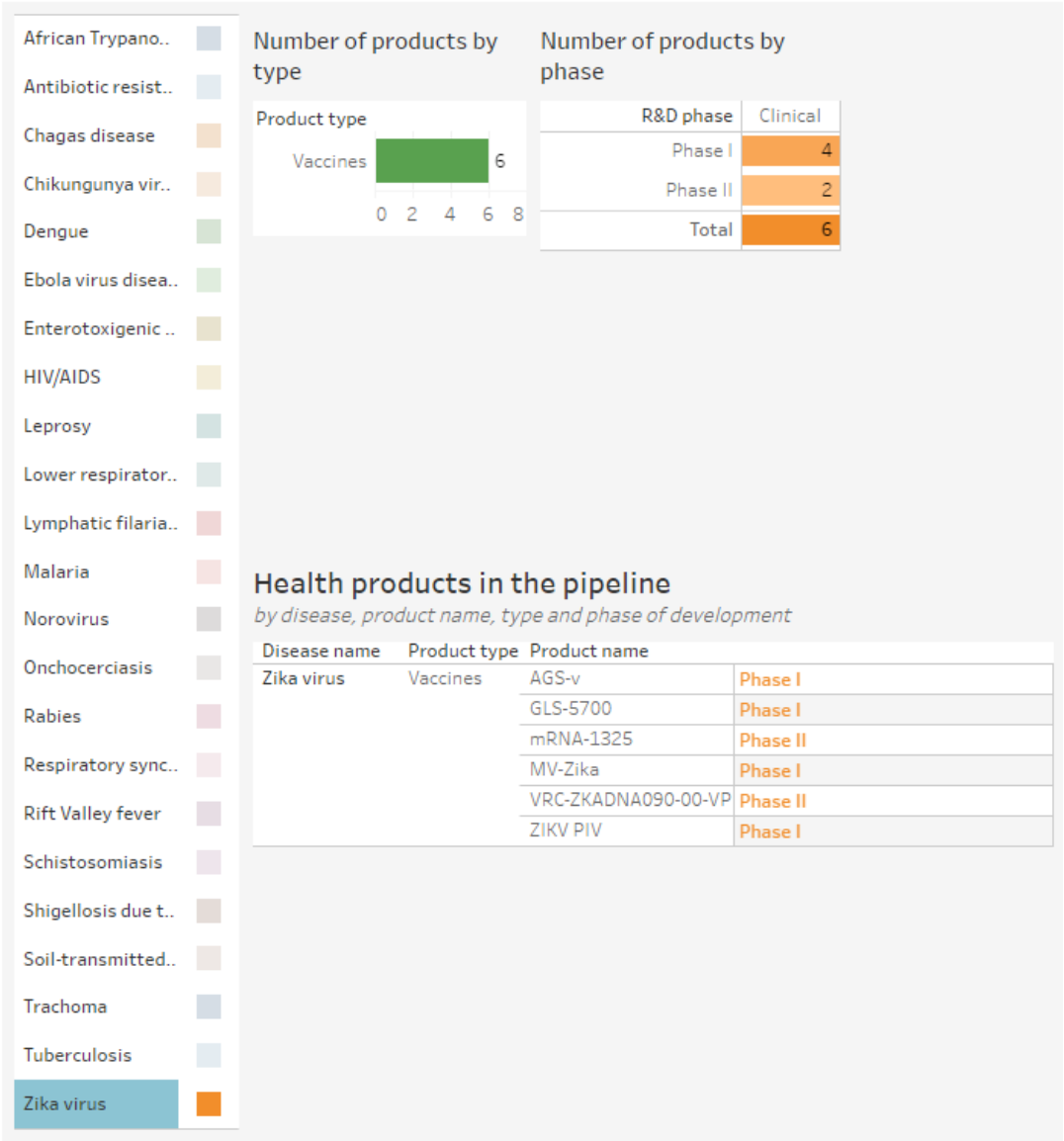
# Ensayos clínicos sobre vacunas:

Data visualization 1

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# Ensayos clínicos sobre vacunas:

**Table 1.** Summary of anti-Zika virus (ZIKV) vaccine candidates currently in clinical trials.

| Type of Vaccine | Developers/Collaborators | Candidate Vaccine Name (If Available) | Stage of Development | Clinical Trial Registration Number |
|---|---|---|---|---|
| Inactivated whole organism | WRAIR/BIDMC/Harvard/ NIAID/Sanofi Pasteur | | Clinical (Phase 1) | NCT02963909 NCT02952833 NCT02937233 |
| DNA | GeneOne Life Science, Inc/Inovio Pharmaceuticals | GLS-5700 | Clinical (Phase I) | NCT02809443 NCT02887482 |
| DNA | VRC/NIAID | VRC ZIKV DNA | Clinical (Phase I) | NCT02840487 NCT02996461 |
| Synthetic peptide | NIAID | AGS-v | Clinical (Phase I) | NCT03055000 |
| Measles-vectored | Themis Bioscience | MV-ZIKA | Clinical (Phase I) | NCT02996890 |
| mRNA | Valera (Moderna) | mRNA-1325 | Clinical (Phase I) | NCT03014089 |

WRAIR: Walter Reed Army Institute of Research, BIDMC: Beth Israel Deaconess Medical Center, NIAID: National Institutes of Allergy and Infectious Diseases, VRC: Vaccine Research Center.

Monica A. McArthur Zika Virus: Recent Advances towards the Development of Vaccines and Therapeutics. Viruses 2017, 9, 143;

# Ensayos clínicos sobre vacunas: ICTRP

A Phase 1, Multicenter, Double-Blind, Placebo-Controlled, Randomized (Intra-Group) Clinical Trial to Evaluate Two Doses of Three Sequentially Escalating Cohort of Zika Virus Vaccine Inactivated (Adsorbed) (BBV121) in Healthy Adult Dengue Sero-Negative and Dengue Sero-Positive Volunteers [05-2017]

Country: India
Participants: Normal healthy male and female volunteers aged between 18 and 65 year
Intervention: Zika vaccine is an inactivated virus vaccine
Outcomes: safety (lab, AE, SAE post vaccination)
Sponsor: private
Not recruiting

A Phase 2/2B, Randomized Trial to Evaluate the Safety, Immunogenicity and Efficacy of a Zika Virus DNA Vaccine in Healthy Adults and Adolescents [o3-2017]
Countries: Puerto Rico, United States
Participants: part A: 18 to 35; Part B: 15 to 35; Exclusion Criteria: Breast-feeding or planning to become pregnant while participating through 12 weeks after the last product administration
Intervention: VRC-ZKADNA090-00-VP
Outcomes: Antibody response 0 to 28 days post product administration; Confirmed cases of Zika Day 0 through Day 672
Sponsor: VRC, NIAID, NIH and private
Recruiting

# Ensayos clínicos sobre vacunas: ICTRP

A Non-blinded Cluster Randomised Controlled Trial to Assess the Efficacy of Wolbachia-infected Mosquito Deployments to Reduce Dengue Incidence in Yogyakarta, Indonesia [03-2017]
Country: Indonesia
Participants: 3-30 years old; Resided in the study area every night for the 10 days preceding illness onset
Intervention: Wolbachia-infected Aedes aegypti mosquitoes
Outcomes: Zika incidence rate ratio in Wolbachia-treated versus untreated clusters [Time Frame: 24 months participant enrolment]
Sponsor: University
Not recruiting

A Randomized, Double-Blind, Controlled, Parallel Group Study With the INTERCEPT Blood System for Red Blood Cells in Regions at Potential Risk for Zika Virus Transfusion-Transmitted Infections (RedeS Study) and Treatment Use Open-Label Extension Study [01-2017]
Countries: Puerto Rico, United States
Participants: 18  Patients who are required or expected to require a transfusion of RBC component(s).
Intervention: INTERCEPT Blood System for Red Blood Cells
Outcomes: Treatment emergent antibodies; AE; adjusted hemoglobin increment averaged over multiple transfusion
Sponsor: Private
Recruiting

# Ensayos clínicos sobre vacunas: ICTRP

A Phase 1/2, Randomized, Placebo-Controlled, Dose-Ranging Study to Evaluate the Safety and Immunogenicity of mRNA 1325 Zika Vaccine in Healthy Adults in a Non-endemic Zika Region[01-2017]
Country: United States
Participants: 18 to 49 years of age. - Women of childbearing potential must agree to be heterosexually inactive or agree to consistently use any of the following methods of contraception from at least 21 days prior to enrollment and through 3 months after the final vaccination; Male subjects must use an acceptable method of birth control throughout the entire study and agree to refrain from donation of sperm from the time of first vaccination until 3 months following the last vaccination
Intervention: mRNA-1325
Outcomes: Types, frequency, and severity of serious adverse events (SAE), adverse events of special interest (AESI) and adverse events considered related to study drug [Time Frame: Through 13 months of study participation]
Sponsor: Private
Recruiting

VRC 320: A Phase I, Randomized Clinical Trial to Evaluate the Safety and Immunogenicity of a Zika Virus DNA Vaccine, VRC-ZKADNA090-00-VP, Administered Via Needle and Syringe or Needle-free Injector, PharmaJet, inHealthy Adults [01-2017]
Countries: United States
Participants: 18 to 50 years; excludes female-specific: Breast-feeding or planning to become pregnant while participating through 12 weeks after the last study vaccination
Intervention: VRC-ZKADNA090-00-VP
Outcomes: safety and tolerability of v ZIKV DNA vaccine through 44 weeks of study participation; magnitude and the frequency of ZIKV-specific antibody response as measured by neutralization assay
Sponsor: NIAID
Not recruiting

# Ensayos clínicos sobre vacunas: ICTRP

Phase I, Randomized, Double-blinded, Placebo-Controlled Dose De-escalation Study to Evaluate Safety and Immunogenicity of Alum Adjuvanted Zika Virus Purified Inactivated Vaccine (ZPIV) in Adults in a Flavivirus Endemic Area [12-2016]
Country: Puerto Rico
Participants: Must be a male or non-pregnant, non-breastfeeding female between the age of 21 and 49 years, inclusive at the time of screening and enrollment
Intervention: Zika Virus Purified Inactivated Vaccine (ZPIV)
Outcomes: study withdrawals and discontinuation of study vaccination due to any reason between dosage groups and by pre-vaccination flavivirus immune status [Time Frame: Days 1 to 750]; AE;SAE; Frequency of seroconversion
Sponsor: Private
Recruiting

VRC 320: A Phase I, Randomized Clinical Trial to Evaluate the Safety and Immunogenicity of a Zika Virus DNA Vaccine, VRC-ZKADNA090-00-VP, Administered Via Needle and Syringe or Needle-free Injector, PharmaJet, inHealthy Adults [01-2017]
Countries: Puerto Rico, United States
Participants: 18 to 50 years; excludes female-specific: Breast-feeding or planning to become pregnant while participating through 12 weeks after the last study vaccination
Intervention: VRC-ZKADNA090-00-VP
Outcomes: safety and tolerability of v ZIKV DNA vaccine through 44 weeks of study participation; magnitude and the frequency of ZIKV-specific antibody response as measured by neutralization assay
Sponsor: NIAID
Recruiting

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Phase I, Randomized, Double-blinded, Placebo-Controlled Dose De-escalation Study to Evaluate Safety and Immunogenicity of Alum Adjuvanted Zika Virus Purified Inactivated Vaccine (ZPIV) in Adults in a Flavivirus Endemic Area [12-2016]
Country: Puerto Rico
Participants: Must be a male or non-pregnant, non-breastfeeding female between the age of 21 and 49 years, inclusive at the time of screening and enrollment
Intervention: Zika Virus Purified Inactivated Vaccine (ZPIV)
Outcomes: study withdrawals and discontinuation of study vaccination due to any reason between dosage groups and by pre-vaccination flavivirus immune status [Time Frame: Days 1 to 750]; AE;SAE; Frequency of seroconversion
Sponsor: Private
Recruiting

Double Blinded, Randomized, Placebo Controlled, Dose Finding Trial to Evaluate the Optimal Dose of MV-ZIKA, a New Vaccine Against Zika Virus, in Regard to Immunogenicity, Safety, and Tolerability in Healthy Volunteers [12-2016]
Countries: Austria
Participants: healthy volunteers aged 18 to 55; subjects of child bearing potential must perform reliable method of contraception
Intervention: MV-ZIKA
Outcomes: Immunogenicity: Functional anti-Zika antibodies as measured by PRNT [Time Frame: 56 days]
Sponsor: Private
Recruiting

# Ensayos clínicos sobre vacunas: ICTRP

A Phase 1, First-in-human, Double-blinded, Randomized, Placebo-controlled Trial of a Zika Virus Purified Inactivated Vaccine (ZPIV) With Alum Adjuvant in Healthy Flavivirus-naive and Flavivirus-Primed Subjects.
Country: Puerto Rico
Participants: Must be a male or non-pregnant, non-breastfeeding female between the ages of 18 and 49 years, inclusive, at the time of screening and enrollment
Intervention: IXIARO; YF Vax 17D Strain; Zika Virus Purified Inactivated Vaccine (ZPIV)
Outcomes: AE; SAE; Anti- ZIKV NAbs GMTs; Anti- ZIKV NAbs seroconversion
Sponsor: Private
Recruiting

Phase 1, Double-blinded, Placebo-Controlled Dose De-escalation Study of the Safety and Immunogenicity of Alum Adjuvanted Zika Virus Purified Inactivated Vaccine (ZPIV) Administered by the Intramuscular Route in Flavivirus Naïve Adult Subjects [10 - 2016]
Countries: USA
Participants: Must be a male or non-pregnant, non-breastfeeding female between the age of 18 and 49 years, inclusive at the time of screening and enrollment; Women of childbearing potential* must have a negative serum pregnancy test at screening and a negative urine pregnancy test immediately prior to each vaccination Note: All female subjects are considered of childbearing potential unless postmenopausal or surgically sterilized and >/=3 months have passed since sterilization procedure. Postmenopausal is defined as amenorrhea for >/=12 months without an alternative medical cause. Permanent female sterilization procedures include tubal ligation, bilateral salpingectomy, hysterectomy, bilateral oophorectomy, or successful Essure placement. Women of childbearing potential must use an acceptable method of contraception from one month (30 days) prior to the first vaccination until at least 60 days after the last vaccination; Acceptable methods of contraception include the following: …
Intervention: Biological: Zika Virus Purified Inactivated Vaccine (ZPIV)
Outcomes: local or systemic reactogenicityAE;SAE; GMT; seroconversion
Sponsor: (NIAID)
Recruiting

# Ensayos clínicos sobre vacunas: ICTRP

A Phase 1, Randomized, Double-Blind Placebo-Controlled Clinical Trial to Evaluate the Safety and Immunogenicity of an Accelerated Vaccination Schedule With a Zika Virus Purified Inactivated Vaccine Plus Alum Adjuvant in Healthy Adults [12-2016]
Country: Puerto Rico
Participants: Age 18-50 years old.
Intervention: Zika Virus Purified Inactivated Vaccine (ZPIV)
Outcomes: study withdrawals and discontinuation of study vaccination due to any reason between dosage groups and by pre-vaccination flavivirus immune status [Time Frame: Days 1 to 750]; AE;SAE; Frequency of seroconversion
Sponsor: Private
Recruiting

Double Blinded, Randomized, Placebo Controlled, Dose Finding Trial to Evaluate the Optimal Dose of MV-ZIKA, a New Vaccine Against Zika Virus, in Regard to Immunogenicity, Safety, and Tolerability in Healthy Volunteers [12-2016]
Countries: Austria
Participants: healthy volunteers aged 18 to 55; subjects of child bearing potential must perform reliable method of contraception; 7. All female participants must be willing to undergo serum or urine beta human chorionic gonadotropin pregnancy tests at time points indicated in the Schedule of Procedures and must test negative prior to vaccination. All sexually active males (unless anatomically sterile) must be willing to use an effective method of contraception (such as consistent condom use) from the day of first vaccination until Week 12. If a woman of child-bearing potential, committed to use an effective method of contraception when sexually active with men until Week 12, including: Condoms (male or female) with or without spermicide; Diaphragm or cervical cap with spermicide; Intrauterine device; Hormonal contraception; Successful vasectomy in the male partner (considered successful if a woman reports that a male partner has [1] documentation of azoospermia by microscopy, or [2] a vasectomy more than 2 years ago with no resultant pregnancy despite sexual activity post-vasectomy).
Outcomes: Immunogenicity: AE; SAE [Time Frame: 56 days]; IFN-? ELISPOT responses to prM, Env, Cap, and NS1 peptides; Elisa titers, neutralization etc
Sponsor: National Institute of Allergy and Infectious Diseases (NIAID); Walter Reed Army Institute of Research
Recruiting

# Ensayos clínicos sobre vacunas: ICTRP

Phase I, Placebo-Controlled, Double-Blind Study To Evaluate The Safety, Tolerability, AND Immunogenicity Of GLS-5700, Administered ID Followed By Electroporation In Dengue Virus-Seropositive Adults [08-2016]
Country: Puerto Rico
Participants: 18-65 years.
Intervention: GLS-5700
Outcomes: AE;SAE; Binding antibody titers to Zika envelope; Neutralizing antibody response against Zika virus
Sponsor: Private
Recruiting

VRC 319: A Phase I/Ib, Randomized Clinical Trial to Evaluate the Safety and Immunogenicity of A Zika Virus DNA Vaccine, VRC-ZKADNA085-00-VP, in Healthy Adults [07-2016]
Countries: USA
Participants: 18 to 35 years old
Intervention: ZIKV DNA vaccine VRC-ZKADNA085-00-VP
Outcomes: safety and tolerability through 44 weeks of study participation]; magnitude and frequency of ZIKV-specific antibody response as measured by neutralization assay
Sponsor: National Institute of Allergy and Infectious Diseases (NIAID)

Phase I, Open-label, Dose-Ranging Study to Evaluate the Safety, Tolerability, and Immunogenicity of GLS-5700 Administered ID Followed by EP in Dengue Virus-Naïve Adults
Country: Canada; United States
Participants: Age 18-65 years; Women of child-bearing potential agree to use medically effective contraception(oral contraception, barrier methods, spermicide, etc.) or have a partner who is sterile from enrollment to 3 months following the last injection, or have a partner who is medically unable to induce pregnancy. Sexually active men who are considered sexually fertile must agree to use either a barrier method of contraception during the study, and agree to continue the use for at least 3 months following the last injection, or have a partner who is permanently sterile or is medically unable to become pregnant
Intervention: GLS-5700
Outcomes: SEA;AE; Binding antibody titers to Zika envelope; Neutralizing antibody response against Zika virus
Sponsor: Private