

# What is a clinical trial ?

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- Although there are many definitions of clinical trials, they are generally considered to be **biomedical or health-related research studies in human beings** that follow a pre-defined protocol.
- ClinicalTrials.gov includes **both interventional and non-interventional** types of studies.
  - Interventional studies are those in which the research subjects are assigned by the investigator to a treatment or other intervention, and their outcomes are measured.
  - Non Interventional studies are those in which individuals are observed and their outcomes are measured by the investigators.

# European definition



- **'Clinical trial'**: any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of one or more investigational medicinal **product(s)**, and/or to identify any adverse reactions to one or more investigational medicinal **product(s)** and/or to study absorption, distribution, metabolism and excretion of one or more investigational medicinal **product(s)** with the object of ascertaining its (their) safety and/or efficacy

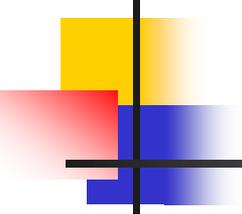
*"very **product oriented**"*

# European definition



- « non-interventional trial ' : a study where the medicinal product(s) is (are) prescribed in the usual manner in accordance with the terms of the marketing authorisation. The assignment of the patient to a particular therapeutic strategy is not decided in advance by a trial protocol but falls within current practice and the prescription of the medicine is clearly separated from the decision to include the patient in the study. No additional diagnostic or monitoring procedures shall be applied to the patients and epidemiological methods shall be used for the analysis of collected data » **DIRECTIVE 2001/20/EC**

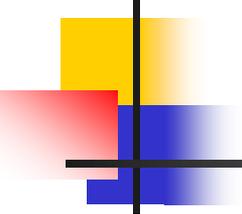
# What are the different types of clinical trials? (1/2)



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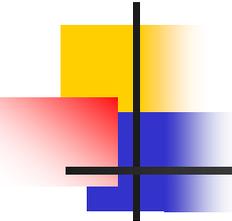
- **Treatment trials** test experimental treatments, new combinations of drugs, or new approaches to surgery or radiation therapy. (fundamental, development, confirmatory, exploratory research...: phase « 0 » to IV)
- **Prevention trials** look for better ways to prevent disease in people who have never had the disease or to prevent a disease from returning. These approaches may include medicines, vaccines, vitamins, minerals, or lifestyle changes.
- **Diagnostic trials** are conducted to find better tests or procedures for diagnosing a particular disease or condition.

# What are the different types of clinical trials? (2/2)



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- **Screening trials** test the best way to detect certain diseases or health conditions.
- **Quality of Life trials** (or Supportive Care trials) explore ways to improve comfort and the quality of life for individuals with a chronic illness.



# Who sponsors clinical trials?

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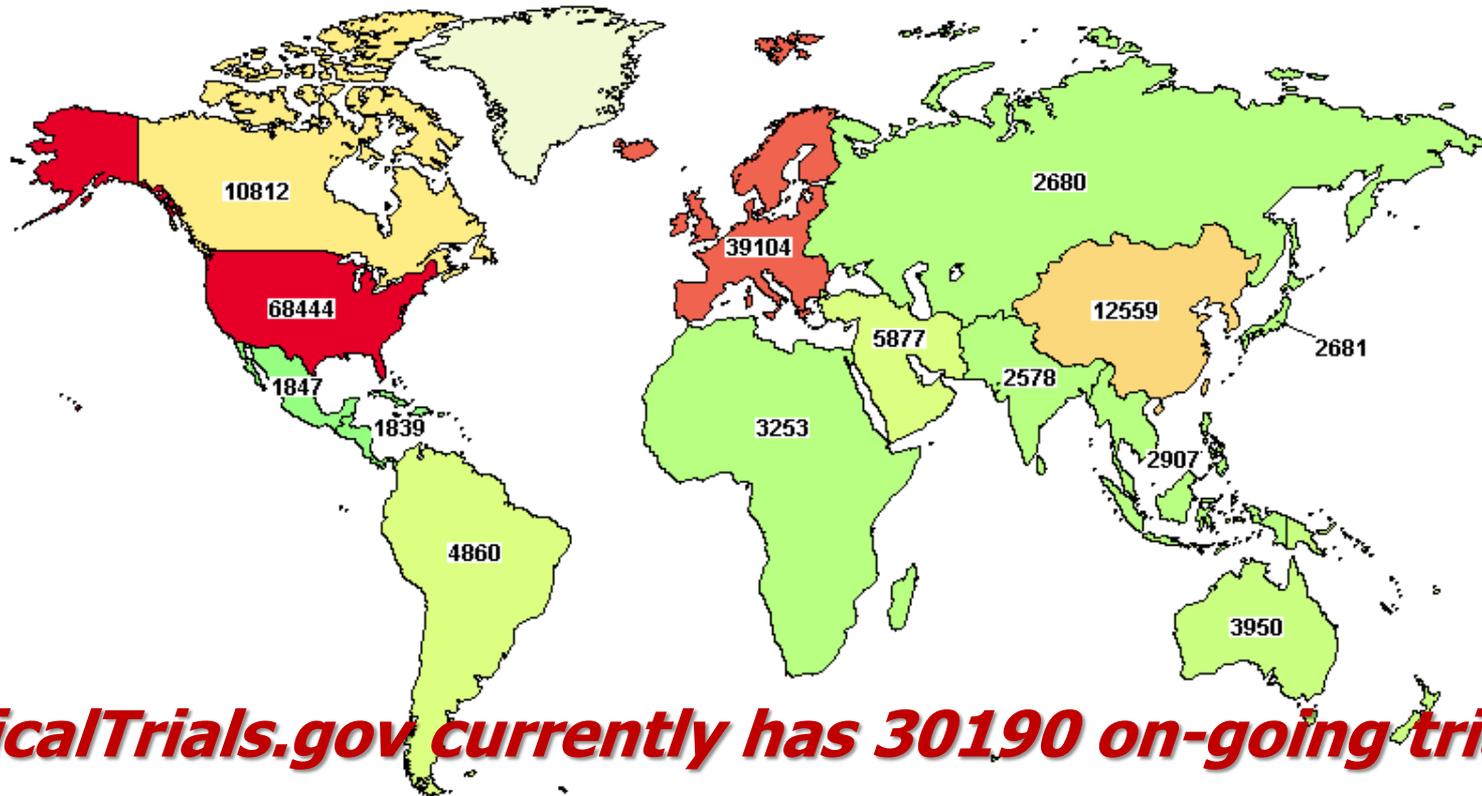
- Clinical trials are sponsored or funded by a variety of organizations or individuals such as:
  - Clinical Research Network
  - Government
  - Industry
  - University/Organization
  - National Institutes of Health

Trials can take place in a variety of locations, such as hospitals, universities, doctors' offices, or community clinics.

# International *ClinicalTrials.gov* currently has **145 136 trials** (120.294 Y-1) in **185 countries** (178 Y-1)

## Map of All Studies in ClinicalTrials.gov

Click on the map below to show a more detailed map (when available) or search for studies (when map not available).



***ClinicalTrials.gov* currently has 30190 on-going trials**

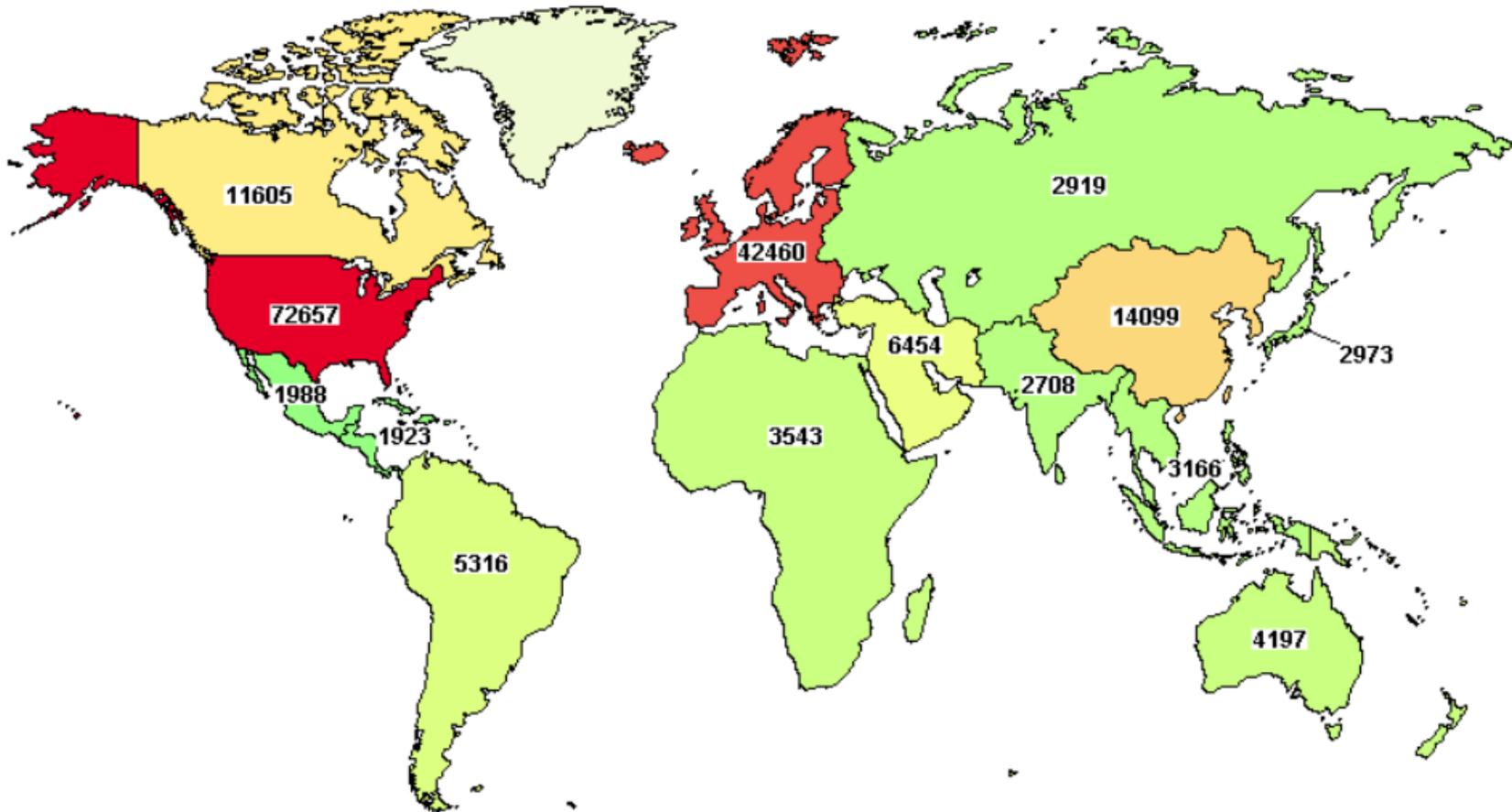
Colors indicate number of studies with locations in that region

Least  Most

Labels give exact study count

# International

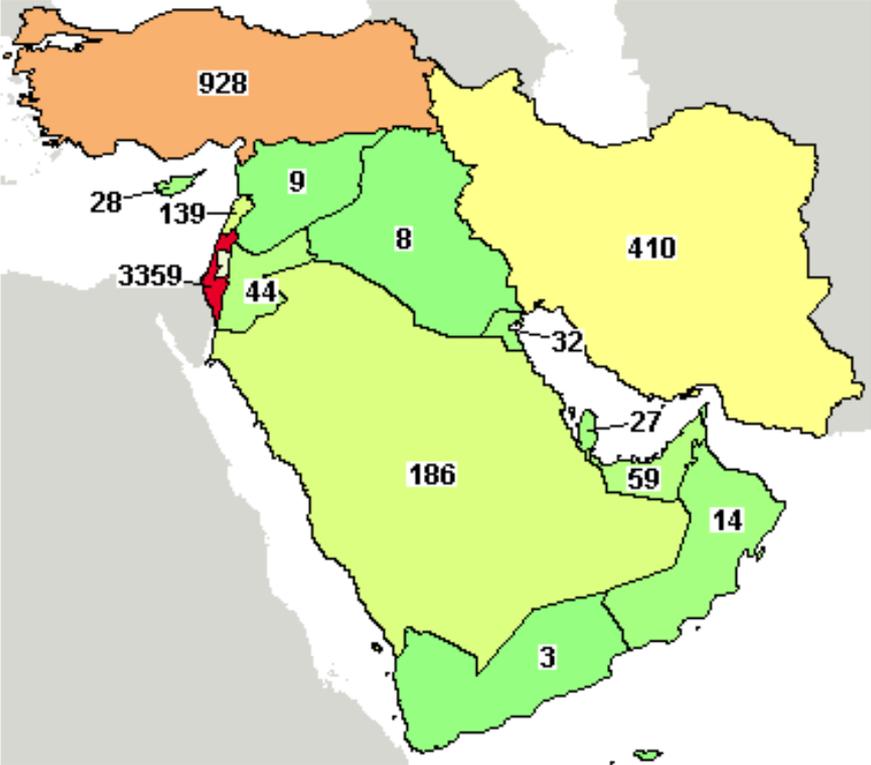
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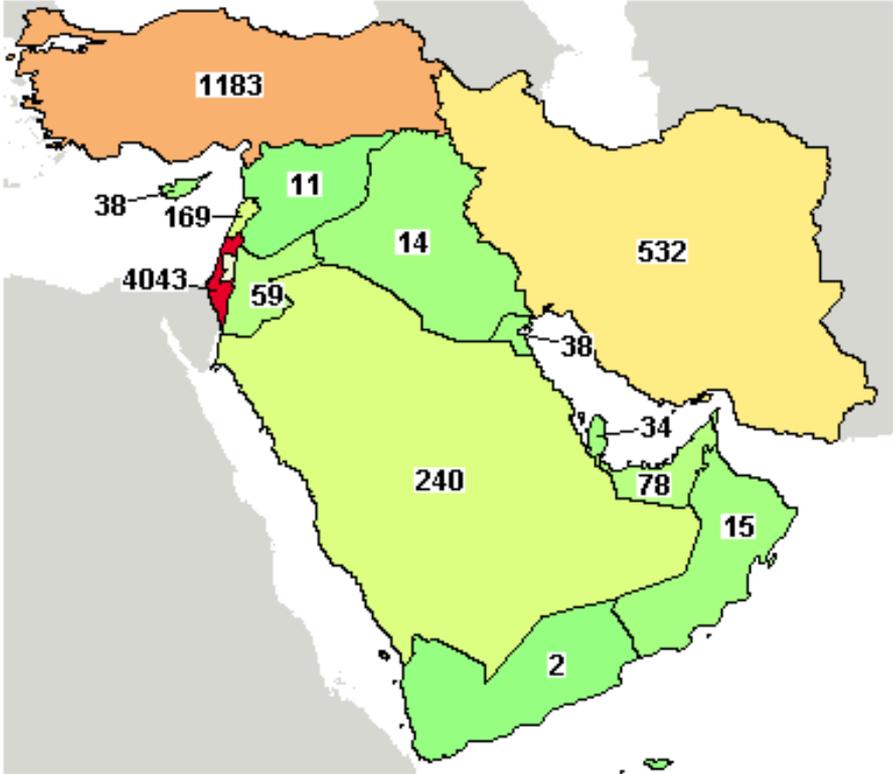
# Middle East

*ClinicalTrials.gov currently has*

*2012*



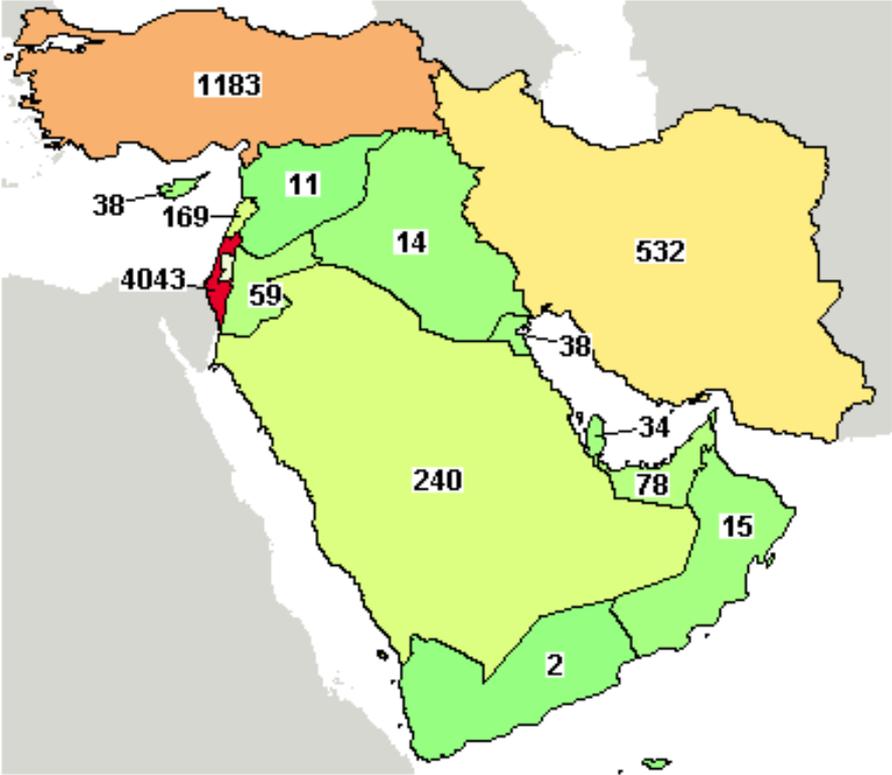
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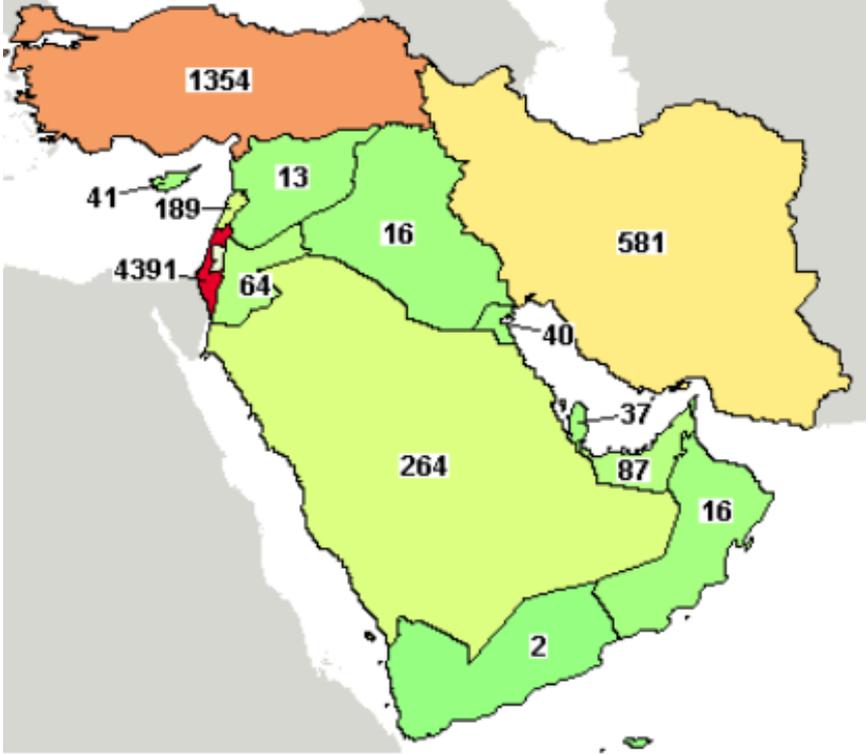
# Middle East

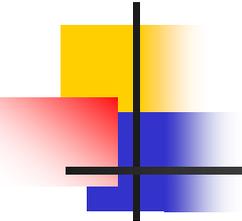
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**2013 Jan**



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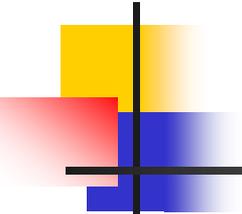




# Examples of sponsors/trials on clinical-trials.gov: « treatment trials »

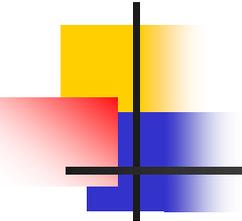
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- **An 8-week Study to Evaluate the Dose Response of AHU377 in Combination With Valsartan 320 mg in Patients With Mild-to-moderate Systolic Hypertension**
- Interventions: Drug: LCZ696 400 mg; Drug: AHU377 400 mg + valsartan 320 mg; Drug: AHU377 200 mg + valsartan 320 mg; Drug: AHU377 100 mg + valsartan 320 mg; Drug: AHU377 50 mg + valsartan 320 mg; Drug: valsartan 320 mg; Drug: placebo
- **Funded By & Sponsor: Novartis Pharmaceuticals ; Phase: Phase II**
- Study Design: Allocation: Randomized; **Intervention** Model: Parallel Assignment; Masking: *Double Blind* (Subject, Investigator);
- **Primary Purpose: Treatment** ; Outcome Measures: reduction in mean SBP; dose-response relationship in DBP lowering of ascending doses of AHU377 in combination with valsartan 320 mg; changes in mean 24 hour ambulatory SBP, DBP, daytime and nighttime SBP/DBP of ascending doses of AHU377 in combination with valsartan 320mg as compared to valsartan 320mg monotherapy; sub-group analysis of age (< 65 and ≥ 65); Frequency of adverse events, serious adverse events, and notable laboratory abnormalities



# Examples of sponsors/trials on clinical-trials.gov: « treatment trials »

- **Prognostic Value of the Circadian Pattern of Ambulatory Blood Pressure for Cardiovascular Risk Assessment**
- Interventions: Drug: Any antihypertensive medication alone or in combination; Device: Ambulatory blood pressure monitoring
- **Sponsors: University of Vigo; Servicio Gallego de Salud ; NCT00741585 ; Completion : Dec 2020 ; Primary Purpose: Treatment**
- **Study Design:** Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; **Intervention** Model: Parallel Assignment; Masking: Open Label; Outcome Measures: To evaluate 1) the impact of circadian time of treatment in cardiovascular, cerebrovascular and renal risk assessment.; 2) the influence of circadian time of treatment in BP control; 3) the prevalence of an altered (non-dipper) BP profile in patients with resistant hypertension as a function of the circadian time of treatment.; 4) the influence of diabetes and circadian time of treatment in the prevalence of an altered (non-dipper) BP profile.; 5) the influence of age and circadian time of treatment in the prevalence of an altered (non-dipper) BP profile.; 6) the prevalence and cardiovascular risk profile of white-coat hypertension.; 7) the prevalence and cardiovascular risk profile of masked hypertension.; 8) potential differences between men and women.; 9) the impact of changes in ambulatory BP in cardiovascular, cerebrovascular and renal risk assessment.

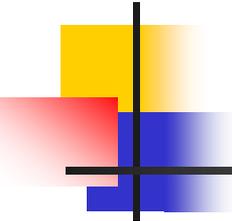


# Examples of sponsors/trials on clinical-trials.gov: « treatment trials »

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## Lebanon

- **Efficacy and Safety of BI 10773/BI 1356 Fixed Dose Combination in Treatment naïve and Metformin Treated Type 2 Diabetes Patients**
- Interventions: Drug: high dose BI 10773 placebo; Drug: low dose BI 10773 placebo; Drug: BI 10773; Drug: linagliptin; Drug: high dose FDC placebo; Drug: low dose FDC placebo; Drug: linagliptin placebo; Drug: BI 10773 high dose; Drug: BI 10773 low dose
- **Sponsors: Boehringer Ingelheim Pharmaceuticals; Eli Lilly and Company , Phase: Phase III**
- Study Design: Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; **Intervention** Model: Parallel Assignment; Masking: *Double-Blind*; **Primary Purpose: Treatment**
- NCT Number: NCT01422876
- Outcome Measures: Change from baseline in glycosylated hemoglobin (HbA1c); Change from baseline in fasting plasma glucose; Change from baseline in body weight

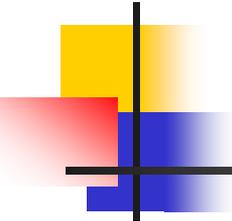


# Examples of sponsors/trials on clinical-trials.gov: « diagnostic trials »

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- **HPV Testing for Cervical Cancer Screening Study**

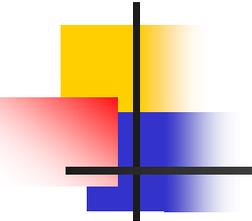
- Intervention: Procedure: Cervical cancer screening undertaken by HPV testing as a single primary screening test with cytology triage of women who are HPV positive
- **Sponsors: University of British Columbia; Canadian Institutes of Health Research (CIHR) NCT00461760 ; Completion Date: March 2014**
- Study Design: Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; **Intervention** Model: Parallel Assignment; Masking: *Single Blind* (Subject); **Primary Purpose: Diagnostic**
- Outcome Measures: Histologically confirmed greater than or equal to CIN2 detected at 2 years in both the control and the safety-check arms.; Histologically confirmed greater than or equal to CIN3 detected over the 4 years post recruitment in the control and intervention arms will be evaluated and compared as a surrogate marker for estimating reductions in the incidence of cervical cancer.; Detection of histologically confirmed greater than or equal to CIN3 in the participants allocated to 6-month retesting.; The total estimated cost per woman screened and the total estimated cost per quality-adjusted life-year gained for each technology.; Clearance of HPV infection in women who are HPV positive at recruitment; HPV type specific prevalence in the screening population



# Examples of sponsors/trials on clinical-trials.gov: « diagnostic trials »

## Lebanon

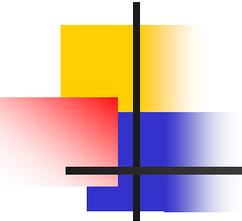
- **Trial of Screening for ALOA-IgG AtheroAbzyme Test**
- Conditions: Myocardial Ischemia; Acute Coronary Syndrome
- Interventions: Device: ALOA IgG-Elisa; Device: ALOA IgG-AtheroAbzyme
- **Sponsor: Omicron Pharmaceuticals**
- Phase: Phase III
- Study Design: Allocation: Non-Randomized; **Intervention** Model: Parallel Assignment; Masking: *Open Label*;
- **Primary Purpose: Diagnostic**
- NCT Number: NCT01272986
- Completion Date: March 2011
- Outcome Measure: Measuring the degree of oxidized low-density lipoprotein (LDL) by ALOA- IgG AtheroAbzyme in healthy and cardiovascular disease patients



# Examples of sponsors/trials on clinical-trials.gov: « educational »

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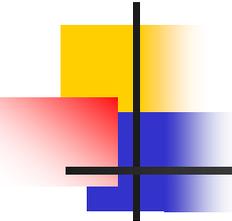
- **Australian Screening Mammography Decision Aid Trial: A Decision Aid for Women Aged 40 Thinking About Starting Mammography Screening**
- Condition: Knowledge of Mammography Screening
- **Sponsor: University of Sydney**
- Study Design: Allocation: Randomized; Endpoint Classification: Efficacy Study; Intervention Model: Parallel Assignment; Masking: *Double-Blind*;
- **Primary Purpose: Educational/Counseling/Training**
- NCT Number: NCT00139048
- Completion Date: February 2007
- Outcome Measures: Assess the change in knowledge about the issues involved in screening mammography in women who have read the decision aid.; elicit womens views on the decision aid including ease of use, content and presentation of information,,; assess the differences in intention to screen; assess the impact of the decision aid on informed choice



# Examples of sponsors/trials on clinical-trials.gov: « screening »

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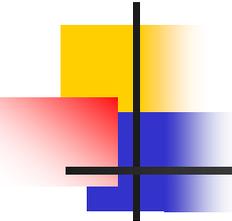
- **Randomized Preventive Vascular Screening Trial of 65-74 Year Old Men in the Central Region of Denmark**
- Conditions: Prevention; Screening; Abdominal Aortic Aneurysms; Peripheral Arterial Disease; Hypertension
- Intervention: Procedure: Screening for hypertension, lower limb atherosclerosis and abdominal aortic aneurysm
- **Sponsors: Viborg Hospital; Aarhus University Hospital**
- Study Design: Allocation: Randomized; Endpoint Classification: Efficacy Study; Intervention Model: Parallel Assignment; Masking: Single Blind (Investigator);
- **Primary Purpose: Screening**
- NCT Number: NCT00662480
- Completion Date: December 2023
- Outcome Measures: All cause mortality; Cardiovascular events



# Examples of sponsors/trials on clinical-trials.gov: « prevention »

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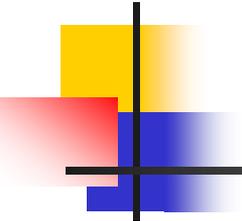
- **Albuminuria Reduction With Renin Angiotensin System Inhibitors in SCA Patients**
- Condition: Sickle Cell Disease
- Intervention: Drug: RAS Inhibitors
- **Sponsor: Assistance Publique - Hôpitaux de Paris**
- Study Design: Endpoint Classification: Efficacy Study; Intervention Model: Single Group Assignment; Masking: Open Label;
- **Primary Purpose: Prevention**
- NCT Number: NCT01195818
- Completion Date: September 2014
- Outcome Measures: Comparison of albuminuria/ urinary creatinin ratio before and after a 6 months RAS inhibitor treatment period; Comparison of albuminuria/ urinary creatinin ratio under RAS inhibitor treatment and after 1 month wash-out period; Comparison of glomerular Filtration Rate (51CR EDTA clearance) before and after a 6 months RAS inhibitor treatment period



# Examples of sponsors/trials on clinical-trials.gov: « prevention »

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- **Hypovitaminosis D : A Link Between Bone/Mineral and Fat/Fuel Metabolism**
- Interventions: Dietary Supplement: Euro D and Ci-CaID; Dietary Supplement: Euro D, Ci-CaID ; NCT01315366 ; Completion Date: January 2013
- **Sponsors:** **American University of Beirut Medical Center; Hotel Dieu de France Hospital; Rafic Hariri University Hospital**
- Study Design: Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor);
- **Primary Purpose: Prevention**
- Outcome Measures: The McAuley index of insulin resistance, bone mineral density at the hip and bone turnover markers (Osteocalcin and cross laps).; Fasting glucose, serum lipids, inflammatory markers (IL-6, CRP), adhesion molecules (sICAM, sVCAM).; Bone mineral density (BMD) at the spine and total body measured by DXA; Body fat mass and body lean mass measured by DXA; Serum DLk1 levels; Adiponectin Receptor expression from subcutaneous fat and muscle biopsies at baseline and follow-up.; .../...

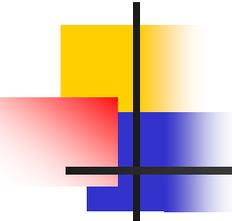


# Examples of sponsors/trials on clinical-trials.gov: « observational »

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## Lebanon

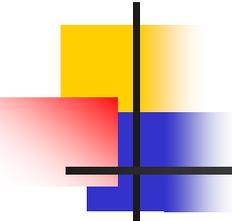
- **An Observational Study of Avastin (Bevacizumab) in Patients With Colorectal Cancer**
- **Sponsor: Hoffmann-La Roche**
- Study Design: **Observational Model: Cohort**; Time Perspective: Prospective
- NCT Number: NCT01266564
- Completion Date: February 2013
- Outcome Measures: Progression-free survival in a real life setting assessed by computer tomography; Overall response rate assessed by computer tomography; Response of Avastin according to the sites of metastases assessed by computer tomography; Chemotherapy regimens used in combination with Avastin; Patient demographics eligible to receive Avastin; Safety: incidence of adverse events



# Examples of sponsors/trials on clinical-trials.gov : « observational »

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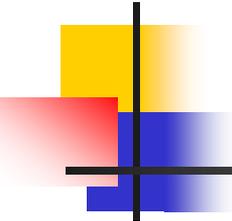
- **MAP-IDM: Identification of Molecular Markers of Sudden Death at the Acute Phase of Myocardial Infarction**
- Intervention: Genetic: Blood sample
- **Sponsor: Hospices Civils de Lyon**
- Study Design: **Observational Model: Case Control**; Time Perspective: Prospective
- NCT Number: NCT00859300
- Completion Date: February 2012
- Outcome Measure: Correlation phenotype/genotype of sudden death at the acute phase of myocardial infarct.



# Examples of sponsors/trials on clinical-trials.gov : « observational »

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- **Case-control Study of Pandemic A/H1N1 Influenza Risk Factors In Lebanon**
- Conditions: A/H1N1 Influenza; Swine Flu
- **Sponsor: St. Jude Children's Research Hospital**
- Study Design: **Observational Model: Case Control**; Time Perspective: Prospective
- NCT Number: NCT01298206
- Completion Date: August 2012
- Outcome Measures: This study will investigate the risk factors with pandemic A/H1N1 virus by measuring the degree of exposure to virus;; This study will characterize influenza viruses causing infection by using molecular and cultural techniques; This study will investigate the risk factors of severe illness or death associated with infection with the pandemic A/H1N1 viruses.



# Examples of sponsors/trials on clinical-trials.gov : « observational »

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- **Rotavirus Burden and Genotypes in a Sentinel Hospital Surveillance System in Lebanon**
- **Sponsors:** American University of Beirut Medical Center; Nini Hospital, Tripoli, Lebanon; Makassed Hospital, Beirut, Lebanon; Rafik Hariri University Hospital, Beirut, Lebanon; Hotel Dieu France, Beirut, Lebanon; Hammoud Hospital, Saida, Lebanon
- Study Design: **Observational Model: Cohort;** Time Perspective: Prospective
- NCT Number: NCT01321216
- Completion Date: June 2013
- Outcome Measures: Estimating the incidence of rotavirus gastroenteritis associated hospitalization in children < 5 years of age; Identifying the most prevalent RV genotypes in the target population included in the surveillance program; Estimating the proportion of diarrhea hospitalization due to RV in children < 5 years of age.; Determining the age and seasonal distribution of RV associated hospitalizations in children < 5 years of age; Determining seasonal changes and year-to-year changes with respect to predominant RV genotypes