Puerto Rico Institute of Statistics

Survey of Science and Technology FY 2012 and FY 2013: Research and Development (R&D)

[Public Sector Organizations]

Purpose – This survey collects data that will be used to estimate the resources dedicated to Research and Development in Puerto Rico. It will also be used for the FY 2012 and FY 2013 Survey of State Government R&D of the U.S. Census Bureau and of the National Science Foundation.

Definitions – Please read the definitions and instructions provided at the end of the questionnaire before giving your answers. These can help you to better understand the information that is being requested.

Questions – The research team is available to answer any questions, and can be contacted by telephone: (787) 993-3336 or by email: cienciaytecnologia@estadisticas.gobierno.pr.

Address – This form, when completed, can be submitted via e-mail (<u>cienciaytecnologia@estadisticas.gobierno.pr</u>), or mailed to the following address: Instituto de Estadísticas de Puerto Rico, P.O. Box 195484, San Juan, PR 00919-5484.

THE INFORMATION YOU PROVIDE IN THIS FORM IS CONFIDENTIAL and is protected under Act 209 of 2003, as amended. Data provided in this form will be used only for statistical analysis by the Puerto Rico Institute of Statistics, the U.S. Census Bureau and of the National Science Foundation and will not be shared with any other public or private entity. The results of the study will be published in a final report, which will be made available to you as a participant in this survey.

THANK YOU for your cooperation. Your response is very important to the success of this study.

1. CONTACT INFORMATION

| 1.1. Agency name |
|--|
| 1.2. Name of the agency's executive director or head of agency |
| |
| 1.3. Name of person who completed this form |
| |
| 1.4. Position |
| 1.5. E-mail address |
| 1.6. Telephone |
| 1.7. Date (mm/dd/yyyy) |

2. INFORMATION ABOUT YOUR AGENCY

| 2.1. Lev | ei of government | | | | |
|------------|--|---|-----------------|-----------------|--|
| | Federal | Commonwealth | of Puerto Rico | | Municipal |
| | Non-for-profit cor | ntrolled and mainly | y financed by g | overnment | |
| 2.2. Wh | at is the main activ | ity of your agency | in Puerto Rico? | ? | |
| | | | | | |
| exa 201 | mple, if your fiscal 1 and ends on June | year ends on June 30 th , 2012. | _ | 2012 would be | ency's fiscal year ending in 2013. For the fiscal period that begins July 1 st , M/DD/YYYY) |
| | en did your fiscal ye en did your fiscal ye | | | | M/DD/YYYY) |
| | nat was your agend erstand the relative in | | | | This information will be used to better your agency]. |
| | | | \$ | | |
| 2.5. As o | of March 12, 2013, | how many people | were employe | d by your agend | cy? |
| Full | Time | | Part time | | |

3. INFORMATION ABOUT RESEARCH AND DEVELOPMENT (R&D) ACTIVITIES IN YOUR AGENCY

Research and Experimental Development (R&D), for the purposes of this survey, is defined as creative work undertaken on a systematic basis in order to increase the stock of knowledge, including knowledge of man, culture and society, and the use of this stock of knowledge to devise new applications.

R&D covers both formal R&D and informal or occasional R&D.

The term R&D covers three activities:

- **Basic research:** experimental or theoretical work undertaken primarily to acquire new knowledge of the underlying foundation of phenomena and observable facts, without any particular application or use in view.
- **Applied research:** original investigation undertaken in order to acquire new knowledge, which differs from basic research in that it is directed primarily towards a specific practical aim or objective.
- **Experimental development:** systematic work, drawing on existing knowledge gained from research and/or practical experience, which is directed to producing new materials, products or devices, to installing new processes, systems and services, or to improving substantially those already produced or installed.

For the purposes of this survey, the term R&D does not cover activities lacking an appreciable element of novelty or routine or activities that do not lead to the resolution of scientific and/or technological uncertainty. [The Appendix of this Questionnaire provides further detail as to the inclusion or exclusion of specific activities].

- 3.1. According to the above definition, <u>did your agency do ANY of the following in Puerto Rico</u> during FY 2012 or FY 2013?
 - Had a division, branch, or office devoted to research and development
 - Performed research and development activities using department/agency staff
 - Funded research or development at another state or local government
 - Funded universities or other nonprofit organizations to perform research and development activities
 - Funded companies or individuals to perform research or development activities
 - Performed or funded other research and development activities, not specified above

| Ν | Ю |
|---|---|
| | |

YES

[If you answered "NO" please go to page 8]

3.1.1. What type of R&D activities did your agency perform in Puerto Rico in FY 2012 or FY 2013, and what proportion of total R&D expenditures were each one?(Check all that apply)

| | Did you | Proportion of | Proportion of |
|--------------------------|----------|---------------|---------------|
| Tuno of activity | perform | total R&D | total R&D |
| Type of activity | this? | expenditures | expenditures |
| | (YES/NO) | FY 2012* | FY 2013 |
| Basic Research | | % | % |
| Applied Research | | % | % |
| Experimental Development | | % | % |

3.1.2. Please describe briefly what type of R&D activities your agency performed.

| | | , ,, | , , | <i>,</i> . |
|----------------------------|--------------------------|-----------------------------|-------------------------|-----------------|
| | | | | |
| 3.2. Which depart name] | ments or divisions with | n your agency perform R&D | activities in Puerto Ri | co? [Specify by |
| | | | | |
| 3.3. In what year d | id your agency begin Res | earch and Development activ | vities in Puerto Rico? | |

^{*} If available.

3.4. Please complete the following tables with information about the **number of people who performed Research and Development activities in your agency in Puerto Rico** during **FY 2013**. Include independently contracted external consultants, but do not include personnel employed by consulting firms or other companies that provide R&D services to your agency. [See Appendix for details regarding who to consider as R&D personnel].

| Number of researchers, technicians and auxiliary | Total | By gender | |
|---|-------|-----------|-----|
| personnel in FY 2013 | Total | Women | Men |
| Researchers (includes scientists, engineers, personnel who manage or coordinate R&D tasks, and research assistants) | | | |
| Technicians | | | |
| Office staff and other auxiliary personnel | | | |

| Time in R&D activities | Average <u>number of hours per week</u> dedicated to R&D activities |
|--|--|
| Researchers | hours per researcher, average |
| Technicians | hours per technician, average |
| Office staff and other auxiliary personnel | hours per person, average |

3.5. Please complete the following chart with information about the number of people engaged in Research and Development activities in your agency in federal fiscal year **FY 2012**:

| Number of researchers, technicians and auxiliary personnel in FY 2012 | Total | By gender | |
|---|-------|-----------|-----|
| | | Women | Men |
| Researchers | | | |
| Technicians | | | |
| Office staff and other auxiliary personnel | | | |

3.6. Please complete the following tables with information about the profile of **researchers** who performed **Research and Development activities** in your agency in Puerto Rico during **FY 2013**.

| Relationship with the agency | Number of |
|------------------------------|-------------|
| | researchers |
| Full time employees | |
| Part time employees | |
| External consultant | |
| Other (specify) | |

[Don't include technicians and auxiliary personnel]

| Researchers' education level | Number of |
|--|-------------|
| (highest level of education completed) | researchers |
| Bachelor Degree | |
| Master | |
| Ph.D. or similar | |
| Medicine Doctor, Juris Doctor or similar | |
| Other (specify) | |

[Don't include technicians and auxiliary personnel]

4. RESEARCH AND DEVELOPMENT (R&D) EXPENDITURES WITHIN YOUR AGENCY

4.1. Please fill in the following table with information about Research and Development (R&D) **expenditures** within your agency in Puerto Rico in each **fiscal year**. [If exact numbers are not available, provide an estimate].

| | Amount spent, in dollars | | |
|---|--------------------------|---------|--|
| Type of expense | FY 2012[if available] | FY 2013 | |
| Remuneration to researchers* (salaries, wages, other compensation, etc.) | \$ | \$ | |
| Salaries and other compensation to R&D support staff (technicians and office staff) | \$ | \$ | |
| Materials purchased and other running costs related to R&D** | \$ | \$ | |
| Equipment and instruments used for R&D activities | \$ | \$ | |
| Buildings and properties used for R&D activities | \$ | \$ | |
| Other R&D expenditures (software, utilities, property and other taxes, etc.) | \$ | \$ | |
| TOTAL, R&D EXPENDITURES | \$ | \$ | |

^{*} Include fringe benefits of employees engaged in R&D in your agency.

^{**}Include contracts for the provision of services necessary to carry out R&D activities. However, exclude the purchase of R&D services, since they will be addressed in a separate question.

4.2. Please complete the following table with information about the sources of financing for Research and Development activities performed within your agency in FY 2012 and FY 2013. This includes R&D performed by your agency's employees, services performed by others in support of an internal R&D project, and administration or management for external R&D projects. [If exact numbers are not available, provide an estimate].

| Sources of financing for internal R&D ac | FY 2012 [if available] | FY 2013 | |
|---|-------------------------------------|---------|----|
| Funding provided by your agency's bu | ıdget | \$ | \$ |
| Funding provided by the Government | of Puerto Rico * | | |
| By which agency or agencies? | | \$ | \$ |
| Subsidy or donation | Contract |] | |
| Funding provided by the U.S. Federal | Government * | | \$ |
| By which agency or agencies? | | \$ | |
| Subsidy or donation | Contract | | |
| Funding provided by companies, foun | dations and other private entities* | | |
| By which agency or agencies? | | \$ | \$ |
| Subsidy or donation | Contract | | |
| Funding provided by other entities (un | Ś | ć | |
| Name of entit | у | ٠, | \$ |
| | TOTAL | \$ | \$ |

^{*} Include only those funds specifically granted for R&D activities, or the portion of other contracts destined specifically to R&D activities.

4.3. Do you expect that R&D expenditures of your agency in Puerto Rico in FY 2014 will:

Increase Remain the same Decrease I don't know

4.3.1. What about during the next three years (FY 2014 to FY 2016)? Expenditures in R&D will:

Increase Remain the same Decrease I don't know

5. INFORMATION ABOUT THE FUNDING OF EXTERNALR&D SERVICES BY YOUR AGENCY

5.1. During FY 2013 **did you fund Research and Development activities** or purchased R&D services to other organizations?

NO YES

| Funding of external R&D activities | | | FY 2012 [if available] | FY 2013 |
|--|----------|-------|------------------------|---------|
| Funding provided to academic institutions of Puerto Rico * | | | ć | ć |
| Subsidy or donation | Contract | | ۶ | ۶ |
| Funding provided to companies or individuals * | | ć | ć | |
| Subsidy or donation | Contract | | ۶ | ۶ |
| Funding provided to other entities | * | | ć | ć |
| Subsidy or donation | Contract | | ۶ | ۶ |
| | | TOTAL | \$ | \$ |

^{*} Include only those funds specifically granted for R&D activities, or the portion of the contracts destined specifically to R&D activities

5.2. In FY 2013, did your agency engage in Research and Development activities as part of an alliance, *joint venture*, or other **collaborative arrangement** with other organizations?

| NO | YES |
|----|--|
| | 5.2.1. With what type of organization? Please specify: |
| | Private company in Puerto Rico |
| | Private company outside Puerto Rico |
| | University in Puerto Rico |
| | University outside Puerto Rico |
| | Other (specify) |

- 6. INFORMATION ABOUT THE NATURE OF RESEARCH AND DEVELOPMENT (R&D) IN YOUR AGENCY IN PUERTO RICO
- 6.1. **During FY 2013**, have Research and Development activities in any of the following areas been performed within your agency? [Please see Appendix for definitions of these activities before responding].

| | | No | Yes | Proportion in total R&D expenditures FY 2013 |
|----------|--|----|-------|--|
| | Natural sciences | | | % |
| | Engineering and technology | | | % |
| | Medical sciences | | | % |
| | Agricultural sciences | | | % |
| | Social sciences | | | % |
| | Humanities | | | % |
| | Other (specify): | | | % |
| | | | TOTAL | 100% |
| Specific | areas | No | Yes | Proportion in total R&D expenditures FY 2013 |
| | Information and Communication Technologies (ICT) | | | % |
| | Nanotechnology | | | % |
| | Biotechnology | | | % |



6.2. What were the socio-economic objectives of the R&D activities in your agency during FY 2012 or FY2013? [Please see Appendix for definitions of these objectives before responding].

| | | No | Yes | Proportion in total R&D expenditures FY 2012 [if available] | Proportion in total R&D expenditures FY 2013 |
|----------|---|----|-----|---|---|
| | Exploration and exploitation of the Earth | | | % | % |
| | Infrastructure and general planning of land use | | | % | % |
| | Control and care of the environment | | | % | % |
| | Protection and improvement of human health | | | % | % |
| | Production, distribution and rational utilization of energy | | | % | % |
| | Agricultural production and technology | | | % | % |
| | Industrial production and technology | | | % | % |
| | Social structures and relationships | | | % | % |
| | Exploration and exploitation of space | | | % | % |
| | Non-oriented research | | | % | % |
| | Other civil research | | | % | % |
| | Defense | | | % | % |
| | Other (specify): | | | % | |
| 7. How i | nuch time did it take you to complete this questionnaire? | | | hours | |

When completed this form, please submit it e-mail you have by to cienciaytecnologia@estadisticas.gobierno.pr or mail it to the following address: Instituto de Estadísticas de Puerto Rico, P.O. Box 195484, San Juan, PR 00919-5484.

APPENDIX – DEFINITIONS

[Taken from Frascati Manual, OCDE, 2002]

Research and Experimental Development (R&D):

comprise creative work undertaken on a systematic basis in order to increase the stock of knowledge, including knowledge of man, culture and society, and the use of this stock of knowledge to devise new applications.

The term R&D covers three activities:

- Basic research: experimental or theoretical work undertaken primarily to acquire new knowledge of the underlying foundation of phenomena and observable facts, without any particular application or use in view.
- Applied research: also original investigation undertaken in order to acquire new knowledge, it differs from basic research in that it is directed primarily towards a specific practical aim or objective.
- Experimental development: systematic work, drawing on existing knowledge gained from research and/or practical experience, which is directed to producing new materials, products or devices, to installing new processes, systems and services, or to improving substantially those already produced or installed.

R&D covers both formal R&D in R&D units and informal or occasional R&D in other units.

For purposes of this survey, the term R&D **does not apply** to activities lacking an appreciable element of novelty, or to routine activities that do not lead to the resolution of scientific and/or technological uncertainty.

The following activities should be excluded from R&D:

- Education and training
- Other related scientific and technological activities, except when carried out solely or primarily for the purposes of an R&D project. That means that the following are excluded: general purpose data collection, routine tests, maintenance of national standards, feasibility studies, specialized healthcare, administrative and legal work connected with patents and licenses, policy-related studies, routine software development, and other specialized activities like collecting, coding, recording,

- classifying, disseminating, translating, analysis and evaluation.
- Other industrial activities of innovation, like the (embodied acquisition technology disembodied), tooling up and industrial engineering, industrial design n.e.c., other capital acquisition, production start-up and marketing for new and improved products. Also excluded are the industrial pre-production and production and distribution of goods and services and the various allied technical services in the business enterprise sector and in the economy at large, together with allied activities using social science disciplines, such as market research.
- The raising, management and distribution of R&D funds to performers, and indirect support activities.

R&D Personnel [question 3.4]: All persons employed directly in R&D should be counted, as well as those providing direct services such as R&D managers, administrators, and clerical staff.

Researchers: professionals engaged in the conception or creation of new knowledge, products, processes, methods and systems and also in the management of the projects concerned.

Managers and administrators engaged in the planning and management of the scientific and technical aspects of a researcher's work also fall into this category.

Postgraduate students at the PhD level engaged in R&D should be considered as researchers.

Technicians: persons whose main tasks require technical knowledge and experience in one or more fields of engineering, physical and life sciences or social sciences and humanities. They participate in R&D by performing scientific and technical tasks involving the application of concepts and operational methods, normally under the supervision of researchers.

Other supporting staff includes skilled and unskilled craftsmen, secretarial and clerical staff participating in R&D projects or directly associated with such projects.



Definitions of research areas [question 6.1.]

Natural sciences: Mathematics and computer sciences, physical sciences, chemical sciences, earth and related environmental sciences and biological sciences.

Engineering and technology: civil engineering, electrical engineering, electronics, chemical engineering, aeronautical and space, mechanical, metallurgical and materials engineering, and their specialized subdivisions, as wells as the science and technology of food production, and specialized technologies.

Medical sciences: basic medicine, clinical medicine and health sciences.

Agricultural sciences: agricultural, fisheries and allied sciences, as well as veterinary medicine.

Social sciences: psychology, economics, educational sciences, anthropology, ethnology, demography, administration, law, linguistics, political sciences, sociology, among others.

Humanities: history, archaeology, numismatics, paleography, genealogy, languages, philosophy, arts, religion, among others.

Specific areas

Information and Communication Technologies (ITC):Refers to the development of software, hardware and information technology services, as well as to technological developments in communications systems.

Nanotechnology: the creation and utilization of materials, devices, and systems sized at the level of atoms and molecules. This includes R&D in the range of 1 to 100 nanometers.

Biotechnology: The application of S&T to living organisms as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods and services.

Socio-economic objectives [question 6.2.]:

Exploration and exploitation of the Earth: covers research with objectives related to the exploration of

the Earth's crust and mantle, seas, oceans and atmosphere, and research on their exploitation. It also includes climatic and meteorological research, polar exploration and hydrology. It does not include soil improvement and land use, research on pollution, and fishing.

Infrastructure and general planning of land use: covers research on infrastructure and land development, including research on the construction of buildings and research into protection against harmful effects in town and country planning but not research into other types of pollution.

Control and care of the environment: covers research into the control of pollution, aimed at the identification and analysis of the sources of pollution and their causes, and all pollutants, including their dispersal in the environment and the effects on man, species (fauna, micro-organisms) and the biosphere. flora, Development of monitoring facilities for the measurement of all kinds of pollution is included. The same is valid for the elimination and prevention of all forms of pollution in all types of environment

Protection and improvement of human health: covers research aimed at protecting, promoting and restoring human health, broadly interpreted to include health aspects of nutrition and food hygiene. It ranges from preventive medicine, including all aspects of medical and surgical treatment, both for individuals and groups, and the provision of hospital and home care, to social medicine and pediatric and geriatric research.

Production, distribution and rational utilization of energy: covers research into the production, storage, transportation, distribution and rational use of all forms of energy. It also includes research on processes designed to increase the efficiency of energy production and distribution, and the study of energy conservation.

Agricultural production and technology: covers all research on the promotion of agriculture, forestry ,fisheries and foodstuff production. It includes: research on chemical fertilizers, biocides, biological pest control and the mechanization of agriculture; research on the impact of agricultural and forestry activities on the environment; research in the field of developing food productivity and technology.

Industrial production and technology: covers research on the improvement of industrial production and technology. It includes research on industrial products and their manufacturing processes, except where they form an integral part of the pursuit of other objectives (e.g. defence, space, energy, agriculture).

Social structures and relationships: covers research on social objectives, as analyzed in particular by social and human sciences, which have no obvious connection with other socio-economic objectives. This analysis includes quantitative, qualitative, organizational and forecasting aspects of social problems.

Exploration and exploitation of space: covers all civil space research and technology. Although civil space research is not in general concerned with particular objectives, it frequently has a specific goal, such as the increase of general knowledge (e.g. astronomy), or relates to particular applications (e.g. telecommunications satellites).

Non-oriented research: This covers all those appropriations or outlays which are earmarked for R&D but which cannot be attributed to an objective. A supplementary breakdown by field of science may be useful.

Other civil research: covers civil research which cannot (yet) be classified to a particular socio-economic objective.

Defense: includes all R&D programs undertaken primarily for defense reasons, regardless of their content or whether they have secondary civil applications. Thus, the criterion is not the nature of the product or subject (or who funds the program) but the objective. The objective of defense R&D is the creation or enhancement of techniques or equipment for use by national, overseas or multinational armed forces.

R&D IN SPECIFIC SECTORS

R&D in software development

For a software development project to be classified as R&D, its completion must be dependent on a scientific and/or technological advance, and the aim of the project must be the systematic resolution of a scientific and/or technological uncertainty.

Software development is an integral part of many projects which in themselves have no element of R&D. The software development component of such projects, however, may be classified as R&D if it leads to an advance in the area of computer software. Such advances are generally incremental rather than revolutionary. Therefore, an upgrade, addition or change to an existing program or system may be classified as R&D if it embodies scientific and/or technological advances that result in an increase in the stock of knowledge. Use of software for anew application or purpose, however, does not by itself constitute an advance.

In addition to the software that is part of an overall R&D project, the R&D associated with software as an end product should also be classified as R&D.

A scientific and/or technological advance in software maybe achieved even if a project is not completed, because a failure can increase knowledge of the technology of computer software by showing, for example, that a particular approach will not succeed.

Should be included in R&D:

- Development of information technology at the level of operating systems, programming languages, data management, communications software and software development tools.
- Development of Internet technology.
- Research into methods of designing, developing, deploying or maintaining software.
- Software development that produces advances in generic approaches for capturing, transmitting, storing, retrieving, manipulating or displaying information.
- Experimental development aimed at filling technology knowledge gaps as necessary to develop a software program or system.
- R&D on software tools or technologies in specialized areas of computing (image processing, geographic data presentation, character recognition, artificial intelligence and other areas).
- R&D producing new theorems and algorithms in the field of theoretical computer science.

Software-related activities of a routine nature which do not involve scientific and/or technological advances or resolution of technological uncertainties are **not to be included** in R&D.

Examples are:

- Business application software and information system development using known methods and existing software tools.
- Support for existing systems.
- Converting and/or translating computer languages.
- Adding user functionality to application programs.
- Debugging of systems.
- Adaptation of existing software.
- Preparation of user documentation.

R&D in the social sciences and humanities

For the social sciences and humanities, an appreciable element of novelty or a resolution of scientific/technological uncertainty is again a useful criterion for defining the boundary between R&D and related (routine) scientific activities. This element may be related to the conceptual, methodological or empirical part of the project concerned. Related activities of a routine nature can only be included in R&D if they are undertaken as an integral part of a specific research project or undertaken for the benefit of a specific research project. Therefore, projects of a routine nature, in which social scientists bring established methodologies, principles and models of the social sciences to bear on a particular problem, cannot be classified as research.

The following are examples of work which might fall into this routine category are generally not R&D: commentary on the probable economic effects of a change in the tax structure, using existing economic data; use of standard techniques in applied psychology to select and classify industrial and military personnel, students, etc., or to test children with reading or other disabilities.

R&D in service activities

The following are among the criteria that can help to identify the presence of R&D in service activities:

- Links with public research laboratories.
- The involvement of staff with PhDs, or PhD students.
- The publication of research findings in scientific journals, organization of scientific conferences or involvement in scientific reviews.
- The construction of prototypes or pilot plants

Examples of R&D in banking and insurance:

- Mathematical research relating to financial risk analysis.
- Development of risk models for credit policy.

- Experimental development of new software for home banking.
- Development of techniques for investigating consumer behavior for the purpose of creating new types of accounts and banking services
- Research to identify new risks or new characteristics of risk that need to be taken into consideration in insurance contracts.
- Research on social phenomena with an impact on new types of insurance (health, retirement, etc.), such as on insurance cover for non-smokers.
- R&D related to electronic banking and insurance, Internet-related services and e-commerce applications.
- R&D related to new or significantly improved financial services (new concepts for accounts, loans, insurance and saving instruments).

Examples of **R&D** in other service activities:

- Analysis of the effects of economic and social change on consumption and leisure activities.
- Development of new methods for measuring consumer expectations and preferences.
- Development of new survey methods and instruments.
- Development of tracking and tracing procedures (logistics).
- Research into new travel and holiday concepts.
- Launch of prototype and pilot stores.

R&D and industrial activities

If the primary objective is to make further technical improvements on the product or process, then the work comes within the definition of R&D. If, on the other hand, the product, process or approach is substantially set and the primary objective is to develop markets, to do preproduction planning or to get a production or control system working smoothly, the work is no longer R&D.

Care must be taken to exclude activities which, although undoubtedly a part of the innovation process, rarely involve any R&D, e.g. patent filing and licensing, market research, manufacturing start-up, tooling up and redesign for the manufacturing process.

Specific cases:

- Prototypes: Included in R&D, as long as the primary objective is to make further improvements.
- Pilot plant: Included in R&D, as long as the primary purpose is R&D.
- Industrial design and drawing: Include design required during R&D. Exclude design for production process.
- Industrial engineering and tooling up: Include "feedback" R&D and tooling up industrial engineering associated with development of new products and new processes. Exclude for production processes.
- **Trial production**: Include if production implies full-scale testing and subsequent further design and engineering. Exclude all other associated activities.
- After-sales service and trouble-shooting: excluded from R&D
- Patent and license work: excluded from R&D.
- Routine tests: excluded from R&D.
- Data collection: excluded from R&D.

Clinical trials

Before new drugs, vaccines or treatments can be introduced on the market, they must be tested systematically on human volunteers to ensure that they are both safe and effective. These clinical trials are divided into four standard phases, three of which take place before permission to manufacture is accorded. For the purposes of international comparison, by convention, clinical trial phases 1, 2 and 3 can be treated as R&D. Phase 4 clinical trials, which continue testing the drug or treatment after approval and manufacture, should only be treated as R&D if they bring about a further scientific or technological advance. Moreover, not all activities undertaken prior to permission to manufacture are considered to be R&D, especially when there is a significant wait after the completion of phase 3 trials, during which marketing and process development activities may be started.

[Most definitions and explanations included in this Appendix are quotations from the Frascati Manual, OCDE,2002. This Manual contains the internationally agreed-upon definitions and methodologies used to estimate there sources dedicated to Research and Development in each country].