Updated on 11 May 2020 according to the Regulations for the awarding of research grants D.R. n.550 of 14 May 2020

BANDO TOTALE CARICO

THE DIRECTOR

- HAVING REGARD TO the Law n. 240 of 30 December 2010, art. 22 and subsequent amendments and additions;
- HAVING REGARD TO the Decree-Law n. 192 of 31 December 2014, converted into Law n. 11 of 27 February 2015;
- HAVING REGARD TO the Law n. 476 of 13 August 1984 and subsequent amendments;
- HAVING REGARD TO the Law n. 335 of 8 August 1995 and subsequent amendments;
- HAVING REGARD TO the Law n. 127 of 15 May 1997 and subsequent amendments;
- HAVING REGARD TO the D.P.R. n. 445 of 28 December 2000;
- HAVING REGARD TO the Law n. 241 of 7 August 1990 and subsequent amendments;
- HAVING REGARD TO the Statute of the University of Florence;
- HAVING REGARD TO the current University Regulations for the implementation of the Law n. 241/1990 and subsequent amendments and additions, regarding access to administrative documents;
- HAVING REGARD TO the Legislative Decree n. 196 of 30 June 2003, Code on the protection of personal data;
- HAVING REGARD TO the current University Regulations on the protection of personal data;
- IN VIEW of the current Code of Ethics of the University of Florence;
- HAVING REGARD TO the D.R. n. 550 of 14 May 2020 of enactment of the "Regulations for the awarding of research grants" pursuant to art. 22 of the law n. 240 of 30 December 2010;
- HAVING REGARD TO the Decree of the Minister of Education, University and Research n. 102 of 9 March 2011 which establishes the gross annual minimum amount of research grants;
- HAVING REGARD TO the resolutions of the Academic Senate and of the Board of Directors respectively of 29 and 30 April 2020 which establish the maximum annual gross amount of research grants;
- RECALLED the President's decree of 09/04/2020 Ref. n. 56053 (Directory n. 471/2020) containing the Guidelines for carrying out the online competition procedures for research grants and scholarships and research;
- GIVEN THAT with the Ministerial Decree 737/2021, published on 5/8/2021, the Ministry of University and Research has defined the distribution and use criteria for the three-year period 2021/23 of the resources referred to in the Fund for the promotion and development of university policies National research programme.
- GIVEN THAT with resolutions of the Academic Senate and the Board of Directors of 14 October 2021, the Programmatic Report containing the initiatives that the University intends to implement pursuant to the Ministerial Decree was approved. 737/2021.
- GIVEN THAT with subsequent resolutions of the Academic Senate and the Board of Directors respectively in the sessions of 16 and 25 February 2022, among the initiatives envisaged in the programmatic report, the issuing of the "University call for funding research projects for young researchers" was approved. independent within the themes of the 2021/27 PNR".

- GIVEN THAT the University Announcement mentioned above provided for the presentation of projects by groups of young researchers whose applications, if positively evaluated, provided for their contractualization with specific research grants pursuant to art. 5 of the Notice and Art. 13 of the University Regulations on the matter, issued with Rectoral Decree no. 68910 (550) of 14 May 2020.
- GIVEN THAT the Rectoral Decree 1401/2022 (Prot. n. 0261768) of 16 November 2022 approved the results of the selection and declared the proposal "BayesMeCOS - Bayesian Methods for Clinical and Observational Studies" among the winning projects;
- GIVEN THAT with the resolution of the Council of the Department of Statistics, Informatics, Applications "G. Parenti" (DiSIA) of the University of Florence dated 20 January 2023, the activation and contractualization of three research grants of the proposing group was approved , of which one with the role of Team Leader and two with the role of Team Member, contract duration 24 months, starting from 02/01/2023 relating to the funded project "BayesMeCOS - Bayesian Methods for Clinical and Observational Studies";
- HAVING TAKEN NOTE of the resignation of two research fellows with the role of team member, Prot.n. 208073 of 09/15/2023 and Prot.n. 207894 of 09/15/2023;
- HAVING REGARD TO the resolution of the Council of the Department of Statistica, Informatica, Applicazioni 'G. Parenti' of 27/09/2023 which approves the opening of a new selection for research grants financed by Department for an amount of €35,000.00 which will be paid entirely by the project DM737_GIOVANI_RICERCATORI_BayesMeCOS - Bayesian Methods for Clinical and Observational Studies- BayesMeCOS - B55F21007810001 in order to continue the research project; COAN N. 90288 del 26/09/2023;
- HAVING REGARD to the positive opinion of the University Research Commission, note Prot.n. 233590/2023 Of 05/10/2023;
- VERIFIED by the Director of the Department the availability of sufficient funds in its budget to cover the amount granted by this Call for Applications;

DECREES

the issuing of the following:
Call for applications, evaluating qualifications and interview for n. 1 grant in the Area of Area Scientifica for carrying out research activities.

Art.1
Object of the Call

A selection is called, based on qualifications and interview, for n. 1 grant for carrying out research activities to be performed as indicated below:

ACADEMIC DISCIPLINE	RESEARCH PROGRAMME	CURRICULAR REQUISITES AND ACADEMIC TITLES AS PER ART.3 OF THE REGULATIONS	ADDRESS OF THE UNIT OF AFFILIATION
SECS-S/01	Title of the Research: Bayesian Methods for Clinical and Observational Studies - BayesMeCOS Scientific Supervisor: Prof.ssa Carla Rampichini	Dottorato di ricerca generico Dottorato di ricerca, o PhD o titolo equivalente conseguito all'estero in ambito scientifico affine all'oggetto del bando Scientific-professional CV responding to the requisites	DISIA Viale Morgagni, 59

The detailed research programme is an integral part of this call.

Art.2
Awarding of the grant – Renewal

The selected candidate will be awarded a grant for the amount of **€ 24.319,56 per year**, inclusive of the social security costs payable by the grant holder. The grant will be paid in deferred monthly instalments.

The grant is awarded for the duration of **14 *months* with effect from 01/12/2023** and may possibly be renewed to the same person for a maximum of **six** years overall, as regulated by art. 22 of Law 240/2010 and subsequent amendments, with the exception of the period in which the grant was received in connection with the research doctorate, within the maximum limit of the legal duration of the PhD programme.
For the purposes of calculating the maximum duration, the periods spent on maternity leave or sick leave are not counted according to the provisions of current legislation.
In the event of renunciation or revocation, the places made available can be assigned to candidates placed in a useful position in the ranking for a period of not less than 12 months and compatibly with the available resources.
The renewal, at the same conditions of the original contract, is decided by the Director of the Department upon request by the Scientific Supervisor. The renewal is subject to the positive evaluation of the activity carried out by the research manager, as well as to the actual budget availability.

Art.3
Requisites for admission to the selection

Candidates who must be in possession of the following requirements on the closing date of the Notice can apply for the selection:

- have obtained the **research doctorate title no more than 5 years ago**, calculated with respect to the expiry date of the announcement. The date from which the eligibility calculation starts is that of the date of discussion of the doctoral thesis.
- not have active contractual relationships with the University of Florence or with other Italian universities falling within the following typologies: Fixed-term researcher referred to in letters A) and B) of article 24 of law 240 of 30 December 2010, Permanent researcher , 1st and 2nd level teacher;
- each candidate at the start date of the contract cannot have been the holder of research grants for a duration such as to exceed, with the fourteen monthly salaries provided for in this Notice, the limit of 6 overall years established in art. 6, paragraph 2 bis of the Law 27/2/2015, n.11. In calculating the 6 years, the period in which the grant was used in conjunction with the PhD without scholarship is not relevant, within the maximum limit of the legal duration of the relevant course;

Requirements:
- DT - Dottorato di ricerca generico
- Dottorato affine - Dottorato di ricerca, o PhD o titolo equivalente conseguito all'estero in ambito scientifico affine all'oggetto del bando

Scientific-professional curriculum suitable for carrying out the research:
• The curricula presented must include the relevant publications produced in the 5 years preceding the deadline of the Call (max 10 publications) and the main research results achieved.

The requirements must be met by the deadline of the Call for Applications.

For the purpose of evaluating the PhD title, the discussion of the thesis with a positive outcome must happen prior to the commencement of the qualification evaluation procedure by the Admissions Board. *(to be included only if the PhD is only a preferential title)*

All academic qualifications obtained abroad (degree, doctorate and any other qualifications) must, as a rule, be previously recognized in Italy according to current legislation on the matter. The equivalence of foreign qualifications, if not yet officially recognised, will be evaluated exclusively for the purposes of the admission of the candidate to this selection by the Admissions Board at the time of assessment of academic titles, based on the appropriate documentation (art.4 para.4).
Candidates in possession of an academic qualification obtained abroad, which has not yet been declared equivalent by the Italian authorities, must send the official translation with the "dichiarazione di valore" of the foreign qualification by the competent Italian diplomatic or consular representations in the country of origin, according to the regulations in force on the subject, within thirty days from the decree approving the selection results and in any case **within 30 days** from the decree approving the selection results and in any case at the time of signing the contract.
In case the documents are not received within this period the candidate will be not be eligible to sign the contract.

Art.4
Submission of the application and the academic titles

The application for participation in the selection, drawn up in accordance with the facsimile set out in **Annex 1**, must be sent to the Director of the Department of Statistica, Informatica, Applicazioni 'G. Parenti' Viale Morgagni, 59 exclusively via electronic means, according to the following methods:

a) by **certified email (PEC)** to the following address: **disia@pec.unifi.it**. The candidates in turn must have a certified PEC email as well.

b) by **email** to the following address: **disia@disia.unifi.it**.

To fill in the application, it is necessary to use the "Online applications" section: https://stlabtest.dinfo.unifi.it/beta/akademia-candidature/
The generated application must be signed by the candidate and sent, according to one of the methods mentioned above, in PDF format together with a scan of a valid photo ID.
Please note: ALL documents must be in PDF format.

The subject line of the email must contain the following: "Application for the grant as announcement D.D. n DA INDICARE of DA INDICARE"

The deadline for submitting the selection application is 23/10/2023 at 01:00 pm) under penalty of exclusion for late submissions.

The interview will be held on **06/11/2023 at 10:00 ONLINE.**

The above information constitutes a formal and final convocation for the interview.

In order to be admitted to the interview all candidates must present a valid ID.

The interview will be carried out electronically in accordance with the Guidelines for carrying out telematic competition procedures for research grants and scholarships and research (D.R. n.56053 (471) of 04/09/2020).

In the application letter the candidate must indicate the exact denomination of the Call they wish to apply to, indicating the Area and the Research project as per art.1.

They must furthermore declare under their responsibility, as provided for in DPR n. 445/2000, the following:

- name and surname, tax identification number (codice fiscale), date and place of birth; citizenship;
- residence and the address of the domicile chosen for the purposes of the selection (specifying the area code and telephone number) as well as the email address for any communications relating to this notice;
- the degree required, the date, the university and the country where it was obtained;
- that they do not currently have any pending administrative or criminal proceedings and, in case of past criminal or civil convictions, list all charges in detail (the date of the judgment, the judicial authority and the type of judgment, the violated rules, the number of proceedings and the penalties reported);
- that they have been dismissed, released from previous employment with a public administration for persistent insufficient performance and that they have never been discharged from other state employment pursuant to art. 127 letter d) of the Consolidated Law 10 January 1957, n. 3, for having obtained the employment through the production of false documents or formally defective, or not to be prevented from public service following disciplinary dismissal;
- that they are not aware of being subjected to criminal proceedings, or to have ongoing criminal proceedings. In the latter case, indicate the offenses for which the criminal proceedings are underway, the Authority and the status of the proceedings;
- that they enjoy civil and political rights;
- that they are not part of the permanent staff of the universities and other bodies indicated in art. 22, paragraph 1, Law n. 240/2010;
- if they are holders of research grants relating to previous periods carried out pursuant to art. 22 of Law 240/2010;
- that they are aware of the bans on accumulation and incompatibilities provided for in art.12 of this announcement;
- that they will promptly communicate any change of residence or address.

Art.5
Documents to be attached to the application

Candidates must attach to the application:

- scan of a valid ID;
- a scientific-professional CV in Italian or in English, using the European template. The CV must be signed and completed with all relevant documents and attachments;
- the scientific publications and articles in pdf format;

- a self-certification relating to the academic qualifications held, both those required for participation in the selection and any further qualifications deemed useful for the assessment, with an indication of the institution that issued them and the date it was awarded **(Annex 2)**;
- for the qualification obtained abroad, if already declared equivalent, attach the relevant documentation; otherwise, attach a copy of the foreign qualification with a translation in Italian or English;
- signed and dated list of all attached titles, awards and certificates and any other document mentioned with all necessary information to retrieve them **(Annex 3)**;
- **(if applicable)** Declaration of acceptance of the online mode for the interview **(Annex 5)**.

In order to allow the subsequent insertion of the data relating to the researcher contract in the MIUR database, the CINECA form **(Annex 4)** must be **completed in full and signed by the candidate**, the content of which must coincide with what is indicated in the application.
The data of the successful candidate will also merge into their individual profile inside the MIUR website **https://loginmiur.cineca.it**, to which the grant holder will have access, once registered.
The Administration cannot be held responsible of the consequences deriving from incorrect indications by the candidate or from any technical/IT issues in submitting the application.

Art.6
Exclusions

Candidates are excluded from participation in the selection when any of these situations occur:

- the application has been submitted after the deadline set out in art.4;
- the application has been submitted after the deadline set out in art. 4they have not attached the required self-declarations regarding the possession of the admission requirements, or that they have produced false or non-compliant declarations, certifications and/or documentation;

The following candidates are NOT ALLOWED under any circumstances to take part to the selection procedure those who have a relationship of kinship and affinity, up to and including the fourth degree, with academic staff belonging to the Department where they are asked to carry out the Research Project, or with the President, the General Manager or a member of the University's Board of Directors, as required by art. 18, paragraph 1 letter c) of Law n. 240, and in accordance with art. 4, paragraph 2, letter c) of the current Code of Ethics of the University of Florence, or with any of the members of the Selection Board.
The Administration may enforce these exclusion measures at any time in all cases of lack of the required prerequisites.
The Administration will carry out checks on the truthfulness of the content of the substitute declarations.

Art.7
Composition of the Admissions Board

The Admissions Board, nominated following the deadline of the call with a decree from the Director of the Department of Statistica, Informatica, Applicazioni 'G. Parenti', published on the Official Register of the University, it will be composed of three members chosen from tenured professors and researchers belonging to the same scientific area in which the research will be carried out. The Board can be supplemented by a representative of the funding body, if applicable. In any case, the research manager whom the grant holder will collaborate with, will be a member of the Admissions Board.

Art.8
Evaluation of qualifications and interview

The Admissions Board will evaluate, for the sole purpose of candidates' admission to the selection, the equivalence of qualifications obtained abroad that have not yet been recognized in Italy according to the legislation in force on the matter.

The Admissions Board will then carry out a comparative evaluation of the candidates by formulating an analytically motivated judgment and identifying the name of the successful candidate. With the same score, the youngest candidate in the ranking precedes.

For the evaluation of the candidates, the Admissions Board will have 100 points, **60** of which to be attributed overall to the candidate's qualifications and scientific professional curriculum and the remaining **40** points to be reserved for the interview.

The evaluation of qualifications will be carried out before the interview.
The Admissions Board will proceed first thing with the assignment of the overall scores to the evaluable items, the qualifications and the curriculum, as indicated below:

- educational qualifications, additional to the requirements for admission: up to a maximum of 40 points
- professional scientific curriculum: up to a maximum of 20 points.

The Admissions Board establishes the following minimum score that candidates must achieve in the evaluation of qualifications in order to be admitted to the interview: 10 points

The Admissions Board establishes the following minimum score that candidates must achieve in the interview in order to be considered suitable: **20** points

The Admissions Board will not proceed with the evaluation of the qualifications, unless all the elements and data necessary for such evaluation are indicated.

As part of the interview, the Admissions Board will proceed to ascertain, among other aspects, the knowledge of the field subject of the call, the clarity of presentation and the suitability of the candidate to carry out the research called for.

Both in the evaluation of the qualifications and the interview, the Evaluation Commission will in particular evaluate the relevance of the profile of the proposers with respect to the topic referred to in the BayesMeCOS project.

The Admissions Board results will send a report with the final evaluation to the Director of the Department for approval.
The results of the evaluation will be published on the University's Official Register and on the Department's own website www.disia.unifi.it.
The results of the selection will be communicated personally to the selected candidate(s) by the Department. Any complaint against the approval decree must be filed to the Director of the Department within ten days from the date of publication, in accordance with art. 12 the current Regulations for the assignment of research grants.

Art.9
Insurance

Research fellows are insured by the University for Civil Liability against Third Parties and for Accidents starting from the beginning of the research activity without charges against them

(information on the University website on the http page: http://www.unifi.it/vp-3514-schema-tipo-di-contratto-per-collaborazione-ad-attivita-di-ricerca.html#assicurazioni).

Art.10
Contract and required documents

The Department will contact the successful candidate in order to sign a contract regulating collaboration in the research activity, after checking the actual availability of the funds.
To such contract must be attached a copy of the insurance policy as per previous article.
The successful candidates must, at the time of signing the contract submit copies of the following documents:

- a valid photo ID;
- tax identification number (codice fiscale);
- resident permit where it is indicated a reason consistent with the research grant (only for non-EU citizens).

Citizens of countries outside of the European Union must be in possession of one of the residence permits provided for by the current immigration legislation in order to sign the contract for research fellowship with the University of Florence. Therefore, it will not be possible to proceed with the stipulation of the contract if the winner is not in possession of a suitable residence permit. If this condition occurs, the aforementioned candidate will be declared lapsed and the contract will be offered to the next suitable candidate in the ranking.

The ascertainment of this condition will be made at the time of signing the contract.
Furthermore, even if the loss of possession of the residence permit occurs after the contract has been signed, such condition will constitute cause for its termination.

In case the candidate holds a foreign title as one of the prerequisites, and then fails to obtain by the competent Italian diplomatic or consular representations in the country of origin, and then submit within 30 days, the required legalisation and declaration of value of such academic title, he or she will be ineligible to sign the contract.

Art.11
Intellectual property

The management of industrial and intellectual property rights deriving from research carried out by university staff is governed by art. 65 of the Industrial Property Code (Legislative Decree n. 30 of 2005 and subsequent amendments) and by the *"Regulation for the management of industrial and intellectual property rights with reference to the research activities carried out by university staff"* issued with D.R. n.82735 (526) of 08/05/2019, which provides that, in the case of bound research, i.e. funded in whole or in part by private entities, or carried out in the context of specific research projects funded by public entities other than University, the industrial property rights that may result belong to the University, which remains the owner of any rights deriving from inventions obtained with the contribution of its researchers, pursuant to art.3 of the aforementioned Regulations.
Pursuant to art.1 para. 3 of the Regulations, the grant holder, with the stipulation of the contract, declares to accept the application of the rules indicated therein.

Art.12
Prohibition of cumulation – incompatibility

The grant cannot be combined with scholarships of any kind, except with those awarded by national or foreign institutions for the purpose of integrating training and research activities with stays abroad.

Research grants cannot be awarded to permanent staff of universities, institutions and public research and experimentation bodies, the National Agency for New Technologies, Energy and Sustainable Economic Development (ENEA) and Italian Space Agency (ASI), as well as of institutions whose scientific specialization diploma has been recognized as equivalent to the title of research doctor pursuant to art.74, fourth paragraph, of the decree of the President of the Republic 11 July 1980, n.382.
Employees serving in public administrations or private entities other than those specified in the paragraph above, with full-time, part-time or fixed term contract, are entitled to hold a research grant on the condition that they be placed on leave without pay for the duration of the research project or that their private employment contract is put on hold.
The awarding of the grant is not compatible with participation in degree programmes of any level including specialist or professional master courses, PhD with scholarship or medical specialization, in Italy or abroad.
The holder of the grant cannot be in a relationship of kinship and affinity up to the fourth degree included with any academic belonging to the Department where the research is carried out, or with the President, the General Manager or a member of the University's Board of Directors, as required by art.18, paragraph 1, letter c) of Law n.240/2010, and in accordance with art.4, paragraph 2, letter c) of the current Code of Ethics of the University of Florence as well as with any member of the Admissions Board as per art.6 of this Call.
The research grant holder can carry out self-employed work only after authorization by the Department Council, having heard the motivated opinion of the scientific director of the grant, after verifying that this activity is:

a. compatible with the research activity set out in the grant;
b. not prejudicial to the conduct of research activities;
c. not in conflict of interest with the specific research activity carried out;

also taking into account the reporting rules set forth by the funding body.

Art.13
Suspension of the contract

The research activity must be suspended for maternity leave. In this case, the provisions of the decree of the Minister of Labour and Social Security 12 July 2007, published in the Official Journal n.247 of 23 October 2007 will apply.
The period of compulsory suspension for maternity will be recovered at the end of the natural expiry of the contract in accordance with the provisions of current legislation.
The research activity can be suspended for grave illness or for serious family reasons and also in this case, the suspension periods can be recovered at the end of the natural expiry of the contract, subject to agreement with the academic in charge and in compliance with the limits imposed by the funds available.
During the period of compulsory maternity leave, the allowance paid by INPS, or by another social security fund, is integrated up to the full amount of the grant with monies paid by the University
In case of maternity or any other type of leave, reference is made to art.22 paragraph 6 of Law n.240/2010
Concerning sick leave, the law that applies is n.296, art.1, paragraph 788 and subsequent amendments and integrations.
The suspension measure is ruled by a decree from the Director of the Department where the research is conducted.

Art.14
Termination of the contract

If the researcher does not continue the activity foreseen by the research program without a justified reason or is responsible for serious or repeated shortcomings, at the motivated request of the Research Manager and with the resolution of the Council of the Department, the termination of the contract can be ordered, pursuant to art.1453 et seq. of the civil code.
The termination measure is ruled by a decree from the Director of the Department where the research is conducted.

Art.15
Withdrawal by the research grant holder

The grant holder has the right to withdraw from the research programme, giving a notice of at least **15 (fifteen)** days addressed to the Director of the Department and to the research project manager.
Failure to do so implies the withholding of the amount corresponding to the period of mandatory advance notice.

Art.16
Attending PhD courses

The research grant holder can attend, as an extra and without the right to any scholarship, PhD courses, provided that he/she passes the required admission tests and, if applicable, pays any fee connected to the courses.

Art.17
Tax and social security provisions

The provisions of Art.4 of the Law n.476 of 13 August 1984 and subsequent amendments and additions, apply to research grants regarding tax matters. As far as social security is concerned, the applicable law is n.335 of 8 August 1995, art.2, paragraphs 26 and following and subsequent amendments.

Art.18
Personal data processing

Candidates are invited to read the "Information for the processing of personal data of interested parties to participate in personnel recruitment procedures or selection procedures for admission to courses with a limited number or for the awarding of research grants, scholarships, collaborative and/or teaching assignments" available at:
https://www.unifi.it/upload/sub/protezionedati/Informativa_SELEZIONI.pdf
The application forms and documents produced by the candidates constitute "administrative documents" with respect to which, except in exceptional cases, the need for confidentiality must be excluded. These documents, once acquired by the selection procedure, are no longer considered to be within the personal sphere of the participants who, therefore, do not take on the role of counter parties, in any claim to access the documents of the procedure by another party. In any case, the provisions of the GDPR (EU Regulation 2016/679 of the European Parliament and of the Council of 27 April 2016 published on the OJEU of 04 May 2016), relating to the protection of individuals with regard to the processing of Personal Data and the movement of such data, will be abided to.

Art.19
Procedure manager

The manager for this selection procedure is Mr. **Niccolò Saccardi**, address Viale Morgagni, 59 - 50134 - Firenze, ph. **055-2751500**, e-mail: **niccolo.saccardi@unifi.it**, Certified e-mail (pec): **disia@pec.unifi.it.**

Art. 20
Final provisions and publication

For all matters not provided for in this announcement, reference is made to the current legislation in force.

The notice will be posted in the University's Official online Register, on: https://www.unifi.it/vp-391-assegni-di-ricerca.html, on the website of the Ministry of Education and Research (MIUR) and on the European Union's Euraxess website.

Florence,

THE DIRECTOR OF THE DEPARTMENT
Prof.ssa Carla Rampichini

UNIVERSITÀ DEGLI STUDI FIRENZE
DISIA DIPARTIMENTO DI STATISTICA, INFORMATICA, APPLICAZIONI "GIUSEPPE PARENTI"
CARLA RAMPICHINI
09.10.2023 14:44:27
GMT+00:00

RESEARCH GRANT

Titolo: "Metodi bayesiani per studi clinici e osservazionali - BayesMeCOS"

Title: "Bayesian Methods for Clinical and Observational Studies - BayesMeCOS"

DESCRIPTION OF THE RESEARCH ACTIVITY

Description: Traditional development of new drugs and biomarkers has followed the "one drug, one target disease" strategy, which is costly and inefficient and often leads to failure. Contrary to this strategy, the project aims to create Bayesian Methods for Clinical and Observational Studies (BayesMeCOS) that study heterogeneous populations, target several diseases, and test various treatments from the pre-clinical and clinical stages. The aim is to provide flexible tools whose interest goes beyond the immediate scope of this project to improve precision medicine. BayesMeCOS aim to provide a methodology that will serve to speed up the drug development process while increasing power of results and biomarker discovery using adaptive randomization. To achieve such a goal, BayesMeCOS will firstly focus on facilitating the identification of subgroups of patients and biomarkers, profiling graphical models to model in a single graph the effect of an external factor on the dependence structure of a multivariate set of variables. Second, BayesMeCOS will create Bayesian adaptive designs that integrate data coming from non-concurrent trials, leveraging Bayesian hierarchical models, and provide a way to analyze the effect of the treatments in the presence of intercurrent events within the Principal Stratification framework. Programs to implement the novel methods will be developed, providing open-source software. Both simulated data and real data will be used to test the proposed methods.

Descrizione: Lo sviluppo tradizionale di nuovi farmaci e biomarcatori ha seguito la strategia "un farmaco, una malattia", che è costosa e inefficiente e spesso porta al fallimento. Contrariamente a questa strategia, il progetto mira a creare Metodi Bayesiani per Studi Clinici e Osservazionali (BayesMeCOS) che studiano popolazioni eterogenee, mirano a diverse malattie e testano vari trattamenti dalle fasi precliniche e cliniche. L'obiettivo è fornire strumenti flessibili il cui interesse va oltre l'ambito immediato di questo progetto per migliorare la medicina di precisione. BayesMeCOS mira a fornire una metodologia che serva ad accelerare il processo di sviluppo dei farmaci, aumentando al contempo la potenza dei risultati e la scoperta di biomarcatori grazie alla randomizzazione adattiva. Per raggiungere questo obiettivo, BayesMeCOS si concentrerà innanzitutto sulla facilitazione dell'identificazione di sottogruppi di pazienti e biomarcatori, profilando modelli grafici per modellare in un singolo grafico l'effetto di un fattore esterno sulla struttura di dipendenza di un insieme multivariato di variabili. Inoltre, BayesMeCOS creerà disegni adattivi bayesiani che integreranno i dati provenienti da studi non concomitanti, sfruttando modelli gerarchici bayesiani, e fornirà un modo per analizzare l'effetto dei trattamenti in presenza di eventi intercorrenti all'interno del quadro della Stratificazione Principale. Saranno sviluppati programmi per implementare i nuovi metodi, fornendo software open-source. Per testare i metodi, saranno impiegati sia dati simulati che reali.

f.to Scientific Supervisor
Prof.ssa Carla Rampichini.

Project proposal

Abstract

Traditional development of new drugs and biomarkers has followed the "one drug, one target disease" strategy, which is costly and inefficient and often leads to failure. Contrary to this strategy, the project aims to create Bayesian Methods for Clinical and Observational Studies (BayesMeCOS) that study heterogeneous populations, target several diseases, and test various treatments from the pre-clinical and clinical stages. The aim is to provide flexible tools whose interest goes beyond the immediate scope of this project to improve precision medicine. BayesMeCOS aim to provide a methodology that will serve to speed up the drug development process while increasing power of results and biomarker discovery using adaptive randomization. To achieve such a goal, BayesMeCOS will firstly focus on facilitating the identification of subgroups of patients and biomarkers, profiling graphical models to model in a single graph the effect of an external factor on the dependence structure of a multivariate set of variables. Second, BayesMeCOS will create Bayesian adaptive designs that integrate data coming from non-concurrent trials, leveraging Bayesian hierarchical models, and provide a way to analyze the effect of the treatments in the presence of intercurrent events within the Principal Stratification framework. Programs to implement the novel methods will be developed, providing open-source software. Both simulated data and real data will be used to test the proposed methods.

Background and general objectives

The drug development process consists of different stages: (i) pre-clinical stage, aiming to discover and develop drug candidates and test them on animals; (ii) clinical stage, in which the efficacy and toxicity of the drugs are tested; (iii) therapy approval for marketing by regulatory agencies; (iv) post-approval research and safety monitoring (Rang and Hill, 2013; Salazar and Gormley, 2017). Traditional pre-clinical and clinical stages assume that the whole population responds to the same treatment in the same manner, thus following the "one drug, one target disease, one population" (Berry, Connor and Lewis, 2015; Pandika, 2018). Parallel-group randomized controlled trials (RCTs) are the gold standard for clinical testing. RCTs can slow down the development of new therapies as, typically, only a single treatment is tested for one population having the same disease. It leads to studies with high costs, slow progress, and inflated failure rates (Berry, Connor and Lewis, 2015; Bothwell et al., 2016; Angus et al., 2019). Only less than 8% of drugs that entered clinical trials were approved from 2011 to 2020 (QLS Advisors, BIO and Informa UK, 2021). Adaptive Clinical Trials (ACTs) are efficient alternatives to RCTs. ACTs can evaluate, at the same time, several treatments for heterogeneous populations with different diseases; they also allow modifications of the study, such as incorporating new drugs at any time, eliminating ineffective treatments, and changing the randomization ratios, dosage, and sample size (Lai, Lavori and Tsang, 2015; Woodcock and LaVange, 2017). The advantages of ACTs are clear, and several studies have already considered an adaptive design, such as I-SPY 2 for breast cancer (Park et al., 2016; Rugo et al., 2016), BATTLE for lung cancer (Kim et al., 2011), STAMPEDE for prostate cancer (Sydes et al., 2009), and INSIGhT for glioblastoma (Alexander et al., 2019). ACTs have shown to be particularly useful in the case of pandemics, as displayed in the REMAP-CAP (Angus et al., 2020), RECOVERY (Horby et al., 2021), and PRINCIPLE (Butler et al., 2021) trials for COVID-19. ACTs highly benefit from Bayesian adaptations, which may be easier to implement than frequentist ones (Gupta, 2012). In fact, regulatory agencies, such as the U.S. FDA, have encouraged the use of Bayesian methods (U.S. Food & Drug Administration Documents / FIND 2019). The Bayesian approach provides: (i) more flexible tools, for both the design and analysis of clinical and pre-clinical studies, than frequentist

methods (Berry et al. 2010), (ii) useful procedures to monitor studies via posterior predictive probabilities that can be updated as new data become available (Berger and Berry 1988; Yin, Lam, and Shi 2017), (iii) natural ways to incorporate expert knowledge, data coming from previous clinical and observational studies, and extra-experimental information, by using informative priors and hierarchical models (Berry et al., 2010), (iv) a rigorous, realistic, and easy-to-interpret decision-theoretic framework (Berger, 1985), and (v) uncertainty quantification of the parameters of interest (Berry et al. 2010). While the evaluation of new medical products is increasingly leveraging Bayesian methods, the frequentist paradigm is predominant since frequentist properties, such as the operating characteristics, remain essential for reporting trial results (Ventz, Parmigiani, and Trippa 2017).

The aim of the project is to create ethical and novel Bayesian Methods for Clinical and Observational Studies (BayesMeCOS) to progress towards personalized medicine, speed up the drug discovery process, and ultimately improve patients' health. Statistical tools to improve the pre-clinical and clinical stages of the studies will be developed. The aim of BayesMeCOS is two-fold. Aim 1: A first focus is on Bayesian methods for the pre-clinical stage of studies aimed at facilitating the identification of subgroups of patients. Such sub-populations may be used for personalized medicine in the clinical stage to: (i) specify inclusion and exclusion criteria for the studies, (ii) identify patient groups that are more likely to benefit from a treatment, (iii) discover biomarkers and gene pathways, key to better understand diseases. To this aim, various techniques such as multi-study factor analysis and multiple graphical models will be exploited. Aim 2: Novel and ethical Bayesian adaptive designs that integrate data coming from non-concurrent trials, change the randomization ratios using covariate dependent models, and provide a way to analyze the study in the presence of intercurrent events, i.e., events that take place after the randomization and may bias the study results, will be investigated. The novel designs will require fewer patients and have higher power rates than RCTs, assigning more patients to promising therapies, all while preserving the operating characteristics required by regulators.

Relevance towards PNR strategic goals

The PNR 2021-2027 prioritizes the promotion of personalized medicine, whose mission is to tailor treatment to individual patient characteristics leveraging various sources of heterogeneity. In line with the expected impacts of Horizon Europe, and especially with Destination n° 5, which aims at "unlocking the full potential of new tools and technologies […] for a healthy society" (see APRE - Agenzia per la Promozione della Ricerca Europea, 2021), this project is essential to the develop personalized medicine. Alexander et al., 2019 highlighted that precision drug development requires not only demonstrating drug efficacy but also: (i) understanding of disease complexities to identify populations defined by biomarkers, (ii) creating efficient designs that make efficient use of multiplexed biomarker screening, (iii) developing assignment algorithms for patients positive for more than one biomarker, and (iv) understanding that clinical trials often present logistic and bureaucratic challenges. BayesMeCOS tackles all these points by (i) creating tools for biomarker identification, (ii) developing efficient and ethical adaptive clinical trials that incorporate external data, (iii) providing tools to improve patient randomization to more effective treatments according to their biomarkers, (iv) creating models for assessing treatment effects in the presence of intercurrent events. A further priority of the PNR 2021-2027 is to accelerate the development and large-scale production and reduce the costs of marketing new drugs. To this aim, BayesMeCOS pursues the achievement of methodological improvements in adaptive trials and trials leveraging external or nonconcurrent sources. The use of external data evidence is still an objective of Horizon Europe, according to Destinations n° 3 "Tackling diseases and reducing disease burden" and n° 4 "Ensuring access to innovative, sustainable and high-quality health care", APRE - Agenzia per la Promozione

della Ricerca Europea, 2021). However, while the evaluation of new medical product development is increasingly incorporating these external data, there is a lack of rigorous statistical methods for the practical integration of these data in high-stakes settings. Finally, Horizon Europe, and hence PNR 2021-2027, supports the Pharmaceutical Strategy for Europe (PSE henceforth), a "patient-centered strategy that aims to ensure the quality and safety of medicines while boosting the sector's global competitiveness" (Directorate-General for Health and Food Safety, 2020). One of the pillars of the PSE is the implementation of the Clinical Trials Regulation (Regulation (EU) No 536/2014), which aims to address new developments in clinical trials, supporting innovative trial designs such as adaptive and complex trials. In line with such scopes, the methodological contribution in the field of adaptive trials can be instrumental in reducing drug costs and decreasing of new drugs' development times. The Clinical Trials Regulation will support the planning and conduct of clinical trials through harmonized international guidance documents such as the ICH E9(R1) Addendum (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use, 2019). BayesMeCOS explicitly aims to develop new methods and models for dealing with intercurrent events in complex designs in the Addendum framework, especially within the Principal Stratum strategy.

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ANNEX 1

TEMPLATE OF APPLICATION FORM

To the Director
of the Department of Statistica, Informatica, Applicazioni 'G. Parenti'
Viale Morgagni, 59
50134 Firenze

I, the undersigned, request to participate in the selection referred to in the announcement issued by the Director's Decree n. ..... of ..... for the award of n. 1 research grant to join the Research Programme: Time series models for economic and finance of the Area Area Scientifica at the Department of Statistica, Informatica, Applicazioni 'G. Parenti'.

Aware that in accordance with articles 75 and 76 of 28/12/00 n.445, in the case of false declarations, false information in the documents or use of false documents, I will incur the penal sanctions referred to and will immediately lose the right to the research grant

I THEREFORE DECLARE

Pursuant to art.19, 46 and 47 of the D.P.R. n.445/2000:

Family name …… First name ……

Place of birth (town)……(province/state and country…….)
Date of birth ……..……

Permanent address (town)……...……
(province/state and country…….……)
street name, n …….……Zip code……..

Domicile during the research project duration, if different from permanent address:
(town)……...……..
(province/state and country…….……)
street name, n …….……Zip code……..

cell. ph.……
Tax ID number (codice fiscale)……..……e-mail .....

Nationality…….

I also declare the following

- ❑ I **hold** the foreign university title (specify if undergraduate, post-grad, etc)……..……, in (specify academic field)…….…….. at the University of……..…… Graduation date…..…… Final mark…….
- ❑ I **hold** an Italian post-graduate degree obtained prior to 1999 in…….……at the University of……..…… Graduation date…..…… Final mark…….
- ❑ I **hold** an Italian post-graduate degree according to D.M. 509/99 Class……...……/S in……..……..at the University of……..…… Graduation date…..…… Final mark…….
- ❑ I **hold** an Italian post-graduate degree according to D.M. 270/04 Class LM-……...……. in……..……..at the University of……..…… Graduation date…..…… Final mark…….
  And not to exceed with this research grant the limit of 6 years total established in Article 6, paragraph 2a of Law n. 11/2015;
- ❑ I **am enrolled in the PhD programme** in ……
  (cycle……) at the University of ……..……....
  Date of commencement…… Ending on……..
  ( ) with grant ( ) without grant
- ❑ I **hold a PhD title** in ……..……...…… at the University of…… Graduation date……. OR – the discussion of my PhD thesis will be held before the date of the evaluation of the titles by the Admissions Board (specify the expected date of discussion of the thesis).....
- ❑ I **hold a Specialisation title** in …….....
  Graduation date……..…… at the University of…….……...
- ❑ I **hold a research grant** (indicate for each grant the university of affiliation and related period)
  from……/……/……. to ……/……/……. at ……
  from……/……/……. to ……/……/……. at ……
  from……/……/……. to ……/……/……. at ……
  from……/……/……. to ……/……/…….at ……..
  And not to exceed with this research grant the limit of 6 years total established in Article 6, paragraph 2a of Law n. 11/2015;
- ❑ I have never received a research grant;
- ❑ I hold the following further academic and/or professional qualifications *(indicate all the data necessary for verification by the structure):*
  ……
  ……
  ……

- ❑ I do not currently have any pending administrative, criminal or civil proceedings as per current legislation; *OR*
- ❑ I have had past criminal convictions (list all charges with the date of the judgment, the judicial authority and the type of judgment, the violated rules, the number of proceedings and the penalties reported);

- ❑ that I have never been dismissed or released from previous employment with a public administration for persistent insufficient performance and that I have never been discharged from other state employment pursuant to art.127 letter d) of the Consolidated Law n.3/1957, for having obtained the employment through the production of false documents or formally defective; and that I have not been prevented from public service following disciplinary dismissal;

- ❑ that I am not aware of being subjected to criminal proceedings;
  OR

- ❑ that I have ongoing criminal proceedings. In such case, indicate the offenses for which the criminal proceedings are underway, the Authority and the status of the proceedings;

- ❑ that I enjoy full civil and political rights;
- ❑ that I am not part of the permanent staff of the universities and other bodies indicated in art.22, paragraph 1, Law n.240/2010;
- ❑ that I am aware of the bans on accumulation and incompatibilities provided for in art.12 of this announcement;
- ❑ that I will communicate any change of residence or contact details.

I, the undersigned, declare that I am aware of the information for the processing of personal data of subjects willing to participate in selection procedures for staff recruitment, research grant/scholarship awarding or participation in restricted access courses and teaching or collaboration contracts. Such information can be consulted at this page:
https://www.unifi.it/upload/sub/protezionedati/Informativa_SELEZIONI.pdf

Date, _____

Signature

Attach a copy of your ID

ANNEX 2

Declaration of affidavit
(Dichiarazione sostitutiva di atto di notorietà)
Given pursuant to art.19 and 47 of DPR n.445 of 28/12/2000

I, the undersigned ……
Place of birth …… Date of Birth…….
Permanent address……..

Aware that pursuant to art.75 and 76 of DPR N.445 of 28/12/00, in the event of false declarations or use of false deeds, I will incur the criminal sanctions referred to and will immediately become ineligible for any assignment of the research grant:

I DECLARE

that all documents attached to the application and listed below are true copies of the originals in my possession:

1) ……
2) ……
3) ……
4) ……
5) ……
6) ……
7) ……
8) ……
9) ……
10) ……

Date, _____

Signature

ANNEX 3

LIST OF ATTACHMENTS

I, the undersigned, (family name and first name)…….....
Place of birth (town)……
(province/state and country……...…….)
Date of birth ……..……

Permanent address (town)……...……
(province/state and country……...…….……)
street name, n ……..……Zip code……..

Domicile during the research project duration, if different from permanent address:
(town)……...……..
(province/state and country…….……)
street name, n ……..……Zip code……..

cell. ph.……

I hereby **ATTACH** to the application the following documents:

1) ……
2) ……
3) ……
4) ……
5) ……
6) ……
7) ……
8) ……
9) ……
10) ……

Date, _____

Signature

ANNEX 4

CINECA form for Research Grant Contracts

(the data provided below must be identical to those submitted in the call for application)

PERSONAL and CONTACT DETAILS

Tax Identification Number (Codice Fiscale) ***(please write clearly and in block letters)***

_____

Family name _____**First name** _____

M/F _____**Date of birth** ***(dd/mm/yyyy)*** _____/_____/_____**Place of birth (town, province, country)**_____ **Nationality** _____

E-MAIL_____**CELL. PH.**_____

ADDRESSES

PERMANENT ADDRESS:

(town) _____

(province/state and country) _____

(street name) _____**n.**_____ **ZIP CODE**_____

DOMICILE: ***(only if different from permanent address)***

(town) _____

(province/state and country) _____

(street name) _____**n.**_____ **ZIP CODE**_____

FISCAL DOMICILE: ***(only if different from permanent address)***

(town) _____

(province/state and country) _____

(street name) _____**n.**_____ **ZIP CODE**_____

ACADEMIC TITLES:

(….) Foreign title_____

( ) Italian Laurea prior to 1999_____

( ) Italian Laurea Specialistica DM 509/99. Class _____/S (_____)

( ) Italian Laurea Magistrale DM 270/04. Class LM-____ (_____)
obtained at the University of _____
Graduation date_____**(A.Y.**_____/_____**) Final mark**_____

( ) Specialisation title in _____**date** _____
A.Y. _____/_____**University of** _____

( ) PhD in_____

Graduation date _____at the University of:_____

Cycle_____ Date commencement_____Date ending_____

months of duration_____

Grant NO ( ) YES ( ) from ___/___/____ to ____/____/____n. months _____

PROFESSIONAL BOARD REGISTRATION N._____

_____

Board's name and address_____

CONTRACT DATA

Unit of affiliation: Statistica, Informatica, Applicazioni 'G. Parenti'

Public call data: Director's Decree n. of

Duration (months): 14 **Contract's beginning date (dd/mm/yyyy):** 01/12/2023

Research Supervisor/Manager: Prof.ssa Carla Rampichini

Title of the research project: Bayesian Methods for Clinical and Observational Studies – BayesMeCOS.

Academic discipline: SECS-S/01

Further disciplines *(if applicable)* _____

Date, _____

Signature

ANNEX 5

Declaration of acceptance for the evaluation session in distant mode of the selection for the assignment of a research grant as per Decree n. ..... **of** ..... **(art.2 Guidelines for carrying out the online public competition procedures for research grants and scholarships (D.R. of 09/04/2020 Ref. n.56053 (Repertory n.471/2020)**

I, the undersigned _____
Tax ID number _____
Place of birth (country) _____ (_____)
Date of birth ____/_____/_____
Permanent address _____

DECLARE

- that I accept the distant mode of this procedure;
- that I will not use any help tools;
- that I guarantee the absence of any person in the room that could provide support during the interview;
- I acknowledge and accept that the administration will have no responsibility for IT technical problems, which could occur during the connection for both the candidate and the Admissions Board.

Date:

Place:

Signature of the candidate
("firma digitale" or handwritten, in full and legible. In case of handwritten signature, a copy of the applicant's ID must also be attached"firma digitale" or handwritten, in full and legible. In case of handwritten signature, a copy of the applicant's ID must also be attached)