CONTRATTO DI SERVIZI

TRA

MSD Italia S.r.l., con socio unico, soggetta a direzione e coordinamento di Merck & Co., Inc., Rahway, New Jersey - USA, sede legale in Roma, Via Vitorchiano n. 151, 00189, partita IVA 00887261006, codice fiscale e iscrizione al Registro delle Imprese di Roma n. 00422760587, in persona dell'Medical Operations Director, Dr. Giorgio Ursillo ("**MSD"**).

E

Università degli Studi di Foggia – Dipartimento di Scienze Mediche e Chirurgiche, con sede legale in Foggia, Via Antonio Gramsci n. 89/91 e sede operativa in Foggia, Via Luigi Pinto n. 1 c/o Policlinico Foggia ospedaliero-universitario partita IVA 03016180717, codice fiscale 94045260711 rappresentata dal Direttore pro tempore del Dipartimento di Scienze Mediche e Chirurgiche, Prof. Gaetano Serviddio; (l'**"UNIVERSITÀ"**)

(Ciascuna "**Parte"** e congiuntamente le "**Parti")**

Premesso che:

A. L' UNIVERSITÀ è specializzata nella conduzione di attività di ricerca scientifica;

B. MSD è una società farmaceutica appartenente al Gruppo multinazionale Merck & Co. Inc. operante nel settore dello sviluppo, produzione e commercializzazione di medicinali la cui attività è altresì focalizzata sulla ricerca clinica e medica;

C. MSD è interessata a realizzare una ricerca denominata "*The RISO study: Regional Immunization Strategies and Operative models: state of the art of pneumococcal age based and risk-group*

SERVICES AGREEMENT

BETWEEN

MSD Italia S.r.l., with sole shareholder, subject to the management and coordination of Merck & Co Inc., Rahway, New Jersey - USA, with registered offices in Rome, Via Vitorchiano n. 151, 00189, VAT N. 00887261006, tax code and registration at the Companies Register of Rome n. 00422760587, in person of Medical Operations Director, Dr. Giorgio Ursillo ("**MSD"**).

AND

University of Foggia – Department of Medical and Surgical Sciences, with registered offices in Foggia, Via Antonio Gramsci n. 89/91 and operational headquarters in Foggia, Via Luigi Pinto n. 1 c/o Policlinico Foggia, VAT Number 03016180717, tax code and registration at the Companies Register of 94045260711, represented by the director pro tempore of Department of Medical and Surgical Sciences, Prof. Gaetano Serviddio; (the "**UNIVERSITY"**)

(Each as "**Party"** and jointly the "**Parties"**)

Whereas:

A. UNIVERSITY is specialized in conducting scientific research activities;

B. MSD is a pharmaceutical company specialized in the sale of medicines, in developing, manufacturing and marketing of medicines, whose activities are also focused on clinical and medical research;

C. MSD is interested in carrying out a research titled *"The RISO study: Regional Immunization Strategies and Operative models: state of the*

vaccination across the 21 Italian Regions" NIS103239 avente ad oggetto una indagine quanti-qualitativa sulla vaccinazione anti-pneumococcica nell'adulto e nei soggetti a rischio, da condurre attraverso questionari semi-strutturati somministrati ai referenti dei programmi di vaccinazione presso gli assessorati alla salute regionali e le aziende sanitarie (il "**Progetto**");

D. MSD intende avvalersi delle competenze e dell'organizzazione dell'UNIVERSITÀ che si è dichiarata disponibile ad accettare l'incarico per l'esecuzione del Progetto.

Tutto ciò premesso si conviene e stipula quanto segue.

1. PREMESSE ED ALLEGATI

1.1. Gli allegati e le premesse costituiscono parte integrante del presente contratto (il "**Contratto"**).

1.2. Le disposizioni del Contratto prevarranno su qualsiasi contrastante disposizione contenuta in qualsivoglia documento cui il Contratto faccia riferimento e/o in qualsivoglia allegato, nonché su qualsiasi altro documento sottoscritto o scambiato tra le Parti con riferimento all'oggetto del Contratto.

2. OGGETTO

2.1. Con la sottoscrizione del presente Contratto, MSD affida all'UNIVERSITÀ l'esecuzione del Progetto come meglio dettagliato nella descrizione dello stesso (il "**Protocollo**"), allegato al Contratto quale Allegato 1, per il quale i Responsabili Scientifici per conto dell' UNIVERSITÀ sono la prof.ssa Rosa Prato e la prof.sssa Francesca Fortunato, rispettivamente professore ordinario e professore associato per il S.S.D. MED/42 – Igiene Generale ed Applicata. Responsabile Scientifico per MSD è il Dr. Gian Marco Prandi. Il Progetto prevede la realizzazione di un report finale, come meglio indicato nella sezione "*Report and Results*" di cui al Protocollo allegato.

art of pneumococcal age based and risk-group vaccination across the 21 Italian Regions" NIS103239 having as its object a quanti-qualitative survey of pneumococcal vaccination in adults and at-risk individuals to be conducted through semi-structured questionnaires to be administered to vaccination program contact persons at regional health departments and local health units. (the "**Project**");

D. MSD means to avail of UNIVERSITY that she has declared itself willing to accept the assignment for the execution of the Project.

NOW THEREFORE, in consideration of the premises the Parties hereto agree and stipulate as follows:

1. PREMISES AND ATTACHMENTS

1.1. The attachments and the premises are integrant part of the present agreement (the "**Agreement**").

1.2. The provisions of the Agreement will prevail upon any conflicting provision contained in any document to which the Agreement may refer and/or in any attachment, as well as upon any other document subscribed or exchanged by the Parties with reference to the purpose of the Agreement.

2. PURPOSE

2.1 By the subscription of the Agreement, MSD assigns to UNIVERSITY the execution of the Project as more specifically detailed in the description of the Project (the "**Protocol**"), attached as Attachment 1 to the Agreement, for which the Scientific Responsibles on behalf of the UNIVERSITY are Prof. Rosa Prato and Prof. Francesca Fortunato, full professor and associate professor, respectively, for S.S.D. MED/42 – Igiene Generale e Applicata. The Scientific Responsible for MSD is Dr. Gian Marco Prandi. The Project foresees the realization of a final report, as better indicated in the "Report and Results" section of the attached

3. OBBLIGHI DELL' UNIVERSITÀ

3.1. L'UNIVERSITÀ si obbliga a svolgere e realizzare il Progetto, nel rispetto di quanto previsto nel Protocollo allegato e:

a. con la massima diligenza possibile, in piena osservanza della normativa vigente ed in particolare della normativa di settore, e con le capacità tecniche e la professionalità richieste dalla tipologia di incarico, nel rispetto dei più alti *standard* qualitativi conosciuti ed applicati nel settore;

b. organizzando e gestendo in modo autonomo le risorse umane impiegate, utilizzando esclusivamente personale regolarmente inquadrato e retribuito ai sensi di legge, soggetto al potere direttivo dell'UNIVERSITÀ;

c. adottando, nell'esecuzione del Contratto, i provvedimenti e le cautele necessari per garantire la vita e l'incolumità del personale addetto e per evitare danni a beni pubblici e privati, nonché osservare e fare osservare tutte le vigenti norme di carattere generale e le prescrizioni di carattere tecnico agli effetti della prevenzione e della sicurezza sul lavoro, ivi comprese quelle di cui al D.lgs. 81/2008 e normativa collegata;

d. attenendosi alle procedure convenute ed alle direttive o indicazioni generali impartite da MSD attraverso i propri rappresentanti, avendo cura di far rispettare le stesse dai propri dipendenti, collaboratori e terzi utilizzati per lo svolgimento dei Servizi, anche ai sensi dell'articolo 1381 c.c.;

e. apportando al Progetto le varianti richieste da MSD, senza aver diritto ad alcun compenso aggiuntivo, a meno che tali varianti non comportino sostanziali modifiche alle prestazioni oggetto del Contratto; in questo specifico caso le Parti concorderanno per iscritto nuovi termini e condizioni contrattuali, tra cui il corrispettivo aggiuntivo.

Protocol.

3. OBLIGATIONS OF THE UNIVERSITY

3.1 UNIVERSITY obliges itself to execute the Project, according to the provision set forth in the attached Protocol:

a. with the greatest possible diligence, in full observance of the current legislation and, in particular, of sector legislation and with technical abilities and professionality required by the type of the assignment, in respect of the highest quality standard known and applied in the sector;

b. organizing and managing independently the human resources employed, utilizing only personnel regularly organized and paid pursuant to law, subject to the directive power of UNIVERSITY;

c. in executing the Agreement, implementing, the needed provisions and cautions to grant life and safety of the engaged personnel and to avoid damages to public and private goods, as well as complying and make all comply with all current general laws and technical provisions to the purposes of prevention and job security, including those of Legislative Decree 81/2008 and related rules;

d. complying with agreed procedures and with general directives or indications established by MSD through its representatives, assuring that the same are respected by its employees, collaborators and third parties engaged for performing the Project, also pursuant to article 1381 of the Italian Civil Code;

e. bringing to the Project changes requested by MSD, without having right to any additional consideration, unless such modifications imply substantial change to the services under this Agreement, in such specific case the Parties shall agree in writing new contractual terms and conditions, among which the additional consideration.

3.2 UNIVERSITY acknowledges and accepts that in any moment MSD may make checks on the actions done by the former to the purpose

3.2. L'UNIVERSITÀ dà atto ed accetta che MSD potrà effettuare in qualsiasi momento controlli sull'operato svolto dalla medesima al fine di verificare il corretto svolgimento del Progetto e il rispetto degli obblighi ed oneri dedotti in Contratto. L'attività ispettiva potrà essere svolta anche da soggetti non legati da rapporti di dipendenza con MSD.	of verifying the proper performance of the Project and the respect of obligations and burdens under the Agreement. The check activity may be carried out even by subjects not having dependency relations with MSD.
3.3. L'UNIVERSITÀ è poi tenuta ad un generale obbligo di correttezza e dovrà assicurare, anche ai sensi dell'articolo 1381 c.c., che il personale di cui si avvale nello svolgimento del Progetto si astenga dal:	3.3 UNIVERSITY is also required to a general obligation of correctness and must assure, also pursuant article 1381 of the Italian Civil Code, that the personnel engaged for performing the services refrain from:
a. porre in essere comportamenti od iniziative idonei a recare pregiudizio all'immagine ed alla reputazione di cui godono MSD e le altre società del gruppo MSD nonché al prestigio dei prodotti MSD e in ogni caso contrari ai principi di cui al successivo articolo 7;	a. putting in place behaviors or initiatives able to prejudice the image and reputation of MSD and of the other companies of the MSD group as well as the prestige of MSD products and, in any case, contrary to the principles set forth in article 7;
b. comunicare e/o divulgare a terzi notizie e informazioni di cui venga a conoscenza durante la realizzazione del Progetto;	b. communicating and/or making known to third parties news and information obtained during the performance of the Project;
c. spendere il nome di MSD o far credere a terzi che vi sia autorizzata, o assumere alcun impegno per conto di MSD senza la preventiva autorizzazione scritta della medesima o far altrimenti intendere la concessione di premi o altri benefici di qualunque tipo ai soggetti con cui l'UNIVERSITÀ entrerà in contratto per l'esecuzione del Progetto, in particolare tenendo in considerazione la qualità di dipendenti pubblici di tali soggetti.	c. spending the name of MSD or letting third parties believe to be authorized to do it, or undertaking commitments on behalf of MSD without its prior written authorization or making otherwise understand the granting of prizes or other benefits of any kind to those with whom UNIVERSITY will get in touch for the execution of the Project, in particular considering the profile of public employees of such subjects.
4. DURATA	**4. DURATION**
4.1. Fatto salvo quanto previsto al successivo articolo 10, il Contratto avrà una durata di **12** mesi a decorrere dalla data di sottoscrizione dello stesso. È espressamente escluso ogni tacito rinnovo.	4.1. Without prejudice to provisions of following article 10, the Agreement will have a duration of **12** months starting from the date of subscription of the same. It is expressly excluded any tacit renewal.

5. CORRISPETTIVO	**5. CONSIDERATION**
5.1. A titolo di corrispettivo per la realizzazione del Progetto, previa verifica della corretta esecuzione delle prestazioni richieste e dei documenti elaborati, MSD pagherà all'UNIVERSITÀ gli importi forfettari e omnicomprensivi indicati nell'Allegato 2 (il **Corrispettivo**).	5.1. As consideration for the performance of the Project, with prior verification of regular execution of the requested performances, MSD will pay to UNIVERSITY the forfait and all-inclusive amounts indicated, for the Project, in the Attachment 2 (the "**Consideration**").
5.2. L' UNIVERSITÀ dichiara di essere a perfetta conoscenza di tutte le condizioni, obblighi, oneri, modalità e prescrizioni tecniche che possono essere connessi all'espletamento del presente incarico e di avere accettato il Corrispettivo ritenendolo remunerativo sotto ogni profilo.	5.2 UNIVERSITY declares to be perfectly aware of all conditions, obligations, burdens, modalities and technical prescriptions that may be connected with the fulfillment of the present assignment and to have accepted the Consideration deeming it profitable under any profile.
5.3. Per le liquidazioni del fatturato, l'UNIVERSITÀ dovrà esibire, su richiesta di MSD, in originale o fotocopia autenticata, consentendone la fotocopiatura a MSD, il Documento Unico di Regolarità Contributiva ("**DURC**"), rilasciato dagli Istituti previdenziali successivamente alla data in cui è stato erogato il Servizio cui si riferisce il pagamento, unitamente ad una dichiarazione secondo cui i versamenti attestati dal DURC sono riferiti ai soggetti impiegati nella esecuzione dei Servizi. In mancanza, MSD avrà il diritto di non effettuare il pagamento e, in ogni caso, non potrà essere ritenuta responsabile del ritardo nella liquidazione del Corrispettivo.	5.3 For the payment of invoiced amounts, UNIVERSITY shall show, upon MSD request, in original or notarized copy, allowing MSD to photocopy it, the Unique Document of Regular Contribution ("DURC") released by Social Security Institutes after the date in which the Project, to which payment refers, has been provided, jointly with a declaration stating that payments declared by DURC are referred to subjects employed in the Project execution. Lacking this, MSD shall have the right not to make the payment and, in any case, shall not be considered responsible for the delay in paying the Consideration.
5.4. Le Parti, esercitando la facoltà prevista dall'art. 4 comma 3 del D.lgs. n. 231 del 2002 e successive modifiche, concordano espressamente che MSD effettuerà il versamento del Corrispettivo a 60 (sessanta) giorni dalla data di ricezione della fattura.	5.4 The Parties, exercising the faculty provided by article 4, paragraph 3 of Legislative Decree n. 231 of 2002 and following changes, expressly agree that MSD will make the payment of the Consideration at 90 (ninety) days from the date of invoice receipt.
6. RESPONSABILITÀ E GARANZIE	**6. RESPONSIBILITIES AND WARRANTIES**
6.1. L' UNIVERSITÀ dichiara:	6.1 UNIVERSITY declares:
a. di essere in possesso di ogni autorizzazione amministrativa o di altro tipo o licenza richiesta per il regolare espletamento della	a. to own every administrative authorization or license required for the regular performing of its own activity as well as for performing

propria attività nonché per lo svolgimento del Progetto;	of the Project;
b. di avere la capacità professionale, tecnica ed amministrativa richiesta per l'adempimento del Contratto;	b. to have professional, technical and administrative capacity as required for the fulfillment of the Agreement;
c. di disporre delle attrezzature e materiali adeguati a soddisfare pienamente le esigenze di MSD per l'esecuzione del Progetto.	c. to have available equipment and material suitable to fully satisfy MSD needs for the execution of the Project.
6.2. L'UNIVERSITÀ garantisce e si obbliga, nell'ambito della gestione a proprio rischio delle attività oggetto del Contratto, a tenere indenne e manlevare, sia in via giudiziale che stragiudiziale, MSD da:	6.2 UNIVERSITY warrants and undertakes, in the frame of the management at its risk of the activities under the Agreement, to hold MSD indemnified and harmless, both in judicial and extrajudicial, from:
a. qualsiasi danno provocato alla stessa o ai terzi dalla sua attività o dall'attività di suoi dipendenti e/o collaboratori, fornitori, nonché di terzi, nonché da violazioni delle obbligazioni di cui al Contratto o da fatti accidentali;	a. any damage caused to the same or to thirds from its activity or from its employees' activity and /or collaborators, suppliers and of thirds as well and from violations of the obligations under the Agreement or from incidental facts;
b. qualsiasi eventuale pretesa o azione dei propri dipendenti, collaboratori e/o terzi derivanti dalla violazione delle obbligazioni dell'UNIVERSITÀ, ivi incluse le obbligazioni assunte con la sottoscrizione del Contratto o comunque connesse con lo svolgimento del Progetto, intervenendo, ove occorra, nei relativi giudizi e rimborsando le relative spese di difesa di MSD, restando quest'ultima in ogni caso estranea ad ogni rapporto tra l'UNIVERSITÀ ed i propri dipendenti, collaboratori e/o terzi.	b. any possible claim or action of own employees, collaborators and/or thirds deriving from the infringement of UNIVERSITY's obligations, including those undertaken subscribing this Agreement or in any way connected to the performance of the Project, intervening, when necessary, in the relevant judgements and reimbursing the relevant defense costs of MSD, the latter remaining at any rate extraneous to any relationship between UNIVERSITY and its own employees, collaborators and thirds.
6.2.b.1. Più in particolare, ove MSD sia convenuta in giudizio da dipendenti dell' UNIVERSITÀ per qualsiasi pretesa o azione relativa a quest'ultima, anche se del caso ai sensi dell'art. 29 d.lgs. n. 276/2003, l'UNIVERSITÀ si obbliga, nei tempi e modi previsti dalla legge, a dar seguito alla chiamata in causa di MSD costituendosi in giudizio, ovvero, quand'anche la chiamata sia mancata, ad intervenirvi volontariamente in qualità di garante, assumendo in capo a sé ogni responsabilità circa la lite pendente e/o in ogni caso accettando le domande da MSD formulate nei suoi confronti.	6.2.b.1 More in particular, if MSD is sued in court by employees of UNIVERSITY for any claim or action related to the latter, also, if the case, pursuant article 29 of legislative decree n. 276/2002, UNIVERSITY undertakes, within time and ways established by law, to follow up the summon of MSD, appearing in court or, even if not convened, to intervene voluntarily as guarantor, assuming on itself any responsibility about the pending litigation and/or accepting in any case the requests formulated by MSD against it.
	6.3 UNIVERSITY undertakes to communicate in writing to MSD, as soon as it becomes aware of, any beginning of legal actions

6.3. L'UNIVERSITÀ si obbliga a comunicare per iscritto a MSD, non appena ne venga a conoscenza, l'eventuale instaurazione di giudizi aventi ad oggetto trattamenti retributivi, contributi previdenziali e/o premi assicurativi che siano dovuti in relazione al periodo di esecuzione del Contratto, nonché a fornire, su richiesta di MSD, copia dei relativi documenti, dopo aver oscurato i dati personali ivi contenuti.	pertaining remuneration, social security contributions and/or insurance premiums which may be due in relation to the time of Agreement execution, as well as to supply, upon request of MSD, copies of relevant documents, after blinding personal data contained therein.
6.4. Le Parti si danno atto che il Progetto e i suoi risultati saranno elaborati in forma completamente anonima dall'UNIVERSITÀ. MSD riceverà, pertanto, i risultati del Progetto, in forma anonima. In nessun caso verranno forniti a MSD dati che possano ricondurre a singoli pazienti non essendo interesse di MSD ricevere dati che non siano così protetti.	6.4 The Parties acknowledge that the Project and its results will be processed completely anonymously by UNIVERSITY. MSD will, therefore, receive the results of the Project, anonymously. Under no circumstances will data be provided to MSD that could lead back to individual patients as it is not in MSD's interest to receive data that is not so protected.
7. COMPLIANCE	**7. COMPLIANCE**
7.1. L'UNIVERSITÀ dichiara di conoscere ed accettare i principi e le norme etiche a cui si ispira MSD, contenute in particolare nel suo Modello di Organizzazione Gestione e Controllo ex D. Lgs. 231/2001, nel suo Codice Etico e nel *Foreign Corrupt Practices Act* statunitense. MSD non avalla in alcun modo comportamenti o azioni che siano contrari a tali leggi e principi; qualsiasi condotta contraria agli stessi costituirà causa di immediata risoluzione del Contratto ai sensi dell'art. 10.	7.1. UNIVERSITY declares to know and to accept principles and ethical rules that inspire MSD, contained in particular in its Organization, Management and Control Model pursuant Legislative Decree 231/2001, in its Ethical Code and in the US *Foreign Corrupt Practices Act*. MSD does not endorse, in any way, any behavior or action contrary to such laws and principles; any conduct contrary to them will be reason of immediate resolution of the Agreement pursuant to article 10.
7.2. L'UNIVERSITÀ si impegna a non effettuare pagamenti diretti od indiretti di denaro o altre attività ad alcun Funzionario Pubblico, come di seguito definito, ove tale pagamento sia finalizzato a influenzarne le decisioni o l'attività con riferimento all'oggetto del Contratto od ogni altro aspetto dell'attività di MSD. Per **Funzionario Pubblico** si intende qualsiasi persona ricompresa nella definizione di "Pubblico Ufficiale" di cui all'art. 357 c.p., incluse, a titolo esemplificativo e non limitativo, (i) le persone che agiscano quali funzionari, impiegati o dipendenti a qualsivoglia titolo di un governo o di un'organizzazione pubblica internazionale,	7.2. UNIVERSITY undertakes not to make any direct or undirect payment of money or other activity to any Public Official, as defined forward, where such payment aims to influence decisions or activities with reference to this Agreement's purpose or to any other aspect of MSD activity. **Public Official** means any person covered by the definition of "Public Official" referred in article 357 of the Italian Criminal Code, including, for example but not limited to, (i) persons who act as officials, clerks or dependents, in any capacity, of a government or of an international public organization, or (ii) the representatives or officials of political

o (ii) i rappresentanti o funzionari di partiti politici o candidati ad incarichi politici od amministrativi pubblici.	parties or candidates to public political or administrative appointments.
7.3. L' UNIVERSITÀ si impegna a rispettare i più elevati *standard* etici e di *compliance*, ivi inclusi i diritti umani fondamentali, a trattare in modo equo ogni individuo, a rispettare l'ambiente, ad adottare un sistema di gestione e controllo della propria attività che assicuri il rispetto dei su menzionati *standard* e principi. L'UNIVERSITÀ riconosce e accetta l'importanza di un comportamento etico nell'adempimento del Contratto. Senza pregiudizio di alcuna delle obbligazioni quivi previste, l'UNIVERSITÀ si impegna a rispettare la lettera e lo spirito del Codice di Condotta dei *Partner* Commerciali del gruppo Merck & Co. Inc. (Kenilwort, NJ, USA), consultabile al seguente link [http://www.msd.com/about/how-we-operate/code-of-conduct/home.html] nell'esecuzione del Contratto.	7.3. UNIVERSITY undertakes to respect the highest ethical and compliance standards, including fundamental human rights, to equally treat any individual, to respect the environment, to adopt a system for managing and controlling its own activity that assures the respect of aforesaid standard and principles. UNIVERSITY recognizes and accepts the importance of an ethical behavior in fulfilling the Agreement. Without prejudice for any of the obligations established herein, UNIVERSITY undertakes to respect letter and spirit of the Code of Conduct of the commercial partners of Merck & Co Inc., Rahway, New Jersey, USA Group, consultable at the following link [http://www.msd.com/about/how-we-operate/code-of-conduct/home.html], in the execution of the Agreement.
7.4. L'UNIVERSITÀ dichiara e garantisce che essa stessa e i suoi rappresentanti legali non sono presenti in alcuna lista pubblicata dagli Stati Uniti d'America o dall'Unione Europea di soggetti sottoposti a restrizioni ovvero nessun'altra lista del medesimo tipo pubblicata in altro Stato in qualsiasi modo connesso ai Servizi, definite congiuntamente "**Denied Parties List**". Ad oggi le *Denied Parties List* comprendono:	7.4. UNIVERSITY declares and warrants that it and its legal representatives are not included in any list, published by the United States of America or by European Union, of subjects burdened by restrictions nor any other list of same kind published in another State in any way connected to the Project, jointly defined as "**Denied Parties List**". To date, the Denied Parties List comprehend:
• la lista del Dipartimento del Tesoro degli Stati Uniti d'America delle Persone Bloccate o Segnalate Specificamente (la "**SDN List**") (http://www.treasury.gov/ofac/downloads/t11sdn.pdf);	• US Treasury Department's list of Specifically Blocked or Designated Persons ("the "**SDN List**") (http://www.treasury.gov/ofac/downloads/t11sdn.pdf);
• la lista di persone soggette a restrizioni del Dipartimento del Commercio degli Stati Uniti d'America (http://www.bis.doc.gov/dpl/thedeniallist.asp);	• List of persons subject to restrictions of USA Commerce Department (http://www.bis.doc.gov/dpl/thedeniallist.asp);
• lista delle persone giuridiche soggette a restrizioni del Dipartimento del Commercio degli Stati Uniti d'America (http://www.bis.doc.gov/entities/default.htm); e	• List of juridical persons subject to restrictions of USA Commerce Department (http://www.bis.doc.gov/entities/default.htm); and

• la lista consolidata di persone fisiche, giuridiche e dei gruppi soggetti alle sanzioni finanziarie dell'Unione Europea (http://eeas.europa.eu/cfsp/sanctions/consol-list_en.htm). L'UNIVERSITÀ dichiara e garantisce di non essere direttamente controllata, con una percentuale del capitale sociale pari o maggiore del 50%, da una persona presente nella SDN List. L'UNIVERSITÀ dichiara e garantisce che comunicherà immediatamente a MSD se essa stessa, o un suo rappresentante legale, sia stato inserito in una delle *Denied Parties List* o se sia divenuta controllata, con una percentuale del capitale sociale pari o maggiore del 50%, da una persona presente nella SDN List. In caso di inaccuratezza o violazione delle dichiarazioni e garanzie fornite nel presente articolo 7.5, MSD avrà il diritto a propria assoluta discrezione di risolvere il Contratto con effetto immediato ai sensi dell'art. 1456 c.c. e dell'art. 10 del Contratto.	• The consolidated list of physical and juridical persons and of groups subject to financial fines of European Union (http://eeas.europa.eu/cfsp/sanctions/consol-list_en.htm). UNIVERSITY declares and warrants not to be directly owned, with a percentage of the UNIVERSITY capital equal to or higher than 50% by a person included in the SDN List. UNIVERSITY declares and warrants to notify MSD immediately if it or one of its legal representatives has been put in one of the Denied Parties Lists or if it has become owned, with a percentage of the UNIVERSITY capital equal to or higher than 50% by a person present in the SDN List. In case of inaccuracy o violation of the declarations and warranties provided in this article 7.5, MSD will have right, in its absolute discretion, to resolve the Agreement with immediate effect pursuant to article 1456 of the Italian Civil Code and of article 10 of the Agreement.
7.5. L'UNIVERSITÀ dichiara e garantisce che, prima dell'entrata in vigore del presente Contratto, nessuno dei suoi dirigenti o amministratori era presente nelle liste di persone escluse, di seguito elencate. Successivamente alla data di entrata in vigore del Contratto l'UNIVERSITÀ si obbliga verificare e a informare per iscritto e senza ritardo MSD prima dell'esecuzione di qualsiasi prestazione prevista dal Contratto se alcuno dei suoi dipendenti, collaboratori o fornitori si trovi in una delle liste di persone escluse sopra menzionate. In tale evenienza MSD avrà la facoltà di recedere dal Contratto a propria assoluta discrezione e con effetto immediato, senza il pagamento di penali o indennità a favore dell'UNIVERSITÀ. Per liste di persone escluse si intendono: (1) la lista dell'*Office of Inspector General*, del U.S. *Department of Health and Human Services*, che elenca le persone condannate per delitti ai danni di qualsiasi programma sanitario statunitense, (2) qualsiasi lista di un'autorità federale degli Stati Uniti che elenchi le persone che non possono eseguire forniture a loro favore.	7.5. UNIVERSITY declares and warrants that, before the Agreement has come into force, none of its managers or directors was in the lists of excluded persons indicated below. Afterwards the date of entry into force of this Agreement, UNIVERSITY undertakes to verify and to inform MSD in writing and without delay, before the execution of any performance under the Agreement, if any of its employees, collaborators or suppliers is in one of the aforesaid lists of excluded persons. In such case, MSD is entitled to withdraw from the Agreement in its absolute discretion and with immediate effect, without paying any fine or indemnity to UNIVERSITY. For Lists of excluded persons it is intended: (1) Office of Inspector General, of U.S. Department of Health and Human Services list, which lists persons condemned for crimes against any US health program, (2) any list of an US federal authority that lists persons who cannot make any supplies in their favor.

8. RISERVATEZZA	**8. CONFIDENTIALITY**
8.1. L'UNIVERSITÀ è a conoscenza del fatto che tutte le informazioni relative al Contratto, a MSD ed al Progetto, che le siano state messe a disposizione da MSD di cui comunque sia venuta a conoscenza nell'esecuzione del Contratto, ivi incluse le informazioni segrete ai sensi degli artt. 98 ss. Del Codice della Proprietà Industriale, costituiscono informazioni riservate (le "**Informazioni Riservate"**).	8.1. UNIVERSITY is aware that all the information related to the Agreement, to MSD and to the Project, made available by MSD and that it has become aware of during the execution of the Agreement, also including the secret information pursuant article 98 and following of the Industrial Property Code, are confidential information (the "**Confidential Information**").
8.2. L'UNIVERSITÀ si obbliga a trattare come strettamente confidenziali e a non divulgare le Informazioni Riservate nonché a utilizzarle esclusivamente ai fini dell'esecuzione del Contratto.	8.2. UNIVERSITY undertakes to process the Confidential Information as strictly confidential and not to disclose them and to use them exclusively for the execution of the Agreement.
8.3. L'UNIVERSITÀ si obbliga inoltre a:	8.3. Moreover, UNIVERSITY undertakes:
a. adottare tutte le misure necessarie a evitare che le Informazioni Riservate vengano a conoscenza di terzi;	**a.** to adopt any needed measure to avoid that the Confidential Information are known by thirds;
b. limitare la comunicazione delle Informazioni Riservate ai soli dipendenti, assistenti, collaboratori, consulenti o altri incaricati che abbiano un'effettiva necessità di conoscerle per l'esecuzione del Contratto;	**b.** to limit the communication of the Confidential Information only to dependents, assistants, collaborators, consultants or other appointed having real need to know them for the execution of the Agreement;
c. non rendere pubbliche o accessibili le Informazioni Riservate a meno che ciò non le sia consentito espressamente per iscritto da MSD.	**c.** not to make the Confidential Information public or accessible, unless expressly authorized in writing by MSD.
8.4. In caso di cessazione o risoluzione, a qualsiasi titolo, del Contratto, l'UNIVERSITÀ dovrà restituire a MSD tutti i documenti contenenti Informazioni Riservate.	8.4. In case of termination or resolution, for any reason, of the Agreement, UNIVERSITY shall give back to MSD all documents containing Confidential Information.
8.5. Gli obblighi di cui al presente articolo vincoleranno l'UNIVERSITÀ, anche per l'operato dei propri dipendenti, assistenti, collaboratori, consulenti o altri incaricati, per tutta la durata del Contratto nonché successivamente alla sua cessazione per qualsiasi causa per un periodo di 5 (cinque) anni.	8.5. The obligations under this article will bind UNIVERSITY, also for the actions of its own dependents, assistants, collaborators, consultants or other appointed, for the whole duration of the Agreement as well as following its termination for any reason for a period of 5 (five) years.

9. DIRITTO D'ISPEZIONE	**9. INSPECTION RIGHTS**
9.1. L'UNIVERSITÀ riconosce a MSD il diritto di ispezionare, verificare e/o, su richiesta specifica di MSD, ricevere copia della documentazione contabile relativa all'esecuzione del Contratto. In generale, l'UNIVERSITÀ si impegna a fornire copia della documentazione connessa all'esecuzione del Contratto come, ad esempio, ed a titolo non esaustivo: fatture e ricevute di fornitori, pagamenti effettuati a terzi e ogni altra fonte documentale idonea a giustificare i movimenti finanziari scaturenti dal Contratto.	9.1. UNIVERSITY recognizes to MSD the right to inspect, verify and/or, upon specific request by MSD, to receive copy of accounting documentation and/or any other documentation related to the execution of the Agreement (collectively "Documentation").In general, UNIVERSITY undertakes to supply copy of the Documentation as, for example but not exhaustively, vendors' invoices and receipts, payments to thirds and any other document source suitable to justify the financial transactions deriving from the Agreement.
9.2. Il personale o i consulenti autorizzati di MSD con il supporto di personale dell'UNIVERSITÀ, potranno svolgere ispezioni e verifiche presso quest'ultima o nel luogo ove sono custoditi i documenti contabili, in qualsiasi giorno lavorativo dandone ragionevole preavviso. In caso di richiesta d'invio dei documenti contabili gli stessi dovranno essere forniti entro un tempo massimo di tre giorni.	9.2. Personnel or authorized consultants of MSD, with support of COMPANY's personnel, can make inspections and checks at seat of the latter or at the place where accounting documentation are kept, in any business day, giving reasonable notice. In case of request of sending the accounting documents, these must be supplied within a maximum time of three days.
9.3. Il diritto d'ispezione di cui al presente articolo potrà essere esercitato fino a 5 (cinque) anni dal termine delle attività relative al Contratto.	9.3. The inspection right set in this article can be exercised until 5 (five) years from the termination of the activities related to the Agreement.
9.4. Nel caso in cui, nel corso delle ispezioni effettuate ai sensi del presente articolo 9, vengano individuate irregolarità nell'esecuzione del Contratto, MSD potrà valutarle anche ai fini dell'esercizio del proprio diritto di risolvere lo stesso ai sensi dell'art. 1456 c.c. e del successivo articolo 10.	9.4. In case, during inspections carried out according to this Section 9, irregularities are identified MSD will assess them also for the purposes of exercising its right to immediately terminate the Agreement pursuant to article 10.
10. RISOLUZIONE E RECESSO	**10. TERMINIATION AND WITHDRAWAL**
10.1. Le Parti convengono che MSD avrà facoltà di risolvere il presente Contratto, ai sensi e per gli effetti dell'articolo 1456 c.c.:	10.1. The Parties agree that MSD shall have right to terminate this Agreement, pursuant to and for the purposes of Article 1456 of Italian Civil Code:
a. qualora l'UNIVERSITÀ commetta una grave violazione della normativa vigente nell'esecuzione del Progetto;	a. whether UNIVERSITY, in executing the Project, makes a serious infringement of the current legislation;

b. al verificarsi di anche una violazione degli obblighi di cui agli articoli 3.1 (b), 3.1 (c), 6.1, 6.3, 7, 8.2, 8.3, 9 e 11.	b. upon occurrence of a violation of the obligations pursuant articles 3.1 (b), 3.1 (c), 6.1, 6.3, 7, 8.2, 8.3, 9 and 11.
Fatto salvo il diritto di MSD al risarcimento di ogni e qualsiasi danno, diretto ed indiretto subito, ivi incluso il danno all'immagine.	without prejudice of MSD right to compensation of every and any suffered damage, direct or indirect, damage of image included.
10.2. La risoluzione si verificherà di diritto nel momento in cui MSD comunicherà all'UNIVERSITÀ mediante PEC che intende avvalersi della clausola risolutiva espressa ai sensi dell'articolo 1456 c.c.	10.2. The termination will occur by right at the moment MSD notifies UNIVERSITY, through certified electronic mail (PEC), to want to avail of the express resolution clause pursuant to article 1456 of Italian Civil Code.
10.3. MSD avrà inoltre il diritto di risolvere il Contratto previa diffida da notificarsi ai sensi e per gli effetti dell'art. 1454 c.c., in ogni altro caso di inadempimento da parte dell' UNIVERSITÀ, anche parziale, delle proprie obbligazioni previste nel Contratto, fatto salvo il diritto di MSD al risarcimento di ogni e qualsiasi danno, diretto ed indiretto subito, ivi incluso il danno all'immagine.	10.3. Furthermore, MSD will have right to resolve the Agreement prior warning to be notified pursuant to and for the purposes of article 1454 of the Italian Civil Code, in any other case of failure, even partial, of UNIVERSITY's obligations under the Agreement, without prejudice of MSD right to the compensation of every and any suffered damage, direct and indirect, damage of image included.
10.4. Resta salva la facoltà di MSD di recedere dal Contratto senza corrispettivi né indennità, in ragione delle proprie mutate strategie commerciali o aziendali, con preavviso di 30 (trenta) giorni da comunicarsi a mezzo raccomandata a.r. che potrà essere anticipata via fax (nel qual caso farà fede la data del fax).	10.4. It remains untouched MSD faculty to withdraw from the Agreement without considerations nor indemnity, due to its changed commercial or UNIVERSITY strategies, with notice of 30 (thirty) to be notified by registered letter with return receipt that can be anticipated through fax (in this case the fax date will make faith).
10.5. In caso di esercizio del diritto di recesso da parte di MSD ai sensi del precedente articolo 10.4, l'UNIVERSITÀ avrà diritto a percepire esclusivamente il Corrispettivo maturato sino alla data del recesso, e nessun altro importo sarà al medesimo dovuto a qualsiasi titolo.	10.5. In case MSD exercises the withdrawal right pursuant to preceding article 10.4, UNIVERSITY shall have right to receive only the Consideration accrued until withdrawal date and no other amount will be due to it for any reason.
11. INTEGRITA' E SICUREZZA DEI DATI E PROTEZIONE DEI DATI PERSONALI	**11. DATA INTEGRITY; DATA PRIVACY; AND DATA SECURITY.**
11.1. **Validità dei dati**. Qualsiasi documentazione o dato relativo o connesso alle attività svolte nell'ambito dei Servizi, inclusa, senza limitazione alcuna, qualsiasi documentazione cGMP, deve essere	11.1. **Data Validity.** Any documentation or data relevant or related to activities performed, including without limitation any cGMP documentation, must be original, accurate, legible, controlled,

originale, accurata, leggibile, controllata, protetta da procedure che ne consentano il ripristino in caso di perdita e protetta da manipolazioni o perdite intenzionali o involontarie. Queste obbligazioni devono essere adempiute per tutto il periodo di conservazione di tali dati e documentazione da parte dell' UNIVERSITÀ.	retrievable, and safe from intentional or unintentional manipulation or loss. These items are required throughout the retention period of such data / documentation.
11.2 **Data Privacy**. i) Definizioni	11.2.**Data Privacy**. i) Definitions
(A) Per "Legge sulla protezione dei dati" si intende qualsiasi legge sulla protezione dei dati, sulla sicurezza dei dati o sulla privacy, tra cui, a titolo esemplificativo ma non esaustivo, il Regolamento generale sulla protezione dei dati personali (REG UE 2016/679 di seguito anche solo "GDPR") e qualsiasi normativa nazionale relativa a tali argomenti, nonché le Leggi che regolano le telefonate in uscita o l'uso di posta elettronica, o altri strumenti che possano avere una qualche rilevanza in relazione al trattamento di dati, alla sicurezza dei dati o alle leggi sulla privacy, alle quali ciascuna delle Parti, secondo i casi, è soggetta considerando le obbligazioni previste nel presente Contratto.	(A) "Data Protection Law" means any data protection, data security or privacy Law, including, without limitation, the EU General Data Protection Regulation 2016/679 (the "GDPR") and any national implementing legislation relating thereto, any Laws governing outbound telephone calls or transmission of electronic mail, facsimile messages or text messages and any other communication-related data protection, data security or privacy Laws, to which either Party, as applicable, is subject in connection with this Agreement.
(B) Per "Legge" si intende qualsiasi legge, ordinanza, norma, regolamento e disposizione lecita applicabile di qualsiasi autorità pubblica (incluse, e solo a titolo esemplificativo, interpretazioni e decisioni di, o accordi con, qualsiasi autorità regolatoria competente) alla quale una delle Parti, secondo i casi, è soggetta in relazione all'Accordo di servizio.	(B) "Law" means any applicable laws, ordinances, rules, regulations and lawful orders of any public authority (including, and by way of example only, interpretations and decisions of, or agreements with, any competent regulatory authority) to which either Party, as applicable, is subject in connection with the Agreement.
(C) Per "Dati personali" si intende qualsiasi dato relativo a una persona identificata o identificabile, inclusi i dati che identificano una persona o che potrebbero essere utilizzati per identificare, localizzare, rintracciare o contattare una persona. I Dati personali comprendono sia elementi identificativi diretti, come un nome, un numero di identificazione o una qualifica univoca, sia elementi identificativi indiretti, come la data di nascita, un numero di identificazione univoco di un dispositivo mobile o indossabile, le informazioni che potrebbero	(C) "Personal Information" means any data relating to an identified or identifiable individual, including data that identifies an individual or that could be used to identify, locate, track, or contact an individual. Personal Information includes both directly identifiable information, such as a name, identification number or unique job title, and indirectly identifiable information such as date of birth, unique mobile or wearable device identifier, information that could be used to identify a household, telephone number, key-coded data, online identifiers, such as IP addresses, or personal activities, behavior or preferences, and includes any

essere utilizzate per identificare un nucleo familiare, un numero di telefono, i dati codificati con chiave, gli identificatori online, come gli indirizzi IP o le attività personali, il comportamento o le preferenze; comprendono inoltre tutti i dati che sono "dati personali" ai sensi del GDPR o termini simili ai sensi di altre leggi sulla protezione dei dati.	data that constitutes "personal data" under the GDPR or similar terms under other Data Protection Law.
(D) Per "Trattare" si intende qualsiasi operazione o insieme di operazioni sui Dati personali o su una serie di Dati personali, tramite mezzi automatizzati o meno, come la raccolta, la registrazione, l'organizzazione, la conservazione, l'accesso, l'adattamento o la modifica, il recupero, la consultazione, l'uso, la divulgazione mediante trasmissione, diffusione o la messa a disposizione in altra forma, la valutazione, l'analisi, la segnalazione, la condivisione, l'allineamento o la combinazione, la restrizione, la cancellazione o la distruzione.	(D) "Process" means to perform any operation or set of operations on Personal Information or sets of Personal Information, whether or not by automated means, such as collection, recording, organization, structuring, storage, access, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, evaluation, analysis, reporting, sharing, alignment or combination, restriction, erasure or destruction.
(E) Per "Violazione dei Dati personali" si intende la distruzione accidentale o dolosa, la perdita, l'alterazione, la divulgazione o l'accesso non autorizzato ai Dati personali, trasmessi, archiviati o altrimenti trattati.	(E) "Personal Data Breach" means an accidental or unlawful destruction, loss, alteration, unauthorized disclosure of or access to Personal Information, transmitted, stored or otherwise Processed.
(F) Per "Clausole contrattuali standard" si intendono le clausole contrattuali standard approvate con decisione della Commissione Europea (EU) 2021/914, secondo quanto indicato nell'allegato al Contratto per il Trattamento dei Dati ("DPA" o "CTD"), o nella forma emendata o sostituita di volta in volta dalle decisioni della Commissione Europea o da altra Legge applicabile sulla protezione dei dati.	(F) "Standard Contractual Clauses" means the standard contractual clauses approved by EU Commission Implementing Decision (EU) 2021/914, as set out in Annex to the DPA, or as may be amended or replaced from time to time by European Commission decisions or other applicable Data Protection Law.
(G) Riguardo ai termini "Titolare", "Interessato" e "Trattamento", ciascuno di essi ha il significato attribuito dal Regolamento generale sulla protezione dei dati dell'Unione Europea 2016/679 (il "GDPR"), indipendentemente dal fatto che il GDPR sia applicabile nello specifico contesto.	(G) "Controller", "Data Subject" and "Processing" each have the meaning given in the European Union General Data Protection Regulation 2016/679 (the "GDPR"), irrespective of whether GDPR applies in any particular context.
(H) Nel caso in cui le definizioni in questa clausola fossero incoerenti con le definizioni fornite dalla Legge sulla protezione dei dati, la definizione fornita dalla Legge applicabile sulla protezione dei dati prevarrà limitatamente all'incongruenza, a condizione che da tale	(H) In the event the definitions in this Section are inconsistent with the definitions given similar terms or concepts under Data Protection Law, then the definition given any such similar term or concept under that applicable Data Protection Law shall prevail to the extent of the

incongruenza consegua una definizione più ampia di tale termine o concetto.	inconsistency, so long as such inconsistency results in a broader definition of such term or concept
ii) Legge sulla protezione dei dati; informative, consenso e autorizzazioni.	ii) *Data Protection Law; Notices, Consent and Authorizations*
(A) L'UNIVERSITÀ dovrà rispettare la Legge sulla protezione dei dati in relazione all'esecuzione del Progetto e ai suoi obblighi nell'ambito del presente Contratto, incluso, a titolo esemplificativo ma non esaustivo, in caso di Trattamento di eventuali Dati personali. MSD potrà condividere i dati personali acquisiti in ragione del presente accordo e per gli scopi ad esso connessi all'interno del proprio Gruppo (società collegate, controllate e/o che ne detengono il controllo), e, in particolare, con la capogruppo negli USA (Merck & Co Inc., 126 East Lincoln Ave. – P.O. Box 2000 Rahway, New Jersey 07065 - USA), in conformità con quanto previsto della Legge sulla protezione dei dati. A tale riguardo, si rappresenta che Merck & Co Inc., 126 East Lincoln Ave. – P.O. Box 2000 Rahway, New Jersey 07065 - USA, ha adottato delle Binding Corporate Rules approvate nell'Unione Europea dalle autorità garanti della Privacy degli Stati Membri e ha inoltre in atto ulteriori misure supplementari idonee a garantire un livello adeguato di protezione dei dati trasferiti fuori dall'Unione Europea.	(A) Supplier shall comply with Data Protection Law in connection with performing the Project and its obligations under this Agreement, including, without limitation, in any Processing of any Personal Information. MSD will be entitled to transfer data collected for the execution of the Project and for purposes of this agreement also in the headquarters of Merck & Co Inc., 126 East Lincoln Ave. – P.O. Box 2000 Rahway, New Jersey 07065 - USA, and/or inside its Group in USA, in anyway always in compliance with provisions of Data Protection Law. In this respect, Merck & Co Inc., 126 East Lincoln Ave. – P.O. Box 2000 Rahway, New Jersey 07065 – USA, has adopted some Binding Corporate Rules approved by the Member State Data Protection Authorities throughout the European Union and has adopted additional supplemental measures able to guarantee an adequate level of protection of data transferred outside UE.
(B) L'UNIVERSITÀ dichiara e garantisce che:	(B) UNIVERSITY represents and warrants that:
(a) Con riferimento ai Dati personali trattati ai sensi del presente Contratto, salvo quanto diversamente o ulteriormente previsto e stabilito nel Contratto sul trattamento dei dati (allegato sub 3 del Contratto), (i) l'UNIVERSITÀ avrà cura di fornire tutte le informative e raccoglierà e manterrà validi ed efficaci nel corso del presente Contratto tutti i consensi, le approvazioni, le autorizzazioni e i diritti necessari per consentirle di trattare tali Dati personali, anche per il caso di, a titolo esemplificativo e non esaustivo, condivisione dei Dati personali con MSD, le sue Affiliate o i rispettivi agenti o rappresentanti, secondo quanto previsto dal presente Contratto e per qualsiasi scopo previsto da una legge, inoltre (ii) l'UNIVERSITÀ tratterà tali Dati personali solo in conformità a tali informative, consensi, approvazioni e autorizzazioni.	(a) With respect to any Personal Information Processed under this Agreement, unless the DPA (attached sub 3 of this Agreement) provides differently or further (i) Supplier will provide all notices and will maintain in effect during this Agreement all consents, approvals, authorizations, and rights necessary, to Process any such Personal Information, including, without limitation, sharing any Personal Information with MSD, its Affiliates, or their respective agents or representatives, for any of them to use such Personal Information as contemplated in this Agreement and for any regulatory purposes, and (ii) Supplier will Process such Personal Information only in accordance with any such notice, consents, approvals and authorizations.

(b) L'UNIVERSITÀ tratterà i Dati personali in relazione al presente Contratto solo laddove ciò sia lecito.	(b) UNIVERSITY will Process Personal Information in connection with this Agreement only where it is lawful.
iii) *Assistenza e cooperazione*. L'UNIVERSITÀ fornirà tutta l'assistenza e le informazioni che MSD può ragionevolmente richiedere, (i) affinché MSD possa ottemperare agli obblighi posti a capo di MSD stessa ai sensi della Legge sulla protezione dei dati (tra cui, a titolo esemplificativo e non esaustivo, rispondere alle richieste di soggetti interessati che esercitano i loro diritti ai sensi della Legge sulla protezione dei dati, effettuare valutazioni d'impatto sulla protezione dei dati, consultare le autorità regolatorie competenti, notificare alle autorità regolatorie competenti e ai soggetti interessati le violazioni dei Dati personali e assicurare la protezione dei Dati personali), come pure per consentirle di dare riscontro a qualsiasi reclamo, lamentela o richiesta avanzata da parte di una persona o autorità regolatoria competente e (ii) per verificare che l'UNIVERSITÀ adempia alle previsioni di questa clausola e alla Legge sulla protezione dei dati.	(iii) *Assistance and Cooperation.* UNIVERSITY will provide all assistance and information MSD may reasonably request, (i) for MSD to comply with MSD's obligations under Data Protection Law (including, without limitation, in responding to requests from individuals exercising their rights under Data Protection Law, conducting data protection impact assessments, consulting with competent regulatory authorities, notifying relevant competent regulatory authorities and individuals of Personal Data Breaches, and ensuring Personal Information protection) and otherwise investigate and address any other complaint, inquiry, request or concern by an individual or competent regulatory authority, and (ii) for Supplier to demonstrate Supplier's compliance with the provisions of this Section and compliance with Data Protection Law.
iv) *Trattamento dei dati:* in relazione al Progetto previsti dal presente Contratto che prevedano il trattamento di Dati personali da parte dell'UNIVERSITÀ per conto di MSD, l'UNIVERSITÀ, prima di avviare l'esecuzione di tali Servizi, dovrà aver sottoscritto un Data Processing Agreement (DPA), secondo quanto previsto dall'Allegato sub 3 con le modifiche che MSD ritenga ragionevolmente necessarie e si atterrà ai termini di tale DPA nel corso dell'esecuzione dei Servizi e per il periodo di tempo anche eventualmente più lungo previsto in tale DPA.	*(iv) Data Processing* In connection with the Project under this Agreement, which involve UNIVERSITY Processing Personal Information on behalf of MSD, Supplier will, by the start of the Project, have entered into a Data Processing Agreement attached sub Attachment 3 of this Agreement, with such changes as MSD deems reasonably necessary (each a "DPA"), and will comply with the terms of that Data Processing Agreement at all times during the term of the Project or such longer period provided in that Data Processing Agreement.
v) *Adempimenti inerenti alla privacy*. Ad eccezione delle modifiche opportune al raggiungimento di uno standard di settore più elevato o che siano richieste dalla Legge sulla protezione dei dati, l'UNIVERSITÀ manterrà in vigore e applicherà le procedure sulla privacy e sulla sicurezza dei dati dell'UNIVERSITÀ così come note e comunicate a MSD in occasione della due diligence più recente condotta su tali procedure da MSD; in ogni caso l'UNIVERSITÀ non può ridurre gli standard di sicurezza previsti da tali procedure, applicando successivamente procedure privacy e di sicurezza dei dati che prevedano	*(v) Privacy Practices*. Except for changes made consistent with meeting a higher industry standard or Data Protection Law, UNIVERSITY shall maintain in effect and consistently apply UNIVERSITY's privacy and data security practices disclosed to MSD in connection with the due diligence most recently conducted on those practices in connection with this Agreement; provided that UNIVERSITY may not reduce the standards in those practices by subsequently disclosing privacy and data security practices that would be a degradation of the previously disclosed practices.

standard meno elevati. L'UNIVERSITÀ dichiara e garantisce che tutte le informazioni fornite dall'UNIVERSITÀ in sede di due diligence sono vere, accurate e complete al momento della esecuzione della due diligence, e alla Data di decorrenza del presente Contratto, se successiva alla esecuzione della verifica. L'UNIVERSITÀ informerà MSD circa qualsiasi modifica apportata a tali procedure relative alla privacy e alla sicurezza dei dati.	UNIVERSITY represents and warrants that all responses provided by UNIVERSITY in any such due diligence are true, accurate and complete when made, and if later, as of the Effective Date of this Agreement. UNIVERSITY will provide notice to MSD of any change to such privacy and data security practices.
12. DIRITTI DI PROPRIETÀ INTELLETTUALE	**12. INTELLECTUAL PROPERTY RIGHTS**
12.1. A MSD spettano – in via esclusiva e senza alcuna limitazione – tutti i diritti di proprietà intellettuale e/o industriale (ivi inclusi, a titolo meramente esemplificativo, i diritti patrimoniali d'autore, i diritti su marchi, brevetti, disegni e modelli ornamentali, *know-how*, i diritti di sfruttamento e di uso, etc.) originati dai o esistenti sui risultati (in tutte le manifestazioni ed espressioni) dell'attività svolta dall'UNIVERSITÀ per l'esecuzione del Progetto e del Contratto, incluso il report di cui al Protocollo, fatto salvo il diritto morale degli autori dell'opera autoriale che costituisca divulgazione dei risultati del Progetto, nonché degli autori//inventori ad essere indicati come tali nella eventuale domanda di privativa industriale. In particolare, MSD sarà proprietaria unica ed esclusiva di tutti i diritti e contenuti del Progetto realizzato dall'UNIVERSITÀ e sarà libera di usare i relativi risultati per fini di ricerca scientifica e didattica, nonché per tutti gli scopi e le finalità ulteriori da MSD unicamente determinati.	12.1. MSD shall be entitled - exclusively and without any limitation - to all intellectual and/or industrial property rights (including, but not limited to, patrimonial copyrights, rights to trademarks, patents, ornamental designs, know-how, rights of exploitation and use, etc.) originated from or existing on the results (in all manifestations and expressions) of the activity carried out by the UNIVERSITY for the execution of the Project and the Contract, including the report referred to in the Protocol, without prejudice to the moral right of the authors of the authorial work constituting disclosure of the results of the Project, as well as of the authors//inventors to be indicated as such in the eventual application for industrial property rights. In particular, MSD shall be the sole and exclusive owner of all rights and contents of the Project carried out by the UNIVERSITY and shall be free to use the results thereof for scientific and educational research purposes, as well as for all further purposes and purposes solely determined by MSD.
12.2. L'UNIVERSITÀ dichiara espressamente di riconoscere MSD quale titolare esclusivo di tutti i diritti di proprietà intellettuale relativi alle informazioni, ai dati e alle conoscenze trasmessi da MSD all'UNIVERSITÀ per l'esecuzione del Contratto o da quest'ultima elaborati per la realizzazione del Progetto (la "**Proprietà Intellettuale"**) e prende atto che tale materiale è concesso all'UNIVERSITÀ soltanto ed esclusivamente in licenza d'uso non esclusiva, gratuita e perpetua per fini di ricerca scientifica e didattica.	12.2. UNIVERSITY declares expressly to recognize MSD as exclusive holder of all intellectual property rights relevant to information, data and knowledges transmitted by MSD to UNIVERSITY for the execution of the Agreement or elaborated by the latter for the accomplishment of the Project (the "**Intellectual Property**") and acknowledges that such material is granted to UNIVERSITY only and exclusively in use license. 12.3. As the owner of industrial property rights, MSD will be entitled to disseminate the results of the Project. In particular, the

12.3. Quale co-titolare dei diritti di privativa industriale, MSD avrà facoltà di divulgare i risultati del Progetto. In particolare l'UNIVERSITÀ si impegna a presentare almeno un abstract ad un congresso nazionale/internazionale e/o un paper a un periodico scientifico, sulla base di una *peer review*, avente ad oggetto i risultati del Progetto previa condivisione con MSD almeno 60 (sessanta) giorni di anticipo rispetto alla data di consegna; l'UNIVERSITÀ si obbliga ad apportare le modifiche indicate al solo ed esclusivo scopo di eliminare qualsiasi informazione confidenziale fornita da MSD e a considerare le modifiche proposte restando inteso che l'UNIVERSITÀ ed i propri ricercatori autori di tale pubblicazione hanno piena ed assoluta libertà riguardo al contenuto scientifico della pubblicazione per la parte di cui sono gli unici responsabili	UNIVERSITY undertakes to submit at least one abstract to a national/international congress and/or a paper to a scientific journal on the basis of peer review, dealing with the results of the Project after sharing with MSD at least 60 (sixty) days in advance of the delivery date; the UNIVERSITY agrees to make the changes indicated for the sole and exclusive purpose of eliminating any confidential information provided by MSD and to consider the proposed changes with the understanding that the UNIVERSITY and its researchers authors of such publication have full and absolute freedom regarding the scientific content of the publication for the part for which they are solely responsible.
12.4. L'UNIVERSITÀ garantisce che i dati e i materiali ed i documenti elaborati nell'ambito e per l'esecuzione del Progetto sono frutto della propria autonoma ed originale attività e che pertanto non potranno essere violati diritti di proprietà intellettuale di terzi. Resta inteso che, nell'eventualità in cui l'UNIVERSITÀ si sia avvalsa della collaborazione di altre persone nello svolgimento del Progetto, che abbiano diritto a veder riconosciuta la loro opera, nessuna pretesa potrà da questi ultimi essere avanzata nei confronti di MSD. L'UNIVERSITÀ si impegna pertanto ad avvisare anticipatamente tali soggetti degli specifici accordi esistenti con MSD rispetto alla proprietà intellettuale ed industriale, manlevando MSD da qualsiasi responsabilità in merito.	12.4. UNIVERSITY warrants that the data and materials and documents developed within the scope and execution of the Project are the result of its own autonomous and original activity and that therefore no intellectual property rights of third parties may be infringed. It is understood that, in the event that UNIVERSITY has availed itself of the collaboration of other persons in the performance of the Project, who are entitled to have their work recognized, no claim may be made by them against MSD. The UNIVERSITY therefore undertakes to notify such persons in advance of the specific agreements existing with MSD with respect to intellectual and industrial property, releasing MSD from any liability in this regard.
12.5. Resta inteso che l'UNIVERSITÀ non potrà, senza previo consenso scritto di MSD, cedere, *sub*-licenziare, trasferire o concedere in uso a qualsiasi titolo, anche gratuito, la Proprietà Intellettuale, impegnandosi altresì a comunicare qualsiasi violazione dei diritti di privativa di cui venga a conoscenza.	12.5. It is understood that UNIVERSITY shall not, without prior written consent of MSD, assign, sublicense, transfer or grant in use at any title, even free of charge, the intellectual property, also undertaking to communicate any violation of privative rights it become aware of.
12.6. La Proprietà Intellettuale e tutte le informazioni collegate, inclusi gli aggiornamenti, miglioramenti e modifiche, sono considerati	12.6. The Intellectual Property and all relevant information, including updates, improvements and changes, are considered Confidential Information and must be protected and scrupulously processed as such.

Informazioni Confidenziali e dovranno essere protetti e scrupolosamente trattati come tali.	
13. FORZA MAGGIORE	**13. FORCE MAJEURE**
13.1. Nelle ipotesi di caso fortuito o di forza maggiore, l'UNIVERSITÀ non sarà in alcun modo responsabile della mancata o difettosa esecuzione del Progetto, né risponderà di alcuna perdita, danno o lesione che derivino a MSD, siano essi diretti o indiretti, prevedibili o imprevedibili. Nel perdurare di tali cause di impedimento, l'UNIVERSITÀ si riserva il diritto di interrompere l'esecuzione del Progetto, sino al momento in cui valuterà che il superamento degli impedimenti in essere consenta la ripresa dello svolgimento del Progetto.	13.1. In the hypothesis of accidental case or force majeure, UNIVERSITY shall not be in any way responsible of failed or defective supply of the Project nor it will be responsible of any loss, damage or injury resulting to MSD, whether direct or indirect, foreseeable or unpredictable. In the persistence of such causes of impediment, UNIVERSITY reserves the right to interrupt the execution of the Project until it will assess that the overcoming of current impediments allows the restarting of the execution of the Project.
13.2. Qualora le cause di forza maggiore impedissero all'UNIVERSITÀ di eseguire esattamente il Progetto per un periodo superiore ai 30 (trenta) giorni, MSD avrà la facoltà di recedere dal Contratto con effetto immediato e di affidare il Progetto a un diverso fornitore.	13.2. Whether reasons of force majeure prevent UNIVERSITY to correctly execute the Project for a time longer than 30 (thirty) days, MSD shall have right to withdraw from the Agreement with immediate effect and to entrust the Project to a different supplier.
13.3. Costituiscono casi di forza maggiore gli eventi al di fuori del ragionevole controllo dell'UNIVERSITÀ, quali, a titolo esemplificativo ma non esaustivo, attività e/o decisioni governative e/o della Pubblica Amministrazione, e/o delle autorità di controllo del settore sanitario, atti dell'Autorità Militare, limitazioni legali, catastrofi naturali, incendi, esplosioni, sommosse, guerre, epidemie, scioperi, mancanza di energia, trasporti e purché siano su base nazionale e imprevisti.	13.3. Cases of force majeure are events beyond the reasonable control of UNIVERSITY, such as, for example but not exhaustively, activities and/or government decisions and/or of Public Administration and/or of control authorities of healthcare sector, Military Authorities' acts, legal limitations, natural disasters, fires, explosions, riots, wars, epidemics, strikes, lack of energy, transportations, provided they are on national basis and unpredicted.
14. CONTINUITÀ DELL'ESECUZIONE IN CASO DI CONTROVERSIE	**14. EXECUTION CONTINUITY IN CASE OF DISPUTES**
14.1. In caso di controversia e/o contestazione e/o richiesta, relativa all'esecuzione del Progetto, anche non previste e/o straordinarie, nonché ad ogni altro fatto o atto direttamente o indirettamente afferente ad essi, l'UNIVERSITÀ non avrà diritto di sospendere	14.1. In the event of controversy and/or dispute and/or claim, related to the execution of the Project, even unpredicted and/or extraordinary as well as to any other fact or action directly or indirectly pertinent to them, UNIVERSITY shall not have right to suspend the execution of the Project nor to refuse to execute received provisions.

l'esecuzione del Progetto, né potrà rifiutarsi di svolgere le disposizioni ricevute.

14.2. L'UNIVERSITÀ, pur potendo avanzare per iscritto le proprie osservazioni, resterà tuttavia tenuta ad uniformarsi sempre alle disposizioni di MSD, senza poter sospendere o ritardare l'esecuzione del Progetto e ciò a pena di risoluzione del Contratto per inadempimento e del risarcimento di tutti i danni che possano derivare a MSD.

15. VARIE

15.1. L'UNIVERSITÀ si obbliga a non cedere né a subappaltare in tutto o in parte il Contratto e le attività ivi contemplate a terzi senza la preventiva autorizzazione scritta di MSD, restando inteso che in tal caso il subappalto e la cessione non comportano alcuna modificazione agli obblighi e agli oneri dell'UNIVERSITÀ la quale rimane l'unica e sola responsabile nei confronti di MSD della perfetta esecuzione del Contratto, anche per la parte subappaltata o ceduta.

15.2. Ogni comunicazione relativa al presente rapporto contrattuale inviata da una delle Parti avrà efficacia nei confronti dell'altra Parte solo se inviata con posta elettronica certificata o raccomandata a/r agli indirizzi:

per l' UNIVERSITÀ: dipartimentoscienzemediche@cert.unifg.it
indicando: alla cortese attenzione delle prof.sse Rosa Prato e Francesca Fortunato

per MSD: msditaliasrl@pec.it
indicando: alla cortese attenzione del dott. Gian Marco Prandi – Medical Affairs Director, Vaccines

15.3. Le Parti si danno atto che il presente Contratto non istituisce in alcun modo un rapporto di mandato con rappresentanza e non vale a fondare alcun tipo di impresa comune tra le stesse che sono pienamente autonome ed assumono la gestione delle proprie attività

14.2. UNIVERSITY, albeit being allowed to submit its own remarks in writing, will remain however obliged to comply always with MSD's provisions, without being allowed to suspend or delay the execution of the Project, under penalty of termination of the Agreement for failure and of compensation of all damages that could result to MSD.

15. MISCELLANEUS

15.1. UNIVERSITY undertakes not to assign nor to subcontract to thirds all or part of the Agreement and the activities therein without prior written authorization of MSD, being understood that in such case the subcontract and the assignment do not entail any change in the obligations and burdens of UNIVERSITY, who remains the only and sole responsible towards MSD for the perfect execution of the Agreement, for the assigned or subcontracted part as well.

15.2. Any communication related to the present contractual relationship transmitted by one of the Parties will have efficacy towards the other Part only if sent with certified electronic mail or registered letter with return notice to the addresses set out below:

for UNIVERSITY: dipartimentoscienzemediche@cert.unifg.it
indicating: to the kind attention of professors Rosa Prato and Francesca Fortunato

for MSD: msditaliasrl@pec.it
indicating: to the kind attention of Gian Marco Prandi – Medical Affairs Director, Vaccines

15.3. The Parties acknowledge that this Agreement does not create in any way a mandate with representation nor is able to establish any kind of common business between them, who are fully autonomous and undertake the management of their own activities with own means and personnel and at own risk.

con mezzi e personale proprio ed a proprio rischio.	
15.4. Le Parti concordano di non (i) utilizzare il nome o qualsiasi altro segno distintivo dell'altra Parte in qualsivoglia attività senza il preventivo consenso dell'altra Parte, o (ii) rilasciare comunicati stampa o altrimenti diffondere notizie sull'esistenza del Contratto o dei suoi termini e condizioni, senza il preventivo consenso dell'altra Parte; fermo restando che l' UNIVERSITÀ potrà, nella misura necessaria ad adempiere le obbligazioni previste dal Contratto, rivelare a terzi di eseguire una prestazione a favore di MSD.	15.4. UNIVERSITY must not (i) use the name or any other distinctive sign of MSD in any promotional activity, nor (ii) issue press release or otherwise spread news on the existence of the Agreement or its terms and conditions, without prior consent of MSD; it is understood that UNIVERSITY can reveal to thirds to execute a performance in favor of MSD to the extent necessary to accomplish obligations set in the Agreement.
15.5. Il Contratto è regolato e sarà interpretato secondo la legge italiana. Per ogni controversia relativa al presente Contratto, le Parti si impegnano ad adire in via esclusiva il foro di Roma.	15.5. The Agreement is governed and will be construed in accordance with the laws of Italy. For any dispute related to this Agreement, the Parties undertake to exclusively recourse to the Courts of Rome.
15.6. Il presente atto verrà registrato solo in caso d'uso ai sensi dell'art. 5, II comma, del D.P.R.26/04/1986 n. 131 e successive modifiche, a cura e spese della parte richiedente. Le spese di bollo sono a carico di MSD.	15.6. This deed shall be registered only in case of use pursuant to Article 5, Paragraph II of Presidential Decree No. 131 of 26/04/1986, as amended, at the expense of the requesting party. Stamp costs shall be borne by MSD.
16. FARMACOVIGILANZA	**16. PHARMACOVIGILANCE**
16.1 Eventuali eventi avversi raccolti durante lo studio dovranno essere segnalati in accordo alle modalità e tempistiche meglio declinate nel Protocollo.	16.1 Any adverse events collected in the study should be reported in accordance with the manner and timing better declined in the Protocol.
Il presente Contratto è sottoscritto in lingua inglese ed italiana; in caso di conflitto, la lingua italiana prevale	**This Agreement is signed in English and Italian; in case of conflict, the Italian language prevails.**

Letto, confermato e sottoscritto,

MSD ITALIA S.R.L.

Firmato digitalmente da

GIORGIO URSILLO

Dr. Giorgio Ursillo – il legale rappresentante p.t.

SerialNumber = TINIT-RSLGRG78T06H501U
C = IT
Data e ora della firma: 25/11/2024 17:38:51

UNIVERSITA' DEGLI STUDI DI FOGGIA – Dipartimento di Scienze Mediche e Chirurgiche

GAETANO
SERVIDDIO
26.11.2024 15:41:29
GMT+01:00

Dr./Prof. Gaetano Serviddio – Direttore pro-tempore del Dipartimento di Scienze Mediche e Chirurgiche

L'UNIVERSITÀ dichiara di aver preso visione e di conoscere il contenuto delle seguenti disposizioni, che espressamente approva e sottoscrive ai sensi e per gli effetti dell'art. 1341, comma 2, c.c.: artt. 6 (Responsabilità e garanzie), 7 (Compliance), 10 (Risoluzione e recesso), 13 (Forza maggiore), 14 (Continuità dell'esecuzione in caso di controversie) e 15.5 (Foro competente) di cui sopra.

UNIVERSITA' DEGLI STUDI DI FOGGIA – Dipartimento di Scienze Mediche e Chirurgiche

GAETANO
SERVIDDIO
26.11.2024 15:41:29
GMT+01:00

Dr./Prof. Gaetano Serviddio – Direttore pro-tempore del Dipartimento di Scienze Mediche e Chirurgiche

Read, confirmed and subscribed.

MSD ITALIA S.R.L.

Firmato digitalmente da

GIORGIO URSILLO

Dr. Giorgio Ursillo – the legal representative p.t.

SerialNumber = TINIT-RSLGRG78T06H501U
C = IT
Data e ora della firma: 25/11/2024 17:39:25

UNIVERSITY OF FOGGIA – Department of Medical and Surgical Sciences

GAETANO
SERVIDDIO
26.11.2024 15:41:29
GMT+01:00

Dr./Prof. Gaetano Serviddio – director pro tempore of Department of Medical and Surgical Sciences.

UNIVERSITY declares to have read and to know the content of the following provisions which expressly approves and subscribes pursuant to and for the purposes of art. 1341, paragraph 2, Italian Civil Code: articles 6 (Responsibilities and warranties), 7 (Compliance), 10 (Termination and withdrawal), 13 (Force majeure), 14 (Execution continuity in case of disputes) and 15.5 (Jurisdiction) as above.

UNIVERSITY OF FOGGIA – Department of Medical and Surgical Sciences

GAETANO
SERVIDDIO
26.11.2024 15:41:29
GMT+01:00

Prof. Gaetano Serviddio – director pro tempore of Department of Medical and Surgical Sciences

ALLEGATO 1 PROTOCOLLO ALLEGATO 2 IL CORRISPETTIVO ALLEGATO 3 DATA PROCESSING AGREEMENT	ATTACHMENT 1 THE PROTOCOL ATTACHMENT 2 THE CONSIDERATION ATTACHMENT 3 DATA PROCESSING AGREEMENT

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RevOps ID NO: NIS103239	CORE DRC Approval Date: 22-JUN-2023

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SPONSOR:

MSD Italia srl

(here after referred to as the Sponsor)

Via Vitorchiano 151

00189 ROMA (Italy)

TITLE:

The RISO study: **R**egional **I**mmunization **S**trategies and **O**perative models: state of the art of pneumococcal age based and risk-group vaccination across the 21 Italian Regions

INVESTIGATORS:

Rosa Prato, MD and Francesca Fortunato, MD
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University of Foggia
Struttura Complessa di Igiene universitaria
P.O. Colonnello D'Avanzo, Policlinico Foggia ospedaliero-universitario
Viale degli Aviatori, 2 – 71122 Foggia (Italy)

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Version History

Version	***Approval Date***		***Changes***
1	See header	Original	
2		Amendment	
3		Amendment	
4		Amendment	

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Professoressa

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Product: V114	Protocol/Amendment Version No.: 1
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List of Abbreviations

AE	*Adverse event*
EMA	*European Medicines Agency*
FDA	*Food and Drug Administration*
GPRD	*General Practice Research Database*
ICD-9	*International Classification of Disease, 9th Modification*
IEC	*Independent Ethics Committee*
ISERP	*Independent Safety Epidemiology Review Panel*
MoH	*Ministry of Health*
LHU	*Local Health Unit*
NIP	*National Immunization Program*
PASS	*Post-Authorization Safety Surveillance*
PCV	*Pneumococcal Conjugate Vaccine*
PNPV	*Piano Nazionale Prevenzione Vaccinale*
PPSV23	*Pneumococcal Polysaccharide Vaccine*
Q	*Quarter*
RHA	*Regional Health Authorities*
SAP	*Statistical Analysis Plan*
SOP	*Standard Operating Procedure*
SP	*Streptococcus pneumoniae*
VCR	*Vaccine Coverage Rate*

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List of Definitions

Health outcomes: Clinical events or outcomes which may be represented as diagnoses, treatments, or procedures (examples include syncope, disease progression or hypoglycemia collected as study endpoints)

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PROTOCOL SUMMARY

Title	The RISO study: Regional Immunization Strategies and Operative models: state of the art of pneumococcal age based and risk-group vaccination across the 21 Italian Regions
Supplier/Collaborator	Rosa Prato and Francesca Fortunato Università di Foggia
Rationale	To the present day, there is a lack of a complete picture of how and where the pneumococcal sequential vaccination in older adults and frail people is implemented and, if any, the degree of difference in vaccination coverage the different organizational arrangements play. The understanding of strategies for offering and promoting immunization programs as well as pathways, modalities of calling, managing, and delivering vaccinations is a key step to improve the coverage rate and reduce the burden of SP-related diseases. Hence, a quanti-qualitative survey is designed to collect data regarding the implementation and operative models of the pneumococcal age based and risk-group vaccination in all 21 Italian Regions, also considering the availability of new pneumococcal conjugate vaccines.
Primary Objective(s)	• To describe elements related to pneumococcal age based and risk-group vaccination programs and implementations, such as vaccination strategies and pathways, network and operating procedures, training, and campaigns. • To investigate the presence of vaccination data base/registry and its integration with other registry/data base.

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	• To describe the available data related to pneumococcal VCRs.
Study Design	This is a quanti-qualitative survey study to be conducted with an academic Institution through a search of official regional documents on pneumococcal age based and risk-group vaccination and "snowball" interviews to regional vaccination referents and professionals of LHUs and Hospitals based on a semi-structured questionnaire.
Study Population	21 Italian Regions
Study Duration	Approximately 1 year since study start to final reporting
Exposure and Outcome	This study has no health outcomes.
Statistical Methods	The study results will be reported separately for each Region or summarized in aggregate format with descriptive statistics (absolute numbers, percentages, mean and standard deviation). The "free text" data not coded by the Investigators before the data analysis will be presented in the form of listings. No missing data imputation will be conducted given the nature of the study. Anyway, the amount of missing data will be assessed. The statistical analyses will be done using STATA.
Sample Size and Power Calculations	Not applicable
Limitations	Due to the voluntary participation, the representativeness of all Italian Regions is not guaranteed. The not participating regions will be described. Anyway, the documents search will be performed for all regions. Some missing data are expected for the failure for the investigators to identify the most appropriate reference persons for compiling the questionnaire. The direct interview by trained personnel, along with the snowball interview methodology, reduce the number of missing and improve the quality of collected data.

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	Despite this limitation we expect to collect a substantial amount of data for the analysis to be informative. In addition, the description of the amount of the missing data could be itself interesting evidence to describe the real Italian world and the current limitations of the vaccination offer system.

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1 Background and Rationale

1.1 Background

In Italy, the National Health Service has been decentralized since 2001. This endows all the 21 Italian Regional Health Authorities (RHAs) with the responsibility of organizing, delivering, and allocating budget for all health services, including vaccination, with the strategic support of the Ministry of Health (MoH).

The National Immunization Plan (NIP) provides national recommendations and lists the vaccines to be provided by law free-of-charge across Italy to guarantee equity of access to all population; RHAs autonomously plan the strategies for offering and promoting immunization programs and manage the services delivered by their Local Health Units (LHUs) that are committed to providing healthcare services to the population, including vaccinations.

Regarding pneumococcal vaccination, the current NIP (PNPV 2017-2019) recommends the sequential administration of 13-valent pneumococcal conjugate vaccine and 23-valent pneumococcal polysaccharide vaccine (PCV13 + PPSV23) in people aged 65 years (primary cohort) and in people with risk factors starting from the 6th year of age. The vaccinations are delivered by public immunization services and/or General Practitioners and/or Hospitals. The degree of cooperation, the distribution of tasks and responsibilities and the operational models implemented by these entities may vary among RHAs and LHUs and it's also presumable that different setting differently impact on the vaccination coverage rates (VCRs).

In 2021, 20-valent PCV and 15-valent PCV were licensed by the Food and Drug Administration for adults aged ≥18 years. In October 2021, the Advisory Committee on Immunization Practices (1) recommended PCV15 or PCV20 for PCV-naïve adults who are either aged ≥65 years or aged 19–64 years with certain underlying conditions; when PCV15 is used, it should be followed by a dose of PPSV23 ≥1 year later. In 2022, the two new pneumococcal conjugate vaccines were approved for use in adults by the European Medicines Agency (2,3) and by the Italian Medicines Agency (4). More recently, the use of PCV15 was also approved in infants, children and adolescents from 6 weeks to less than 18 years of age (3).

It is known that the updating PNPV 2020–2022 defines the national goals of the vaccination policy and indicates the actions needed for their pursuit at a local, regional, and national level. Its implementation undergoes monitoring and evaluation from the RHAs through a system of

indicators, measuring not only the VCRs, but also the achievement of the consequent health prevention objectives (5).

1.2 Rationale

To the present day, there is a lack of a complete picture of how and where the pneumococcal sequential vaccination in older adults and frail people is implemented and, if any, the degree of difference in vaccination coverage the different organizational arrangements play.

The understanding of strategies for offering and promoting immunization programs as well as pathways, modalities of calling, managing, and delivering vaccinations is a key step to improve the coverage rate and reduce the burden of SP-related diseases. The term “modalities of calling" means the alternative paths/ways Local Health Units (LHUs) have to invite population to receive immunization. For infants, for example, LHUs make an "active call" which means they send a letter, e-mail, text message to infant's parent. In the letter/e-mail/text message are included information about the diseases the immunization will prevent and about the vaccine. Additionally, day and time for date are included. For at risk population and adults, almost no LHUs make an "active call". Instead, they make what is colloquially defined as an "inactive call", which means they provide information about the disease via informational campaigns and/or they ask general practitioners to inform the population and/or they delegate generals practitioners to deliver shots or they do not anyone of the above mentioned and wait for the subject to reach spontaneously the LHU and ask for the vaccination.

Hence, a quanti-qualitative survey is designed to collect data regarding the implementation and operative models of the pneumococcal age based and risk-group vaccination in all 21 Italian Regions, also considering the availability of new pneumococcal conjugate vaccines.

2 Objectives and Hypotheses

2.1 Primary Objective(s) & Hypothesis(es)

- To describe elements related to pneumococcal age-based and risk-group vaccination programs and implementation, such as vaccination strategies and pathways, network and operating procedures, training, and campaigns.

- To investigate the presence of vaccination data base/registry and its integration with other registry/data base.
- To describe the available data related to pneumococcal VCRs.

3 METHODOLOGY

3.1 Summary of Study Design

This is a quanti-qualitative survey study to be conducted with an academic Institution through a search of official regional documents on pneumococcal age based and risk-group vaccination. This mapping review will be performed to customize a semi-structured questionnaire to be used during "snowball" interviews to regional vaccination referents and professionals of LHUs and Hospitals. The snowball process implies that first line responders will actively assist in recruiting second line responders in case formers do not have all the data needed to complete the survey. The academic institution involved in the study is the Department of Medical and Surgical Sciences (Unit of Hygiene) of the University of Foggia.
Academic Institution experts will:

- define the study semi-structured questionnaire in collaboration with the Sponsor
- perform a mapping review of official regional documents on pneumococcal age based and risk-group vaccination
- recruit regional referents and professionals of LHUs and Hospitals participating in the survey
- perform snowball interviews to complete data collection
- analyze the data
- prepare the results report
- disseminate the results in collaboration with the Sponsor.

Data of interest are partially reported in publicly available documents such as recommendations issued by the Regions. Thus, performing a survey is the only way to obtain a more complete picture of pneumococcal age based and risk-group vaccination programs and implementation, allowing to collect existing data not otherwise accessible.

The recruitment of regional referents and professionals of LHUs and Hospitals will be performed through a snowball sampling method starting from the list of members of Interregional Committee for Prevention. LHUs are the local clinical office that perform prevention activities in a defined location, among their activities they perform vaccination campaigns.

All referents will be invited, by email or phone contact, as applicable, to participate in the survey. All referents and experts/professionals recruited by the formers for completing the data collection at local level confirming their willingness to participate and providing their consent to process personal data will participate. Two reminders will be made in order to increase the response rate so to adequately depict the Italian status of art of all the 21 Italian Regions.

Experts, referents, and professionals are almost always part of the committees that make decisions in the region therefore they will know about the point.

The survey is estimated to require about 20 minutes to complete. In addition to the time for questionnaire/interview execution, each participant will be involved also for resolution of any queries that might arise after data quality check.
The overall study duration will be about 12 months.

The planned study timeline is the following:
Participants (i.e., regional referents and professionals of LHUs and Hospitals) recruitment: Q1-Q2 2023
End of data collection and validation: Q3 2023
Final report of study results: Q4 2023

3.2 Study Population

This study is aimed to collect data on the approach followed by the Regions and implemented strategies at local level to offer and administer pneumococcal age based and risk-group vaccination.
So, in the scope of this study the Regions can be considered as investigational subject.

The Region will be included if at least one expert (regional referent and/or professional of LHUs and Hospitals) will confirm the willingness to participate and will provide written informed Consent for personal data processing.

3.3 Inclusion Criteria

- Identification as experts, referents, and professionals for a single Italian Region or Province
- Willingness to complete the survey
- Sign of the informed consent

All inclusion and exclusion criteria will be reviewed by the investigator or qualified designee to ensure that the subject qualifies for the study

- 3.4 Exclusion Criteria Absence of at least one of Inclusion Criteria

4 Variables and Epidemiological Measurements

The following variables will be collected directly by the investigators based on publicly available regional recommendations and through interview to regional referents and experts/professionals responsible for implementation at local level (hospital and/or Local Health Unit) of regional recommendations.

- Region (name), personnel interviewed (role, affiliation)
- LHU (name), personnel interviewed (role, affiliation)
- Hospital (name), personnel interviewed (role, affiliation)
- Date of questionnaire completion (dd/mm/yyyy)

- Existing vaccination recommendations issued by the Region (YES/NO)
    - If YES (data of the last recommendation referred to the NIP 2017-2019 and subsequent should be collected):
        - document ID code (free text)
        - date of publication (dd/mm/yyyy)

- Target population to whom the pneumococcal age based and risk-group vaccination programs are addressed (multiple choice of applicable NIP risk factors and age)
- Program start date (dd/mm/yyyy)
- Existing Operating Procedure to regulate the vaccination program (YES/NO)
    - If YES:
        - document ID code (free text)
        - date of release (dd/mm/yyyy)
- Type of invitation to vaccination (active/inactive)

If active offer:

- Way of contacting for promoting vaccination [letter/telephone call/SMS/face to face/other (free text)]
    - If a professional is involved:
        - Specialist/healthcare professional involved in promoting vaccination [General practitioner/healthcare professional of LHU vaccination centre/Hospital healthcare professional/other (free text)]

        - Training for specialists/healthcare professionals involved in promoting pneumococcal age based and risk-group vaccination from LHU/Hospital (YES/NO)
            - If YES, indicate topics:
                - Streptococcus Pneumoniae infection and related disease (YES/NO)
                - Vaccine (immunogenicity, efficacy, safety, SmPC) (YES/NO)
                - Other (free text)
- Re-contacting in case of 1st contact failure (YES/NO)
    - If YES:
        - Way of re-contacting [letter/telephone call/SMS/face to face other (free text)]

- Way of contacting for planning vaccination appointments [letter/telephone call/specific website/face to face/other (free text)]
    - If a professional is involved:
        - Specialist/healthcare professional accountable for planning appointments for vaccination schedule completion [General practitioner/healthcare professional of LHU vaccination centre/Hospital healthcare professional/healthcare professional of rest home/other (free text)]

- Department/institution accountable for vaccine logistics [LHU pharmacy/Hospital pharmacy/regional pharmacy/other (free text)]
- Specialist/healthcare professional accountable for vaccine administration [General practitioner /healthcare professional of LHU vaccination centre/Hospital healthcare professional/healthcare professional of rest home/other (free text)]
- Training for specialists/healthcare professionals accountable for pneumococcal vaccine administration (YES/NO)
    - If YES, indicate topics:
        - Operating Procedure (YES/NO)
        - Streptococcus Pneumoniae infection and related disease (YES/NO)
        - Vaccine (immunogenicity, efficacy, safety, SmPC) (YES/NO)
        - Other (free text)
- Schedule of vaccine administration:
    - 1 dose PCV
    - 1 dose PCV followed by 1 dose PPSV23 ≥1 years later
    - 1 or more doses PPSV23

  - 1 dose PCV followed by 1 dose PPSV23 ≥8 weeks later (adults with an immunocompromising condition, cochlear implant, or cerebrospinal fluid leak)
  - Repeated PCV vaccinations due to immunodeficiency
- Existence of electronic registry/data base for recording the vaccination status of the subjects undergoing the program (YES/NO)
  - If YES:
    - Recorded information (free text)
    - Integration with other registry/data base (YES/NO/UNKNOWN)

Vaccine Coverage Rate by target population, for:

  - 1 dose PCV
  - 1 dose PCV followed by 1 dose PPSV23 ≥1 years later
  - 1 or more doses PPSV23
  - 1 dose PCV followed by 1 dose PPSV23 ≥8 weeks later (adults with an immunocompromising condition, cochlear implant, or cerebrospinal fluid leak)
  - Repeated PCV vaccinations due to immunodeficiency

- Description of type of data used to calculate the VCR (numerator and denominator - free text)
- Existence of periodic assessment of the VCRs (YES/NO)
- Existence of periodic assessment of the procedure (YES/NO)

- Main critical issues encountered in the implementation of the vaccination offer:
  - Promoting vaccination (YES/NO)
    - If YES:
      - Identification of Specialist/healthcare professional involved (YES/NO)
      - Specialist/healthcare professional training (YES/NO)
      - Identification of way for contacting (YES/NO)
      - Identification of target population for contacting (YES/NO)
      - Other (free text)
  - Planning vaccination appointments (YES/NO)
    - If YES:
      - Identification of Specialist/healthcare professional involved (YES/NO)
      - Identification of way for planning vaccination appointments (YES/NO)

- Identification of target population for planning (YES/NO)
- Other (free text)

- Vaccination administration (YES/NO)
  - If YES:
    - Identification of Specialist/healthcare professional involved (YES/NO)
    - Specialist/healthcare professional training (YES/NO)
    - Identification of the site for vaccination administration (YES/NO)
    - Vaccine purchase/distribution (YES/NO)
    - Other (free text)
- Data base registry/data base for recording the vaccination status (YES/NO)
- Integration with other registry/data base (YES/NO)
- Other (free text)

- Main key operational features of the implemented vaccination offer (free text)

- Existence of outreach campaign for pneumococcal vaccination strategy at local or regional level specific for each target population (YES/NO)
  - If YES:
    - Tools [social media/leaflets/TV and or radio/other (free text)]

- Existing vaccination offer in place before the one described above [YES/NO, If YES specification of date of starting and details (free text)]

- Data sources used for compiling the questionnaire (free text)

The term “modalities of calling" means the alternative paths/ways Local Health Units (LHUs) have to invite population to receive immunization. For infants, for example, LHUs make an "active call" which means they send a letter, e-mail, text message to infant's parent. In the letter/e-mail/text message are included information about the diseases the immunization will prevent and about the vaccine. Additionally, day and time for date are included. For at risk population and adults, almost no LHUs make an "active call". Instead, they make what is colloquially defined as an "inactive call", which means they provide information about the disease via informational campaigns and/or they ask general practitioners to inform the population and/or they delegate generals practitioners to deliver shots or they do not anyone of the above mentioned and wait for the subject to reach spontaneously the LHU and ask for the vaccination. 4.1 Outcomes

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This study has no health outcomes.

4.2 Covariates

Not applicable.

5 Study Flow Chart

	Timing (approximate) - 2023			
Activity	**Q1**	**Q2**	**Q3**	**Q4**
Mapping review of official regional documents and relevant data collection	X			
Identification of the regional referents and professionals of LHUs and Hospitals participating in the survey	X	X		
Data collection through the snowball interviews*		X	X	
Data coding and analysis				X
Final Report preparation				X

* before recruiting any referent involved in data collection his/her consent to process personnel data should be obtained

The reported timing is not mandatory but recommended to meet the overall study timelines.

6 Study Procedures

6.1 Study Procedures

The Study Diagram in Section 5 summarizes the study procedures to be performed. Individual study procedures are described in detail below.

6.1.1 Administrative Procedures

6.1.1.1 Protection of Human Subjects

This study will not require patient informed consent, because no patients are involved in the study, however, the study will require informed consent of the experts. This study will not require patient IRB/EC review because no patients are involved in the study.

See paragraph 6.1.1.2 and 9.1.4 for protection of personal information of personnel of RHA/LHU/Hospital responsible for completion and reviewing of the questionnaire.

6.1.1.2 Mapping review

Before starting with data collection through the interview and in the scope of tuning the interview, the Investigators will gather up (e.g., in the Institutional websites) the official documents/data sources reporting the data of interest for the study. All data not included in the source documents will be collected by interviewing the regional referents and professionals of LHUs and Hospitals, as applicable.

6.1.1.3 Recruitment of participants

The recruitment of regional referents and professionals of LHUs and Hospitals will be performed through a snowball sampling method starting from the list of members of Interregional Committee for Prevention.

For each RHA/LHU/Hospital confirming willingness to participate, one or more questionnaire compilers (i.e., personnel undergoing interview) should be identified.

Each compiler is responsible for the accuracy of the reported information.

Information sheet and informed consent form about personal data processing will be emailed by the investigators and written consent should be obtained by each compiler before involving him/her in any data collection related to the study. A faxed or scanned copy of the originally signed document is acceptable.

Once a questionnaire compiler has been identified and consented to the processing of his personal data, the investigator will illustrate the objectives of the study and will anticipate the questionnaire that will be the subject of the interview.

No incentive to complete the survey will be offered but responders will be acknowledged in the publications.

6.1.1.4 Interview

The interview will be performed by Investigators specifically trained on the study Protocol and on the snowball methodology. During the interview, data will be collected by the Investigator on the questionnaire or entered directly into the database.

6.1.1.5 Data coding, analysis and Final Report

See section 8.

7 Safety and Product Quality Complaint Reporting and Related Procedures

7.1.1 INVESTIGATOR RESPONSIBILITY:

If adverse events (AEs) or product quality complaints (PQCs) are identified following use of any Sponsor product, then the AE* and/or PQC must be reported according to Table 1. If any health outcomes are described in section 4.1, they must be assessed for AE reportability according to Table 1 (refer to section 4.1 for more information).

*For the purposes of this protocol, the term “AE” collectively refers to the following reportable events (refer to section 7.2 for definitions):

- Serious adverse events (SAEs), including death due to any cause
- Non-serious adverse reactions (NSARs)
- Special situations

AEs, PQCs, and AEs that occur in combination with PQCs, or spontaneously reported events, should all be captured using the AE/PQC report form for each patient and reported according to Table 1.

The investigator must evaluate each SAE for causality and record causality on the report form for each SAE and NSAR reported.

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Patient reported outcomes/questionnaires/surveys which have the potential to collect SAEs following the use of Sponsor product/s will be screened for SAEs, by the investigator or qualified healthcare provider (or designee) and reported according to Table 1.

Table 1: AE and PQC Reporting Timeframes and Process for Investigators

AEs AND PQCs	**INVESTIGATOR TIMEFRAMES** **Investigator to Sponsor [1]**
SAE regardless of causality Serious Special Situation, regardless of causality	24 hours from receipt
NSAR Non-serious Special Situation, regardless of causality	10 CD from receipt
PQC with or without an AE (SAE/NSAR/Special situation)	24 hours from receipt
Follow-up to any AE-submit using above timeframes	
BD-Business Day; CD-Calendar Day	
Non-Sponsor Products: If the investigator elects to submit AEs/PQCs for **non-Sponsor products**, they should be reported to the market authorization holder (MAH) for that product or to the health authority according to the institution's policy or local laws and regulations.	
[1] Investigator to Sponsor: AEs and PQCs for Sponsor products are submitted to Sponsor for reporting to worldwide regulatory agencies as appropriate	
Submitting AEs and PQCs to Local Designated Point of Contact (DPOC): All AEs and PQCs must be submitted to Local DPOC Mailbox FAX *+39 06 36380 985* in English using the AE/PQC reporting form.	

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7.2 DEFINITIONS

7.2.1 Adverse Event (AE)

Any untoward medical occurrence in a patient or clinical investigation subject administered sponsor's product and which does not necessarily have to have a causal relationship with this product. An adverse event can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding, for example), symptom, or disease temporally associated with the use of the product, whether or not considered related to the product. Any worsening (i.e., any clinically significant adverse change in frequency and/or intensity) of a preexisting condition that is temporally associated with the use of the product, is also an adverse event.

7.2.2 Adverse Reaction (AR); also referred to as Adverse Drug Reaction (ADR)

An AE which has a causal relationship with the product, that is, a causal relationship between the product and the adverse event is at least a reasonable possibility.

7.2.3 Serious Adverse Event (SAE)/Serious Adverse Reaction (SAR)

An adverse event or adverse reaction that results in death, is life threatening, results in persistent or significant disability/incapacity, requires inpatient hospitalization, prolongation of existing inpatient hospitalization, is a congenital anomaly/birth defect, or is another important medical event. Other important medical events that may not result in death, may not be life-threatening, or may not require hospitalization may be considered an SAE/SAR when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the other outcomes listed previously. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home and blood dyscrasias or convulsions that do not result in inpatient hospitalization.

7.2.4 Non-serious Adverse Reaction (NSAR)

An adverse reaction that does not meet any of the serious criteria in 7.2.3.

7.2.5 Special Situations

The following special situations are considered important safety information and must be reported, regardless of seriousness or causality, if the investigator becomes aware of them:

- Overdose
- Exposure to product during pregnancy or lactation
- Lack of therapeutic effect
- Off-label use, medication error, misuse, abuse, or occupational exposure
- Suspected transmission via a medicinal product of an infectious agent
- Unexpected Therapeutic Benefit/Effect

7.2.6 Product Quality Complaint (PQC)

Any communication that describes a potential defect related to the identity, strength, quality, purity or performance of a product identified by an external customer. This includes potential device or device component malfunctions.

7.2.7 Malfunction

The failure of a device (including the device component of a combination product) to meet its performance specifications or otherwise perform as intended. Performance specifications include all claims made in the labeling for the device.

7.2.8 Sponsor's product

Sponsor’s product includes any pharmaceutical product, biological product, device, diagnostic agent or protocol-specified procedure, whether investigational (including placebo or active

comparator product) or marketed, manufactured by, licensed by, provided by or distributed by the Sponsor for human use.

7.2.9 Causality Assessment

A causality assessment is the determination of whether or not there is at least a reasonable possibility that a product caused the adverse event. Causality must be recorded on the AE form by the investigator for each reported event in relationship to a Sponsor's product.

Primary Data Collection

The assessment of causality is to be determined by an investigator who is a qualified healthcare professional according to his/her best clinical judgment. Use the following criteria as guidance (not all criteria must be present to be indicative of causality to a Sponsor's product): There is evidence of exposure to the Sponsor's product; the temporal sequence of the AE onset relative to the administration of the Sponsor's product is reasonable; the AE is more likely explained by the Sponsor's product than by another cause.

7.3 AE/PQC Reconciliation

Reconciliation will be performed between the safety database and study data to ensure all reportable AEs and PQCs were reported and received. Starting from when the first patient is enrolled through the end of data collection, all AEs and PQCs will be reconciled on a periodic basis.

8 Statistical Analysis Plan

8.1 Statistical Methods

A final report, including the description of all variables collected, will be prepared approximately within 12 months after study initiation. It will describe the status of pneumococcal age based and risk-group vaccination programs and implementation in the 21 Italian regions and clearly highlight differences among Regions.

The study results will be reported separately for each Region or summarized in aggregate format with descriptive statistics (absolute numbers, percentages, mean and standard deviation).

The "free text" data not coded by the Investigators before the data analysis will be presented in the form of listings.

No missing data imputation will be conducted given the nature of the study. Anyway, the amount of missing data will be assessed.

The statistical analyses will be done using STATA.

8.1.1 Primary Objective(s): Calculation of Epidemiological Measure(s) of Interest (e.g. descriptive statistics, hazard ratios, incidence rates, test/retest reliability)

In order to meet the objectives of the study, in the final report the following results will be presented, separately for each risk-group:

1) the description of pneumococcal vaccination offer, strategies and pathways
2) the information about the implementation of electronic registry/data base for recording the pneumococcal vaccination status of the subjects undergoing the program and its integration with other registries/data bases
3) the description of VCRs

8.1.2 Secondary Objective(s): Calculation of Epidemiological Measure(s) of Interest (e.g. hazard ratios, incidence rates, test/retest reliability)

No secondary objectives.

8.1.3 Exploratory Objective(s): Calculation of Epidemiological Measure(s) of Interest (e.g. hazard ratios, incidence rates, test/retest reliability)

No exploratory objectives.

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8.2 Bias

8.2.1 Methods to Minimize Bias

The survey is addressed to all Italian regions, but it is not guaranteed that all of them will participate. Both the likelihood of participating in the survey and the likelihood of collecting more exhaustive information may be higher among best organized and performing regions; this could be a source of bias.
To minimize potential selection bias of regions involved, many attempts will be done by the Investigators to include al the regions and to identify the most appropriate reference persons for compiling the questionnaire (snowball methodology).

8.2.2 Limitations

Due to the voluntary participation, the representativeness of all Italian Regions is not guaranteed. The regions not participating will be described. Anyway, the documents search will be performed for all regions.

Some missing data are expected for the failure for the investigators to identify the most appropriate reference persons for compiling the questionnaire. The direct interview by trained personnel, along with the snowball methodology, reduce the number of missing and improve the quality of collected data.

Despite this limitation we expect to collect a substantial amount of data for the analysis to be informative. In addition, the description of the amount of the missing data could be itself interesting evidence to describe the real Italian world and the current limitations of the vaccination offer system.

8.3 Sample Size and Power Calculations

Statistical power calculation is not required since this is a descriptive study not involving subjects and hypothesis testing.

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8.4 Data Management

This is a quanti-qualitative survey study conducted with an academic Institution through an interview based on a semi-structure questionnaire to regional referents and professionals of LHUs and Hospitals aimed to investigate strategies and pathways related to immunization practices.

Some data are retrieved directly in official publicly available documents and other data are obtained directly by experts interviewed based on their own experience/knowledge of internal documents not publicly available. All these retrieved data will be entered into an organized study-specific database.
All changes and corrections to the original data will be tracked. The Investigator is responsible for the completeness and accuracy of the data base.
No imputation of missing data will be made.

The “free text” data relevant to each variable will be compared and revised in order to be coded by the Investigator before the data analysis. All data collected for the study should be recorded accurately, promptly, and legibly. The investigator or qualified designee is responsible for recording and verifying the accuracy of data. By signing this protocol, the investigator acknowledges that his/her electronic signature is the legally binding equivalent of a written signature. If this study has been outsourced, the institutional policies of the supplier should be followed for development of data management plans. However, the supplier should ensure compliance with Good Pharmacoepidemiology Practice, and all applicable federal, state, and local laws, rules and regulations relating to the conduct of the study.

The institutional policies of the Investigational site will be followed for development of data management and statistical analysis plans.

The quality checks for data analysis and reporting programming will be limited to the review of outputs/results to ensure accuracy and format of each deliverable. The reviewer will be independent from the performer of the analysis.

Programming Quality

This study will incorporate the following quality checks for data analysis and reporting programming:

- Developing and testing of statistical programs which includes ensuring the programs run successfully and all output are reviewed to ensure they meet the criteria included in the program requirements and specification document (PRS). This includes

validating that all inputs (metadata or parameter values) are correctly specified in the programs and are consistent with the PRS document.

Review of outputs/results to ensure accuracy and format of each deliverable.

9. Administrative and Regulatory Details

9.1 Confidentiality

9.1.1 Confidentiality of Data

By signing this protocol, the investigator affirms to the Sponsor that information furnished to the investigator by the Sponsor will be maintained in confidence. Data generated by this study will be considered confidential by the investigators and the Sponsor, except to the extent that it is included in a publication as provided in the Publications section of this protocol.

9.1.2 Confidentiality of Study Records

By signing this protocol, the investigators agree that the Sponsor (or Sponsor representative), and if applicable Regulatory Agency representatives, may consult and/or copy study documents to verify worksheet/case report form data/questionnaire. By signing this protocol, the investigators agree to treat all study data used and disclosed in connection with this study in accordance with all applicable privacy laws, rules, and regulations.

9.1.3 Confidentiality of Investigator information

By signing this protocol, the investigators recognize that certain personal identifying information with respect to the investigators, and all subinvestigators and study site personnel (if applicable), may be used and disclosed for study management purposes. This information may include:

- name, address, telephone number and e-mail address;
- department address and telephone number;
- curriculum vitae or other summary of qualifications and credentials; and
- other professional documentation.

Consistent with the purposes described above, this information may be transmitted to the Sponsor, and subsidiaries, affiliates and agents of the Sponsor, in your country and other countries, including countries that do not have laws protecting such information. By signing this protocol, the investigator expressly consents to these uses and disclosures.

In order to perform the study, the investigators' name and contact information will be shared with personnel of the RHAs/LHUs/Hospitals involved in the study.

9.1.4 Confidentiality of Questionnaire compiler Information

In the scope of this study certain personal identifying information with respect to the questionnaire compiler of each participating RHAs/LHUs/Hospitals will be used and disclosed for study management purposes. This information includes:

- name
- professional address, telephone number and e-mail address.

Consistent with the study purposes, this information will be transmitted to the Sponsor, and subsidiaries, affiliates and agents of the Sponsor, in your country and other countries, including countries that do not have laws protecting such information.

By signing a Consent for personal data disclosure, in accordance with applicable regulation (General Data Protection Regulation art. 12 and 13 and D. Lgs 196/2003 and subsequent supplements), these professionals expressly consent to the processing of their personal data in connection with this study and in accordance with all applicable privacy laws, rules, and regulations.

9.2 Compliance with Financial Disclosure Requirements

Financial Disclosure requirements are outlined in the US Food and Drug Administration Regulations, Financial Disclosure by Clinical Investigators (21 CFR Part 54). It is the Sponsor's responsibility to determine, based on these regulations, whether a request for Financial Disclosure information is required. It is the investigator's/subinvestigator's responsibility to comply with any such request.

The investigator/subinvestigator(s) agree, if requested by the Sponsor in accordance with 21 CFR Part 54, to provide his/her financial interests in and/or arrangements with the Sponsor to allow for the submission of complete and accurate certification and disclosure statements. The investigator/subinvestigator(s) further agree to provide this information on a Certification/Disclosure Form, commonly known as a financial disclosure form, provided by the

Sponsor or through a secure password-protected electronic portal provided by the Sponsor. The investigator/subinvestigator(s) also consent to the transmission of this information to the Sponsor in the United States for these purposes. This may involve the transmission of information to countries that do not have laws protecting personal data.

9.3 Compliance with Law, Audit and Debarment

By signing this protocol, the investigators agree to conduct the study in an efficient and diligent manner and in conformance with this protocol; generally accepted standards of Good Pharmacoepidemiology Practice (GPP) and all applicable federal, state and local laws, rules and regulations relating to the conduct of the study.

The investigators also agree to allow monitoring, audits, and if applicable regulatory agency inspection of study-related documents and procedures and provide for direct access to all study-related source data and documents.

The Investigators shall prepare and maintain complete and accurate study documentation and, for each investigational subject participating in the study, provide all data, and, upon completion or termination of the study, submit any other reports to the Sponsor as required by this protocol or as otherwise required pursuant to any agreement with the Sponsor.

Study documentation will be promptly and fully disclosed to the Sponsor by the investigators upon request and also shall be made available at the investigators' site upon request for inspection, copying, review and audit at reasonable times by representatives of the Sponsor or any regulatory agencies. The investigators agree to promptly take any reasonable steps that are requested by the Sponsor as a result of an audit to cure deficiencies in the study documentation and worksheets/case report forms/questionnaire.

The investigators must maintain copies of all documentation and records relating to the conduct of the study in accordance with their institution's records retention schedule which is compliant with all applicable regional and national laws and regulatory requirements. If an institution does not have a records retention schedule to manage its records long-term, the investigators must maintain all study- relevant documentation and records relating to the conduct of the study for 5 years after final report or first publication of study results, whichever comes later. Documentation applicable to this type of study may include, in addition to the protocol, worksheets/case report forms/questionnaire, investigational subject source data, investigators' curricula vitae, adverse event reports, correspondence with regulatory authorities. All study documents shall be made available if required by relevant regulatory authorities.

The investigators will promptly inform the Sponsor of any regulatory agency inspection conducted.

Persons debarred from conducting or working on studies by any court or regulatory agency will not be allowed to conduct or work on this Sponsor's studies. The investigators will immediately disclose in writing to the Sponsor if any person who is involved in conducting the study is debarred or if any proceeding for debarment is pending or, to the best of the investigator's knowledge, threatened.

According to European legislation, a Sponsor must designate an overall coordinating investigator for a multi-center study (including multinational). When more than one study site is open in an EU country, the Sponsor will designate, per country, a national principal coordinator (Protocol CI), responsible for coordinating the work of the principal investigators at the different sites in that Member State, according to national regulations. For a single-center study, the Protocol CI is the principal investigator. In addition, the Sponsor must designate a principal or coordinating investigator to review the study report that summarizes the study results and confirm that, to the best of his/her knowledge, the report accurately describes the conduct and results of the study in the study's final report. The Sponsor may consider one or more factors in the selection of the individual to serve as the Protocol CI and or study report CI (e.g., availability of the CI during the anticipated review process, thorough understanding of study methods, appropriate enrollment of subject cohort, timely achievement of study milestones). The Protocol CI must be a participating study investigator.

9.4 Quality Management System

By signing this protocol, all parties agree to following applicable standard operating procedures (SOPs). All parties also agree to ensuring all existing and new study personnel are appropriately trained to ensure the study is conducted and data are generated, documented, and reported in compliance with the protocol and all applicable federal, state, and local laws, rules and regulations. All parties should maintain transparency and open communication in order to effectively manage the study and proactively mitigate any risks.

The Sponsor may conduct routine or for-cause audits to ensure oversight and conduct of the study are completed in accordance with the protocol, quality standards, and applicable laws and regulations. If a significant quality issue (SQI) is identified at any time during the conduct of the study, it must be escalated to the Sponsor immediately. A SQI is any issue with the potential to negatively impact, either directly or indirectly, the rights, safety and well-being of study participants and/or the integrity of the data. In the event an audit or SQI results in corrective or

preventive actions, all parties are expected to appropriately implement the action plan in a timely manner.

10 Publications

After the study completion, a final report summarizing the study results will be prepared by the Investigators and approved by the Sponsor. It will be the basis for all publications and presentations of the study results.

In the scope of scientific exchange, the study results will be published on an international journal.

Moreover, they will be presented to Country Key Decision Makers/Scientific Leaders/Regional Vaccines Committees and National Health Authorities/National Immunization Technical Advisory Group to support the strengthening of vaccination programs.

Any publication related to the study will need to be reviewed/approved by the Sponsor prior to submitting results externally.

Authorship will follow guidelines established by the International Committee of Medical Journal Editors (http://www.icmje.org/).

11. References

1. Miwako Kobayashi et al., 2022. Use of 15-Valent Pneumococcal Conjugate Vaccine and 20-Valent Pneumococcal Conjugate Vaccine Among U.S. Adults: Updated Recommendations of the Advisory Committee on Immunization Practices — United States, 2022. https://www.cdc.gov/mmwr/volumes/71/wr/mm7104a1.htm

2. European Medicine Agency, 2022. Apexxnar pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed). https://www.ema.europa.eu/en/medicines/human/EPAR/apexxnar#authorisation-details-section

3. European Medicine Agency, 2022. Vaxneuvance pneumococcal polysaccharide conjugate vaccine (adsorbed) https://www.ema.europa.eu/en/medicines/human/EPAR/vaxneuvance

4. Agenzia Italiana del Farmaco, 2022. CLASSIFICAZIONE DI MEDICINALI PER USO UMANO AI SENSI DELL'ART. 12 COMMA 5 DEL DECRETO-LEGGE 13 SETTEMBRE 2012 N. 158 CONVERTITO NELLA LEGGE 8 NOVEMBRE 2012 N. 189. https://www.aifa.gov.it/documents/20142/1661124/DETERMINA_22-2022_VAXNEUVANCE.pdf

5. Michele Sabatucci et al., 2021. Improved Temporal Trends of Vaccination Coverage Rates in Childhood after the Mandatory Vaccination Act, Italy 2014–2019. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8230222/

Product: V114	Protocol/Amendment Version No.: 1
RevOps ID NO: NIS103239	CORE DRC Approval Date:22-JUN-2023

12 SIGNATURES

12.1 Investigator

I agree to conduct this study in accordance with the design outlined in this protocol and to abide by all provisions of this protocol (including other project plans and documents referenced from this protocol); changes from the protocol are acceptable only with a mutually agreed upon protocol amendment. I also agree to report all information or data in accordance with the protocol. I understand that information that identifies me will be used and disclosed as described in the protocol and the Use and Disclosure of Personal Data notice provided to me, and that such information may be transferred to countries that do not have laws protecting such information. Since the information in this protocol is confidential, I understand that its disclosure to any third parties, other than those involved in approval, supervision, or conduct of the study is prohibited. I will ensure that the necessary precautions are taken to protect such information from loss, inadvertent disclosure, or access by third parties.

PRINTED NAME	
TITLE	
SIGNATURE	
DATE SIGNED	

PRINTED NAME	
TITLE	
SIGNATURE	
DATE SIGNED	

12.2 Supplier

Product: V114	Protocol/Amendment Version No.: 1
RevOps ID NO: NIS103239	CORE DRC Approval Date:22-JUN-2023

I agree to conduct this study in accordance with the design outlined in this protocol and to abide by all provisions of this protocol (including other manuals and documents referenced from this protocol); changes from the protocol are acceptable only with a mutually agreed upon protocol amendment. I agree to conduct the study in accordance with generally accepted standards of Good Pharmacoepidemiology Practice. I also agree to report all information or data in accordance with the protocol and, in particular, I agree to report any adverse events and product quality complaints as defined in the Safety and Product Quality Complaint Reporting and Related Procedures section. I understand that information that identifies me will be used and disclosed as described in the protocol and in order to perform any agreement between myself and the Sponsor, and that such information may be transferred to countries that do not have laws protecting such information. Since the information in this protocol is confidential, I understand that its disclosure to any third parties, other than those involved in approval, supervision, or conduct of the study is prohibited. I will ensure that the necessary precautions are taken to protect such information from loss, inadvertent disclosure, or access by third parties.

PRINTED NAME	
TITLE	
SIGNATURE	
DATE SIGNED	

MSD

General Guidance for completing Adverse Event and Product Quality Complaint Form

- **Complete all sections** that apply
- **Dates** should be entered as DD-MMM-YYYY. If exact dates are unknown, provide the best estimate. Partial dates are acceptable.
- **Date Received**: Earliest date initial and/or follow up adverse event information is received by company employee or person/agent acting on the company's behalf. For Non-Interventional Studies (NIS), where there is both an Investigator and Supplier, this field should be completed by the Supplier if the Supplier is managing AE/PQC reporting from the Investigator to MSD.
- **Patient/Reporter Details**: Name or initials
    - Anonymized: Patient/reporter details need to be withheld for privacy
    - Unknown: Patient/reporter details are not known
- **Age:** Enter patient's age at onset of event and age unit (days, weeks, months, years), e.g. 24 weeks
- **Age Group:** Enter patient's age group at time of event if Date of Birth or Age is not available
    - Foetus (Prior to birth)
    - Neonate (1 day **-** ≤28 days)
    - Infant (>28 days - ≤1 year)
    - Child (>1 year - <12 years)
    - Adolescent (≥12 years - ≤18 years)
    - Adult (≥18 years - <65 years)
    - Elderly (≥65 years)
- **Product:** Trade/brand name(preferred) Generic Name (acceptable)
- **Action Taken:** Dose (decreased, increased, interrupted, or not changed), Withdrawn, Unknown, NA
- **Lot/Batch/Serial #/ Model#/Catalog#/UDI#**: provide all numbers exactly as they appear on the device or device labeling (including spaces, hyphens, etc.) or pharmaceutical product (lot/batch), as applicable.
- **Seriousness:** Adverse event resulted in:
    - **Hospitalization:** prolonged hospital stay, or an emergency room visit results in hospital admission
    - **Life-threatening**: Substantial risk of dying or continued product use may have resulted in death
    - **Death:** Death (include the date, cause of death, if known)
    - **Disability:** significant, persistent or permanent impairment or diminished quality of life
    - **Medically Significant**: could have jeopardized the patient or required medical or surgical intervention (treatment) to prevent serious outcome
    - **Congenital Anomaly/Birth Defects:** Outcome in a child from exposure to a medical product prior to conception or during pregnancy
    - **Required Intervention related to a device or device component:** Medical or surgical intervention was necessary to preclude permanent impairment of a body function or permanent damage to a body structure (provide details in the narrative)
- **Was the Adverse Event related to the product?** For multiple events, detail in narrative
- **Narrative:** Summary of all relevant medical information (clinical course, treatment) office visit notes, hospital discharge summary (if applicable)

MSD

Adverse Event and Product Quality Complaint Form

Case Details

Date Received	Country of Incidence	Program/Study ID#	Program/Study Name
		NIS103239	RISO Study

Sender Details (Business Partner (BP), Investigator, Vendor, Supplier)

Name/Initials: Email Address:	BP/Vendor ID#

Patient Details (complete in accordance with local privacy laws)

Name/Initials: Address:			Patient/Subject ID#
Anonymized ☐ Unknown ☐	DOB:	Age:	Age Group:
Sex: Male ☐ Female ☐ Unknown ☐	Pregnant: Yes ☐ No ☐ NA ☐	If yes, date of last menstrual period?	

Reporter Details (complete in accordance with local privacy laws)

Name/Initials:		Address:	
Anonymized ☐ Unknown ☐	Phone:	Fax:	Email:
Physician ☐ Pharmacist ☐ Other Health Prof ☐ Consumer ☐ Lawyer ☐		Is the Reporter/HCP willing to be contacted? Yes ☐ No ☐ Unknown ☐	

Product(s) Details

Product Name **Suspect (S) Concomitant (C)**	**Formulation** **Dose/Frequency**	**Indication**	**Start Date** **DD/MMM/YYYY**	**Stop Date** **DD/MMM/YYYY**	**Action Taken**	**Lot/Batch/Serial #/** **Model#/Catalog#/UDI#**

Adverse Event/Product Quality Complaints

Event	**Onset Date**	**Outcome**
		Fatal ☐ Not recovered ☐ Recovered ☐ Recovering ☐ Sequelae ☐ Unknown ☐
		Fatal ☐ Not recovered ☐ Recovered ☐ Recovering ☐ Sequelae ☐ Unknown ☐

Was the event considered Serious? Yes ☐ No ☐ Unknown ☐

If yes, select all that apply (see cover page for details): Hospitalization☐ Life Threatening ☐ Death ☐ Disability ☐ Medically Significant ☐ Congenital Anomaly ☐ Required Intervention (Device/Device Component) (provide details in narrative) ☐ Other (provide details in narrative) ☐

Was the Adverse Event(s) related to the product? Yes ☐ No ☐ Unknown ☐	This is a non-interventional study/program with no HCP assessment of seriousness or causality ☐ (for internal use only)
Is this a Product Quality Complaint? Yes ☐ No ☐ Is the product available for return, if requested? ☐ Yes, provide contact details ☐ No, specify reason (if known)	Medical Devices Only:
	Date Implanted / Date Explanted
	Initial Use ☐ Repeated Use ☐ / Operator of Device: HCP ☐ Non-HCP ☐ Other ☐

Description of Adverse Event(s) and/or Product Quality Complaint: *Information not captured in the fields* (*other products taken by the patient, current medical conditions, relevant medical history, laboratory tests etc.)*

If applicable

Form Completed By:	Date Completed (DD-MMM-YYY):	QC check Completed By:	QC Check Date (DD-MMM-YYY):

ALLEGATO 2 (Corrispettivo)	**ATTACHMENT 2** (Consideration)
A titolo di contributo per l'attività di cui all'art. 2 del Contratto, MSD riconoscerà all'UNIVERSITA' un importo complessivo pari ad Euro 65.116,00 (più IVA), corrisposto dietro presentazione di regolari fatture elettroniche, con le seguenti modalità:	By way of contribution for the activity referred to in Article 2 of the Agreement, MSD will grant UNIVERSITY a total amount of 65,116.00 euros (plus VAT), paid upon presentation of regular electronic invoices, as follows:
1°) Euro 19.534,80 (più IVA) alla ricezione della lista definitiva dei destinatari dei questionari prevista entro 2 settimane dalla firma del contratto;	**1°) Euros 19.534,80 (plus VAT) upon the receipt of the final list of questionnaire recipients expected within 2 weeks of signing the contract;**
2°) Euro 13.023,20 (più IVA) alla conferma della raccolta del 50% dei dati previsti;	**2°) Euros 13.023,20 (plus VAT) upon confirmation of collection of 50% of the expected data;**
3°) Euro 13.023,20 (più IVA) alla conclusione della raccolta dati (100%);	**3°) Euros 13.023,20 (plus VAT) upon completion of data collection (100%);**
4°) Euro 19.534,80 (più IVA) alla consegna del Report prevista entro 12 mesi dalla firma del contratto.	**4°) Euros 19.534,80 (plus VAT) upon delivery of the Report expected within 12 months of signing the contract.**