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| |  |  |  |  | | --- | --- | --- | --- | | **NUOVO STUDIO OSSERVAZIONALE FARMACOLOGICO** | | | | | **I campi contrassegnati con \* sono obbligatori**. | | | | | **Identificazione dello studio** | | | | | Codice dello studio\*: |  | | | | Direzionalità\*: | Prospettica | | | | Retrospettiva | | | | Trasversale | | | | Studio condotto presso\*: | Strutture sanitarie pubbliche (o ad esse equiparate) | | | | Strutture sanitarie private | | | | Medici di Medicina Generale e/o Pediatri di Libera Scelta | | | | Medici che svolgono attivita' libero-professionale | | | |  | |

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| |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Dati anagrafici dell'organizzazione** \* | | | | | | Specificare il ruolo dell'organizzazione: | | Promotore | | | | Richiedente | | | | Ragione sociale: | | | | | | Nazione: | | | | | | Indirizzo: | | | | | | Comune: | | | | | | Provincia: | | | | | | Cap: | | | | | | **Dati anagrafici del promotore (se diverso dal richiedente)** \* | | | | | | Ragione sociale: | | | | | | Nazione: | | | | | | Indirizzo: | | | | | | Comune: | | | | | | Provincia: | | | | | | Cap: | | | | | | **Contact point dello studio** \* | | | | | | Nome: | | | | | | Cognome: | | | | | | E-mail: | | | | | | Telefono: | | | | | | Fax: | | | | | | **Fonte del finanziamento dello studio  *(compilare solo nel caso in cui la fonte del finanziamento non coincida con il promotore)*** | | | | | | Se diversa dal promotore, indicare la fonte del finanziamento o del co-finanziamento dello studio o del supporto materiale, ove previsto: | AIFA (bandi per la ricerca indipendente) | | | | | MIUR | | | | | ISS | | | | | CNR | | | | | Fondazione o Ente Benefico | | | | | altro | | | | | Specificare: | | | | |  | |

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| |  |  | | --- | --- | | **Descrizione dello studio** | | | Titolo dello studio\*: |  | | Title of the study\*: |  | | Scopo\*: | |  |  |  | | --- | --- | --- | |  | | | | descrittivo | analitico (eziologico) | misto | | | Disegno\*: | |  |  |  |  | | --- | --- | --- | --- | |  | | | | | trasversale | di coorte | caso controllo | altro | | |  |  | | Obiettivo primario\*: | |  | | --- | |  | | Efficacia nella pratica clinica (effectiveness) | | Sicurezza | | Uso del farmaco | | Appropriatezza | | Farmacoeconomia | | altro | | se altro obiettivo primario specificare: | | | se altro obiettivo primario, specificare |  | | Descrizione obiettivo primario\*: |  | | Primary objectives\*: |  | | Finalità\*: | |  | | --- | |  |   Conoscitiva | | PASS (Post Authorization Safety Study) | | richiesto da EMA | | richiesto da FDA | | altro | | se altra finalità, specificare: | | Protocollo\* **1** : | | | Versione\*: | | | Data \*: (gg/mm/aaaa) | | | Condizione clinica\*: | | | Numero di soggetti previsti, specificare: | | | In Italia\* : | | | in UE\* : | | | nel Mondo\* : | | | Durata prevista dello studio\* : Unità: giorni mesi anni | | | Data prevista di fine studio (mm/aaaa)\*: | | |

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| |  | | --- | | **Terapia farmacologica in studio** \*  *(ripetere per tutti i farmaci previsti o livelli di ATC previsti di livello III o superiore )* | | ATC\* : | | ATC descrizione\* : | | Specialità medicinale : | | Codice AIC : | | Confezione : | | Principio attivo : | | Note : | | **Dichiarazione condizioni di utilizzo del farmaco**  ***(selezionare tutte le condizioni indicate con l’asterisco e la condizione 3. ove applicabile)*** | | |  | | --- | |  |   \* 1. Il farmaco viene prescritto nelle indicazioni d'uso autorizzate all'immissione in commercio in Italia | | \* 2. La prescrizione del farmaco in esame è parte della normale pratica clinica | | 3. La decisione di prescrivere il farmaco al singolo soggetto è del tutto indipendente da quella di includere il soggetto stesso nello studio (ove applicabile, es. per studi di coorte prospettici) | | |  | | --- | |  |   \*4. Le procedure diagnostiche e valutative devono corrispondere alla pratica clinica corrente | |

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| |  |  | | --- | --- | | **Centro coordinatore** \* | | | Struttura clinica partecipante allo studio \*: | | | Comitato etico competente\* : | | | **Coordinatore / Responsabile dello *(persona fisica che ha il compito di coordinare lo studio)*** \* | | | Qualifica: | | | Nome: | | | Cognome: | | | Disciplina: | | | Coordinatore/Responsabile dello studio *(persona fisica che ha il compito di coordinare lo studio)* | | |  |  | |  |  | |

**1** Inviare il file del protocollo, insieme al presente modulo, all’indirizzo di posta elettronica: [info\_rso@aifa.gov.it](mailto:info_rso@aifa.gov.it).

Data:

Firma del Richiedente: