Assessment report Part II – CZECHIA

1) ADMINISTRATIVE INFORMATION

EU CT number	**2022-501587-17-00**
Member State Concerned	Austria, Belgium, Bulgaria, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Italy, Latvia, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden
Title of the study	A Phase 3, Multicenter, Double-blind Maintenance Study to Assess Long term Safety, Tolerability, and Efficacy of Rocatinlimab in Adult and Adolescent Subjects With Moderateto-severe Atopic Dermatitis (AD) (ROCKET ASCEND) **Multicentrická, dvojitě zaslepená klinická studie fáze III s udržovací léčbou k posouzení dlouhodobé bezpečnosti, snášenlivosti a účinnosti rocatinlimabu u dospělých a dospívajících pacientů se středně těžkou až těžkou atopickou dermatitidou (AD) (ROCKET-ASCEND)**
Name of sponsors	Amgen Inc., USA
IMPs (repeat for PR1, PR2…..)	Substance (name/ code): Rocatinlimab (AMG 451) Marketing authorisation status (MA number, MS where authorised etc): Modified in relation to MA:

Has Part I been submitted prior to the submission of Part II?	Yes ☐ No ☒
If Yes	
Is there already a conclusion on part I?	Yes ☐ No ☐
Is the CT already approved in any member state?	Yes ☐ No ☐

2) GENERAL INFORMATION

Is the CT a low-interventional trial?[1]	Yes ☐ No ☒
First in human ☐, Phase I ☐, II ☐, III ☒, IV☐ NA☐	
Is the CT a cluster trial[2]	Yes ☐ No ☒
Is the CT intended to be performed in more than one member states?	Yes ☒ No ☐
Does the CT involve more than one site in the concerned member states?	Yes ☒ No ☐

[1] If yes – other demands for damage compensation, cfr. Art. 76

[2] If yes – other demands for informed consent, cfr. Art. 30

Does the CT include healthy volunteers?	Yes ☐ No ☒
Does the CT include female?	Yes ☒ No ☐
Male?	Yes ☒ No ☐
Age group	
Adults (18-64 years)	Yes ☒ No ☐
Elderly (>= 65 years)	Yes ☒ No ☐
< 18 years	
In Utero	Yes ☐ No ☒
Preterm Newborn Infants (up to gestational age < 37 weeks)	Yes ☐ No ☒
Newborns (0-27 days)	Yes ☐ No ☒
Infants and toddlers (28 days - 23 months)	Yes ☐ No ☒
Children (2-11 years)	Yes ☐ No ☒
Adolescents (12-17 years)	Yes ☐ No ☒
Does the CT include vulnerable persons?	Yes ☐ No ☒
If yes	
Minors	Yes ☐ No ☐
Incapacitated subjects	Yes ☐ No ☐
Pregnant women	Yes ☐ No ☐
Breastfeeding women	Yes ☐ No ☐
Subjects in emergency situations	Yes ☐ No ☐
Other groups If yes specify:	Yes ☐ No ☐
Are there study-specific procedures and/or interventions beyond the drug application?	Yes ☒ No ☐
If yes	
Specify: blood and urine samples, ECG	

3) INFORMED CONSENT FORM
(Repeat for ICF1, ICR2 ….)

Date/version of Informed Consent Form	**Hlavní souhlas, CZ v.1.0, 13. března 2023** / Globální v.1, 22. února 2023

Does the Informed Consent Form contain the correct title of the CT?	Yes ☒ No ☐
Does the Informed Consent Form contain placeholder for the dated signature of the person performing the interview?	Yes ☒ No ☐
Does this placeholder indicate the qualification of the person performing the interview	Yes ☒ No ☐
Does the Informed Consent Form contain a placeholder for for the dated signature of the subject for the dated signature of legally designated representative?	 Yes ☒ No ☐ NA ☐ Yes ☐ No ☐ NA ☒
Does the subject or the legally designated representative confirm whether a copy of the Informed Consent Form (or the record) has been retained?	Yes ☒ No ☐ NA ☐
Does the subject or the legally designated representative declare that the information is understood?	Yes ☒ No ☐
Additional items may be added according to national requirements For example Does the subject or the legally designated representative confirm whether a copy of the Informed Consent Form (or the record) has been retained?	 Yes ☒ No ☐

Conclusion

If all points are addressed Yes): The Inform Consent Form fulfils the conditions in art. 29, 1.

If not

Questions/queries:

Additional ICFs:

- Souhlas s budoucím výzkumem, CZ v.1.0 z 13. března 2023
- Souhlas s úhradou plateb prostřednictvím Greenphire, CZ v.1.0 z 13. března 2023
- Souhlas s volitelnou podstudií s pořizováním fotografií, CZ v.1.0 z 13. března 2023

Updated versions:

- Hlavní souhlas, CZ v.2.0, 8. září 2023
- Souhlas s budoucím výzkumem, CZ v.2.0 z 8. září 2023
- Souhlas s úhradou plateb prostřednictvím Greenphire, CZ v.2.0 z 8. září 2023
- Souhlas s volitelnou podstudií s pořizováním fotografií, CZ v.2.0 z 8. září 2023

4) WRITTEN INFORMATION

Is the Information sheet sufficiently comprehensive, concise, clear, relevant, and understandable to a layperson?	Yes ☒ No ☐

Does the information sheet describe adequately nature, objectives, benefits, implications, risks, and inconveniences, of the clinical trial?	Yes ☒ No ☐
Does the information sheet adequately describe the subject's rights and guarantees regarding his or her protection, in particular his or her right to refuse to participate and the right to withdraw from the clinical trial at any time without any resulting detriment and without having to provide any justification?	Yes ☒ No ☐
Does the information sheet adequately explain that withdrawal of the informed consent will not affect the results of activities already carried out and the use of data obtained, based on informed consent, before its withdrawal?	Yes ☒ No ☐
Does the information sheet adequately describe the conditions under which the clinical trial is to be conducted, including the expected duration of the subject's participation in the clinical trial?	Yes ☒ No ☐
Does the information sheet adequately describe	
the possible treatment alternatives,	Yes ☒ No ☐
the follow-up measures if the participation of the subject in the clinical trial is discontinued	Yes ☒ No ☐
Post trial treatment options	Yes ☐ No ☐ NA ☒
Does the information sheet provide information about the damage compensation according to national law of concerned member state	Yes ☒ No ☐ NA ☐
Further detailed points to be filled in at a national level –	
If NA	
Does the information sheet adequately inform that no particular arrangements for damage compensation are in place	Yes ☐ No ☐
Does the information sheet provide	
the EU trial number	Yes ☒ No ☐
information about the availability of the clinical trial results (that the summary of the results of the clinical trial and a summary presented in terms understandable to a layperson will be made available in the EU database)	Yes ☒ No ☐
Does the information sheet provide adequate information about planned personal data collection and processing	Yes ☒ No ☐

Does the information sheet provide adequate information about planned collection, storage and future use of biological samples?	Yes ☒ No ☐	
Further detailed points must filled in by member states at national level (in accordance with Regulation (EC) No 45/2001 and **national data protection legislation** implementing Regulation (EU) 2016/679, respectively)	Yes ☒ No ☐	

In the case of a trial with minors. Is there Informed Consent documents adequately paying attentions to the information needs of these subjects?	Yes ☐ No ☐	NA ☒
In the case of a trial with incapacitated subjects. Is there Informed Consent documents adequately paying attentions to the information needs of these subjects?	Yes ☐ No ☐	NA ☒
In the case of a trial in an emergency situation Are there Informed Consent documents to obtain consent from the subject and/or legally designated representative to continue the participation of the subject in the CT after the intervention?	Yes ☐ No ☐	NA ☒

Conclusion

If all points are addressed Yes: The written information fulfils the conditions in art. 28 and 29

If not

Questions/queries:

5) PROTECTION OF PERSONAL DATA

Has a statement been submitted by the sponsor or his or her representative that data will be collected and processed in compliance with Regulation (EC) No 45/2001 and **national data protection legislation** implementing Regulation (EU) 2016/679, respectively –	Yes ☒ No ☐
Further detailed points must filled in by member states at national level For example	
Are the rules for the collection, storage and future use of biological samples of the subject fulfilled?	Yes ☒ No ☐
Is the procedure to pseudonymise the data correct?	Yes ☒ No ☐
Are Initials omitted?	Yes ☒ No ☐
Is there no placeholder for the complete birthday?	Yes ☒ No ☐
Will the coding number maintained in the hand of the investigator or of a trustee?	Yes ☒ No ☐
Is described how long the data will be stored?	Yes ☒ No ☐

Is there a comprehensive description of the aims and scope of data collection?	Yes ☒ No ☐
Is there an indication, whether the data will be transferred to a so called "third party country" with a reduced level of data protection?	Yes ☒ No ☐
Will the subject (or his or her legally designated representative) be asked to consent to the use of his or her data and/or biological samples outside the protocol of the clinical trial for other scientific purposes?	Yes ☐ No ☐ NA ☒
If Yes Will the subject be informed that this consent may be withdrawn at any time by the subject or his or her legally designated representative?	Yes ☐ No ☐ NA ☒

Questions/queries:

6) COMPENSATION

Is there no undue influence, including that of a financial nature, exerted on subjects to participate in the clinical trial	Yes ☒ No ☐
In trials with incapacitated subjects, minors, pregnant or breastfeeding subjects:	
Are no incentives or financial inducements given to the subjects or their legally designated representatives, except for compensation for expenses and loss of earnings directly related to the participation in the clinical trial;	Yes ☒ No ☐

Questions/queries:

7) RECRUITMENT

Is the procedure for inclusion of subjects described in detail in the protocol or a separate document	Yes ☐ No ☐ NA ☒
Is clearly described of what the first act of recruitment is?	Yes ☐ No ☐ NA ☒
Is the recruitment of subjects planned to be done through advertisement	
If yes: Have copies of the advertising material been submitted, including any printed materials, and audio or visual recordings.	Yes ☐ No ☐
Has an outline of the procedures proposed for handling responses to the advertisement been submitted?	Yes ☐ No ☐
Have copies of communications used to invite subjects to participate in the clinical trial been submitted?	Yes ☐ No ☐

Have arrangements for information or advice to the respondents found not to be suitable for inclusion in the clinical trial been described?	Yes ☐ No ☐
Does the person performing the interview has the required qualification according to the law of concerned member states	Yes ☒ No ☐
Are the arrangements for recruitment of subjects adequate?	Yes ☒ No ☐

Questions/queries:

8) SUITABILITY OF THE INVESTIGATOR

MUDr. Marie Selerová Ph.D. (Nemocnice AGEL Nový Jičín)
prof. MUDr. Petra Cetkovská Ph.D. (IFAAD Fakultní nemocnice Plzeň)
MUDr. Yvetta Vantuchová Ph.D. (Fakultní nemocnice Ostrava)
MUDr. Alena Fialová (Kožní ambulance Fialová, s.r.o., Praha)
MUDr. Petr Třeštík (Dermatologická ambulance MUDr. Petr Třeštík, Svitavy)
MUDr. Lucie Petrů (Kožní ambulance Kutná Hora s.r.o., Kutná Hora)
MUDr. Jaroslava Vaněčková (CCR Czech a.s., Pardubice)
prof. MUDr. Jana Třešňák Hercogová Ph.D. (Dermatologie s.r.o., Praha)
MUDr. Romana Macháčková (Dermamedica s.r.o., Náchod)
doc. MUDr. Filip Rob Ph.D. (Fakultní nemocnice Bulovka, Praha)
MUDr. Otakar Komárek (Clintrial s.r.o., Praha)
MUDr. Sylva Zajícová (CCR Ostrava s.r.o, Ostrava)
MUDr. Martina Machková (CCR Prague s.r.o, Praha)
MUDr. Alena Machovcová Ph.D. (Fakultní nemocnice Motol, Praha)
MUDr. Olga Filipovská (Krajská zdravotní – Masarykova nemocnice, Ústí nad Labem)
prof. MUDr. Hana Jedličková Ph.D. (Fakultní nemocnice u sv. Anny, Brno)
MUDr., Bc. Lucie Jarešová (L DermaMedEst s.r.o., Praha)
MUDr. Andrea Vocilková (Praglandia s.r.o., Praha)
MUDr. Naděžda Fišerová (CCR Brno s.r.o.)

Is there an informative CV?	Yes ☒ No ☐
Is previous experience obtained from work with clinical trials described?	Yes ☒ No ☐
Is previous experience obtained from work with patient care described?	Yes ☒ No ☐
Have certificates describing adequate ICH/GPV training been submitted?	Yes ☒ No ☐
Has a financial disclosure been submitted?	Yes ☐ No ☐ NA ☒
Have institutional affiliations, that might influence the impartiality of the investigators been presented?	Yes ☒ No ☐

Further detailed points may be filled in by member states at national level For example Yes ☒ No ☐ Is the investigator qualified in accordance with national Low? *(medical doctor as defined in national law, or a person following a profession which is recognised in the Member State concerned)*

Conclusion – all PIs are approved (list above)

Reason:

9) SUITABILITY OF THE FACILITIES

Has a list of the planned clinical trial sites with name and position of the principal investigators been submitted? Yes ☒ No ☐

and the planned number of subjects at the sites been submitted? Yes ☒ No ☐

- Nemocnice AGEL Nový Jičín, Purkyňova 2138/16, 741 01 Nový Jičín
- Fakultní nemocnice Plzeň, Edvarda Beneše 1128/13 305 99 Plzeň – Bory
- Fakultní nemocnice Ostrava, 17. listopadu 1790/5 708 52 Ostrava - Poruba
- Kožní ambulance Fialová, s.r.o., Jugoslávských partyzánů 1089/15 160 00 Praha 6
- Dermatologická ambulance MUDr. Petr Třeštík, Hraniční 2118/9 568 02 Svitavy
- Kožní ambulance Kutná Hora s.r.o., Rostovská 314/14 101 00 Praha 10
- CCR Czech a.s., Na hřebenech 1718/8, 140 00 Praha 4
- Dermatologie prof. Hercogové s.r.o., Tychonova 44/3, 160 00 Praha 6
- Fakultní nemocnice Bulovka, Budínova 67/2, 180 81 Praha 8
- Clintrial s.r.o., Počernická 1427/16, 100 00 Praha 10
- CCR Ostrava, s.r.o., 28. října 3348/65, 702 00 Ostrava
- CCR Prague s.r.o., Vinohradská 1597/174, 130 00 Praha
- Fakultní nemocnice v Motole, V Úvalu 84/1, 150 06 Praha 5
- Krajská zdravotní a.s. - Masarykova nemocnice, Ústí nad Labem, Sociální péče 3316/12A, 401 13 Ústí nad Labem
- Fakultní nemocnice u sv. Anny v Brně, Pekařská 664/53, 602 00 Brno
- I. DermaMedEst s.r.o., Karlovo náměstí 313/8, 120 00 Praha 2
- Praglandia s.r.o., Ostrovského 253/3, 150 00 Praha 5 – Smíchov
- CCR Brno s.r.o., Hybešova 258/20, 602 00 Brno

Has a written statement been submitted describing the suitability of the clinical trial sites adapted to the nature and use of the investigational medicinal product?
(issued by the head of the clinic/institution at the clinical trial site or by some other responsible person, according to the system in the Member State concerned) Yes ☒ No ☐

Does this statement adequately describe the suitability of facilities, the equipment, ☐	Yes ☒ No
the human resources	Yes ☒ No ☐
the expertise of the site	Yes ☒ No ☐

Conclusion – all trial sites are approved (list above)

10) PROOF OF INSURANCE COVER OR INDEMNIFICATION

Is the arrangement for damage compensation in accordance to **national law**?	Yes ☒ No ☐
Further detailed points must be filled in at the national level	

Questions/queries:

11) FINANCIAL AND OTHER ARRANGEMENTS

Is there a description confirming adequate financing of the clinical trial is ensured?	Yes ☒ No ☐
Are financial transactions and compensation paid to subjects adequate	Yes ☒ No ☐
Are financial transactions and compensation paid to the investigator/site for participating in the clinical trial adequate?	Yes ☐ No ☐ NA ☒
Are any other agreement between the sponsor and the site adequate?	Yes ☐ No ☐ NA ☒

Questions/queries:

12) LIST OF QUESTIONS TO THE SPONSOR/

13) ASSESMENT OF THE SPONSOR´S RESPONSE

Are all queries resolved?	Yes ☒ No ☐
If not specify:	

14) FINAL DECISION

The Clinical trial is approvable	☒

The Clinical trial is not approvable	☐
The Clinical trial is approvable subjects to conditions	☐

In case of approval

The approval is valid for the following trial sites and investigators

List of trial sites and investigators

1. Nemocnice AGEL Nový Jičín, Purkyňova 2138/16, 741 01 Nový Jičín - MUDr. Marie Selerová Ph.D.
2. Fakultní nemocnice Plzeň, Edvarda Beneše 1128/13, 305 99 Plzeň - prof. MUDr. Petra Cetkovská Ph.D.
3. Fakultní nemocnice Ostrava, 17. listopadu 1790/5, 708 52 Ostrava – Poruba - MUDr. Yvetta Vantuchová Ph.D.
4. Kožní ambulance Fialová, s.r.o. Jugoslávských partyzánů 1089/15, 160 00 Praha 6 - MUDr. Alena Fialová
5. Dermatologická ambulance MUDr. Petr Třeštík, Hraniční 2118/9, 568 02 Svitavy - MUDr. Petr Třeštík
6. Kožní ambulance Kutná Hora s.r.o., Kpt. Vosky 781, 284 01 Kutná Hora - MUDr. Lucie Petrů
7. CCR Czech a.s., Třída Míru 2800, 530 02 Pardubice - MUDr. Jaroslava Vaněčková
8. Dermatologie prof. Hercogové s.r.o., Chlumčanského 497/5, 180 00 Praha 8 - prof. MUDr. Jana Třešňák Hercogová Ph.D.
9. Dermamedica, s.r.o. Komenského 420 547 01 Náchod - MUDr. Romana Macháčková
10. Fakultní nemocnice Bulovka, Dermatovenerologická klinika, Budínova 67/2, 180 81 Praha 8 - doc. MUDr. Filip Rob, Ph.D.
11. Clintrial s.r.o., Počernická 1427/16, 100 00 Praha 10 - MUDr. Otakar Komárek
12. CCR Ostrava, s.r.o. 28. října 3348/65 702 00 Ostrava - MUDr. Sylva Zajícová
13. CCR Prague s.r.o., Vinohradská 1597/174, 130 00 Praha 3 - MUDr. Martina Machková
14. Fakultní nemocnice v Motole, Dermatovenerologické oddělení, V Úvalu 84/1, 150 06 Praha 5 - MUDr. Alena Machovcová, Ph.D.
15. Krajská zdravotní a.s. - Masarykova nemocnice Ústí nad Labem oz, Kožní oddělení, Sociální péče 3316/12A, 401 13 Ústí nad Labem - MUDr. Olga Filipovská
16. Fakultní nemocnice u sv. Anny v Brně, I. Dermatovenerologická klinika, Pekařská 664/53, 602 00 Brno - prof. MUDr. Hana Jedličková Ph.D.
17. L DermaMedEst s.r.o., Karlovo náměstí 313/8, 120 00 Praha 2 - MUDr. Bc. Lucie Jarešová
18. Praglandia s.r.o., Ostrovského 253/3, 150 00 Praha 5 – Smíchov - MUDr. Andrea Vocilková
19. CCR Brno s.r.o., Hybešova 258/20, 602 00 Brno – MUDr. Naděžda Fišerová

List of documents on the basis of which the decision was made:

1. Hlavní souhlas, CZ v.2.0, 8. září 2023
2. Souhlas s budoucím výzkumem, CZ v.2.0 z 8. září 2023
3. Souhlas s úhradou plateb prostřednictvím Greenphire, CZ v.2.0 z 8. září 2023

4. Souhlas s volitelnou podstudií s pořizováním fotografií, CZ v.2.0 z 8. září 2023
5. K1_ Recruitment arrangements_For Publication_version 1_20/02/2023
6. L2_ Other subject information material_ClinCard Fee Schedule_FP_version 1_31/01/2022
7. L2_ Other subject information material_ClinCard EC packet_FP_version 1_29/7/2021
8. L2_ Other subject information material_ClinCard Cardholder Msg Templates_FP_version 1_07/04/2022
9. L2_ Other subject information material_ClinCard Cardholder FAQ_FP_version 1_26/10/2022
10. L2_ Other subject information material_ClinCard Card Carrier_FP_version 1_31/01/2022
11. L2_Other Subject Information Material_Thank you letter_NFP_version 1.0_20/02/2023
12. L2_Other Subject Information Material_Patient card_FP_version 1.0_14/03/2023
13. L2_Other Subject Information Material_GDPR_NFP_version 3.3_7/11/2022
14. N3_List of sites_FP (version 1, 29/05/2023)
15. M1_ CV Investigator Komarek Otakar_Clintrial sro_NFP (12/10/2022)
16. M1_ CV Investigator Machackova Romana_Dermamedica sro_NFP (12/10/2022)
17. M1_ CV Investigator Rob Filip_FN Bulovka_NFP (12/10/2022)
18. M1_ CV Investigator Tresnak Hercogova_Dermatologie prof Hercogove sro_NFP (1/11/2022)
19. M1_ CV Investigator Vaneckova Jaroslava_CCR Czech as_NFP (25/10/2022)
20. M1_CV Investigator Filipovska Olga_Krajska zdravotni as_NFP (11/10/2022)
21. M1_CV Investigator Jaresova Lucie_L DermaMedEst sro_NFP (14/03/203)
22. M1_CV Investigator Jedlickova Hana_FN u Sv Anny v Brne_NFP (20/10/2022)
23. M1_CV Investigator Machkova Martina_CCR Prague sro_NFP (24/10/2022)
24. M1_CV Investigator Machovcova Alena_FN v Motole_NFP (18/10/2022)
25. M1_CV Investigator Vocilkova Andrea_Praglandia sro_NFP (18/10/2022)
26. M1_CV Investigator Zajicova Sylva_CCR Ostrava sro_NFP (11/10/2022)
27. M1_CV Investigator_Cetkovska Petra_FN Plzen_NFP (18/10/2022)
28. M1_CV Investigator_Fialova Alena_Kozni ambulance Fialova_NFP (7/10/2022)
29. M1_CV Investigator_Petru Lucie_Kozni ambulance Kutna Hora_NFP (3/11/2022)
30. M1_CV Investigator_Selerova Marie_Nemocnice AGEL Novy Jicin_NFP (19/10/2022)
31. M1_CV Investigator_Trestik Petr_Dermatologicka ambulance Trestik_NFP (15/11/2022)
32. M1_CV Investigator_Vantuchova Yvetta_FN Ostrava_NFP (18/10/2022)
33. M1_ CV Investigator Fiserova Nadezda_CCR Brno sro_NFP (04/04/2023)
34. M3_GCP certificate Investigator_Alena Fialova_FP (10/10/2022)
35. M3_GCP certificate Investigator_Petr Trestik_FP (05/12/2022)
36. M3_GCP certificate Investigator_Olga Filipovska_FP (07/12/2020)
37. M2_ DoI Investigator Hercogova_Dermatologie prof Hercogove sro_NFP (30/03/2023)
38. M2_ DoI Investigator Komarek_Clintrial sro_NFP (22/02/2023)
39. M2_ DoI Investigator Machackova_Dermamedica sro_NFP (21/02/2023)
40. M2_ DoI Investigator Rob_FN Bulovka_NFP (21/02/2023)
41. M2_ DoI Investigator Vaneckova_CCR Czech as_NFP (14/03/2023)
42. M2_DoI Investigator Vocilkova Andrea_Praglandia sro_NFP (21/02/2023)
43. M2_DoI Investigator_Cetkovska Petra_FN Plzen_NFP (21/02/2023)

44. M2_DoI Investigator_Fialova Alena_Kozni ambulance Fialova_NFP (02/03/2023)
45. M2_DoI Investigator_Filipovska Olga_Krajska zdravotni as_NFP (20/02/2023)
46. M2_DoI Investigator_Jaresova Lucie_L DermaMedEst sro_NFP (14/03/2023)
47. M2_DoI Investigator_Jedlickova Hana_FN u Sv Anny v Brne_NFP (14/03/2023)
48. M2_DoI Investigator_Machkova Martina_CCR Prague sro_NFP (23/02/2023)
49. M2_DoI Investigator_Machovcova Alena_FN v Motole_NFP (20/02/2023)
50. M2_DoI Investigator_Petru Lucie_Kozni ambulance Kutna Hora_NFP (01/03/2023)
51. M2_DoI Investigator_Selerova Marie_Nemocnice AGEL Novy Jicin_NFP (21/02/2023)
52. M2_DoI Investigator_Trestik Petr_Dermatologicka ambulance Trestik_NFP (29/03/2023)
53. M2_DoI Investigator_Vantuchova Yvetta_FN Ostrava_NFP (02/03/2023)
54. M2_DoI Investigator_Zajicova Sylva_CCR Ostrava sro_FP
55. M2_ DoI Investigator Fiserova_CCR Brno sro_NFP (22/05/2023)
56. N2_Decision on the registration of Non-state healthcare facility_CCR Brno sro_NFP (29/07/2022)
57. N1_Site suitability form_CCR Brno sro_NFP (22/05/2023)
58. N2_Decision on the registration of Non-state healthcare facility_Krajska zdravotni as_NFP (24/01/2022)
59. N2_Decision on the registration of Non-state healthcare facility_Agel Novy Jicin_NFP (27/09/2022)
60. N2_Decision on the registration of Non-state healthcare facility_CCR Czech as_NFP (14/09/2022)
61. N2_Decision on the registration of Non-state healthcare facility_Clintrial sro_NFP (01/02/2021)
62. N2_Decision on the registration of Non-state healthcare facility_Dermamedica sro_NFP (10/12/2021)
63. N2_Decision on the registration of Non-state healthcare facility_Dermatologie Prof Hercogove sro_NFP (09/04/2021)
64. N1_Site suitability form_Nemocnice Agel Novy Jicin_NFP (21/02/2023)
65. N1_Site suitability form_Kozni ambulance Fialova_NFP (02/03/2023)
66. N1_Site suitability form_FN Plzen_NFP (21/02/2023)
67. N1_Site suitability form_FN Ostrava_NFP (02/03/2023)
68. N2_Decision on the registration of Non-state healthcare facility_Kozni ambulance Kutna Hora_NFP (21/10/2020)
69. N1_Site suitability form_Dermatologická ambulance Dr Trestik_NFP (29/03/2023)
70. N1_ Site suitability form_Kozni ambulance Kutna Hora_NFP (01/03/2023)
71. N2_Decision on the registration of Non-state healthcare facility_ Kozni ambulance Fialova_NFP (23/02/2004)
72. N1_Site suitability form_CCR Czech as_NFP (14/03/2023)
73. N1_Site suitability form_Clintrial sro_NFP (22/02/2023)
74. N1_Site suitability form_Dermamedica sro_NFP (21/02/2023)
75. N1_Site suitability form_Dermatologie prof Hercogove sro_NFP (30/03/2023)
76. N1_Site suitability form_FN Bulovka_NFP (21/02/2023)
77. N1_Site suitability form_CCR Ostrava sro_NFP (21/02/2023)

78. N1_Site suitability form_CCR Prague sro_NFP (23/02/2023)
79. N1_Site suitability form_FN u Sv Anny v Brne_NFP (14/03/2023)
80. N1_Site suitability form_FN v Motole_NFP (20/02/2023)
81. N1_Site suitability form_Krajska zdravotni as_NFP (20/02/2023)
82. N1_Site suitability form_L DermaMedEst sro_NFP (23/03/2023)
83. N1_Site suitability form_Praglandia sro_NFP (21/02/2023)
84. N2_Decision on the registration of Non-state healthcare facility_CCR Ostrava sro_NFP (05/04/2019)
85. N2_Decision on the registration of Non-state healthcare facility_CCR Prague sro_NFP (18/03/2019)
86. N2_Decision on the registration of Non-state healthcare facility_L DermaMedEst sro_NFP (04/12/2018)
87. N2_Decision on the registration of Non-state healthcare facility_Praglandia sro_NFP (02/03/2022)
88. N2_Decision on the registration of Non-state healthcare facility_Dermatologicka ambul Dr Trestik_NFP (04/08/1997)
89. O2_ Proof of coverage sponsor or investigator_Amgen sro_NFP (version 1, 27/03/2022)
90. O2_Insurance statement amendment_NFP (version 1, 17/07/2023)
91. P1_Compensation trial participants_Financial coverage (02/11/2022)
92. P1_Compensation trial participants_Contact Details for Invoicing form Part II (21/03/2023)
93. R1_ Compliance on the collection and use of personal data_NFP (version 1.0, 17/02/2023)
94. S1_ Compliance on the collection use and storage of biological samples_NFP (version 1.0, 10/03/2023)
95. D4_Patient facing documents PRO_CZ_2022-501587-17_20210146_NFP_version 1_23/06/2022
96. D4_Patient facing documents Training_CZ_2022-501587-17_20210146_NFP_version 1_13/10/2020

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In Olomouc – 20-09-2023