

Protocol Deviation Log

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|---------------|-------|----------------------------|---|------|
| Site #: | 184 | Site/Institution/Facility: | Medical University of Innsbruck Department of Neurology Anichstraße 35, 6020 Innsbruck, Austria | Page |
| Investigator: | Scpp1 | | | 21 |

| Patient Number | Date (dd mm yyyy) | Deviation Occurred | Action(s) Taken | Impact on Trial | Investigator's Signature |
|----------------|----------------------|--|-----------------|---|-----------------------------|
| 006 | 21 Feb 2018 | Visit outside of expected windows (+1d) (V0) | none | none | SP |
| 184-004 | 08 MAR 2018 | V1 had to be re-scheduled because the patient was unable to come at this visit (+4d) | none | none | SP |
| 012 | 16 APR 2018 | patient had an AE which could be related to CH | CH reduced | none (before don't mind phone) | SP |
| 006 | 19 MAR 2018 | interference of sleeping disorders + medication dropped (RH) | CH changed | none (no PD results, after don't mind phone) | SP |
| 006 | 08 03 2018 MAR | increasing of lung function (AE) | — — — | none (no PD results) | SP |
| 006 | 26 01 2018 JAN | change of CH due to AE (grippe) Infekt + chogen-Infekt | CH changed | none | SP |

Principal Investigator's Signature:

Initials:

Date:

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| Site #: | 154 | Site/Institution/Facility: | Medical University of Innsbruck Department of Neurology Anichstraße 35, 6020 Innsbruck, Austria | Page |
| Investigator: | Sepp | | | 21 |

| Patient Number | Date (dd mm yyyy) | Deviation Occurred | Action(s) Taken | Impact on Trial | Investigator's Signature |
|----------------|----------------------|--|-----------------|-------------------------|-----------------------------|
| 006 | 18 FEB 2018 | change of CR due to operation of the eye | CR changed | None | Sepp |
| 006 | 05 FEB 2018 | — u — | — u — | — u — | Sepp |
| 009 | 13 MAR 2018 | change of CR (Heart, CAG) | CR changed | None (CRD not in CR) | Sepp |
| 154-009 | 11 MAY 2018 | Notre Zylinder von V1 (Sticht 16.5.18) weg Nun 11.5.2018) weg | CR changed | None (CRD nicht in CR) | Sepp |
| 154-009 | 11 May 2018 | CR verändert (begin. Jochschmerz + weitere 4 pt-here) | CR changed | Zeit-dauer reduktion | Sepp |
| 154-010 | 17 May 2018 | CR verändert (mit 100% verdrängt) | CR changed | None | Sepp |

Principal Investigator's Signature:

Initials:

Date:

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| Site #: | 1B4 | Site/Institution/Facility: | Medical University of Innsbruck Department of Neurology Anichstraße 35, 6020 Innsbruck, Austria | Page |
| Investigator: | Prof. Peter Sepp | | | 31 |

| Patient Number | Date (dd mm yyyy) | Deviation Occurred | Action(s) Taken | Impact on Trial | Investigator's Signature |
|----------------|---------------------------------|--|---|--------------------|-----------------------------|
| 015 | 11 May 2018 | CR changed (Merkelen + Reuestand i.v.) bei AE Brustschmerzen (erod.) | NONE | NONE | W |
| 018 | 26 Aug 2018 18.10-20.10-2018 | CR changed: Perthaler 2018 1x bei Refluxkrankheit (erod.) | NONE | NONE | W |
| 151-014 | 24 Oct 2018 | Konvergenz von MA aufgrund von Kollisionsanomalie (z. u. 2018) | keine Anomalie Kollisions | NONE | W |
| 012 | 15 Mar 2018 | einmal 2018 2-0-2 ergriffen verschieden | NONE Credulität am Tag (erod.) | NONE | W |
| 151-014 | 24 Oct 2018 | CR changed: STRET Headgear | NONE | NONE | W |
| 018 | 06 Nov 2018 | Meiste musste verschieben (erod.) da Patient Meiste verschieben beide & dann mit dem auf nicht mehr können dann mit dem auf nicht mehr können (initials: 31 verschieben) | NONE MA am 04.10.2018 stet 2. u. 2018 | NONE | W |

Principal Investigator's Signature:

(initials: 31 verschieben)

Date:

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|---------------|--|--|------|
| Site #: | Site/Institution/Facility: Medical University of Innsbruck Department of Neurology Anichstraße 35, 6020 Innsbruck, Austria | | Page |
| Investigator: | Prof. Sepp | | 4_1_ |

| Patient Number | Date (dd mm yyyy) | Deviation Occurred | Action(s) Taken | Impact on Trial | Investigator's Signature |
|----------------|----------------------|--|-----------------|----------------------------------|-----------------------------|
| 024 | 22 Nov 2018 | CH changed due to arterial hypertension (AC) | CH changed | NO | 14.12.18 |
| 024 | 23 Nov 2018 | CH changed med. Maße - TEO ore → CT zuvor durchgeführt | CH changed | NO (CT zuvor) | 17.12.18 |
| 014 | 28 Nov 2018 | STU kenne das später abgeplant weil es der Pat. nicht gut gefallen ist | STU + 1d | NO | 28.12.18 |
| 030 | 11 Dec 2018 | CH changed (Cholesterinmed. Verlet) | CH changed | NO (keine change in Symptome) | 14.12.18 |
| 043 | 08 May 2019 | (18d nach W-1) Mordanschlag von VO auf 8.5.2019 ↳ versch. der Zeitstrahlers wg Patienten-schweregrad | | | 14.8.5.19 |
| 043 | 08 May 2019 | Bepirn Medikation (Hoxen + Streptolud) | CH changed | NO | 14.8.5.19 |

Principal Investigator's Signature:

Initials:

Date:

| Protocol ID/Number: | | | NMS-Nab Study | | | Site Name/Number: | | IBK | |
|-------------------------------|------------|-------------------|------------------------------|--|---------------|-------------------|--------------------------------|-----------------------------------|--------------------|
| Protocol Title (Abbreviated): | | | Nablon | | | | | | |
| Principal Investigator: | | | Ao.Univ.-Prof.Dr.Klaus Seppi | | | Page number [1]: | | | |
| Ref No. | Subject ID | Date of Deviation | Date Identified | Deviation Description | Dev. Type [2] | Resulted in AE? | Did Subject Continue in Study? | Meets IRB Reporting Req. (Yes/No) | IRB Reporting Date |
| 1 | 042 | 24.12 | | CR changed (Clasmax) due to AE | due to AE | yes | yes | No | |
| 2 | 1041-031 | 21.01.2018 | | CR changed | due to AE | yes | yes | No | |
| 3 | 1041-017 | 7.11.2018 | | SFU 2 down with AE due to clasp | no | no (CFU) | No | No | |
| 4 | 1041-012 | 15.1.2018 | | V1 3 days too late | no | yes | No | No | |
| 5 | 048 | 15.1.2018 | | Time between 10.8.11 and 15.1.2018 too short | no | yes | No | No | |
| 6 | 048 | 3.6.18 | | antibiotic treatment started due to AE | due to AE | yes | yes | | |
| 7 | 034 | 10.4.18 | | Compliance bad (CET 10.4.18) | due to AE | yes | No | No | |

not influence by table

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