sequanamedical

Vernieuwers in de behandeling van

diuretica-resistente vochtoverbelasting

leverziekte – maligne ascites – hartfalen

VFB Dag van de Tips

Lies Vanneste, Director IR – 24 april 2021

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Disclaimers

Regulatory disclaimer:

- The **alfa**pump® system has not yet received regulatory approval in the United States and Canada. Any statement in this presentation about safety and efficacy of the **alfa**pump® system does not apply to the United States and Canada. In the United States and Canada, the **alfa**pump® system is currently under clinical investigation (POSEIDON Study) and is being studied in adult patients with refractory or recurrent ascites due to cirrhosis. For more information regarding the POSEIDON clinical study see www.poseidonstudy.com.
- DSR® therapy is still in development and it should be noted that any statements regarding safety and efficacy arise from ongoing pre-clinical and clinical investigations which have yet to be completed. DSR® therapy is not currently approved for clinical research in the United States or Canada. There is no link between DSR® therapy and ongoing investigations with the **alfa**pump® system in Europe, the United States or Canada.

COVID-19 disclaimer:

- Sequana Medical is closely following the evolution of the COVID-19 global health crisis and is in constant dialogue with its partners to assess the impact and adapt its operations as necessary.
- Sequana Medical has put in place mitigation plans to minimise delays. The impact of increased demands on the healthcare systems, restrictions on non-essential hospital visits and procedures, social-distancing and travel restrictions may result in further delays to execution of clinical studies and impact sales.
- Sequana Medical will continue to update the market as needed and whenever possible.

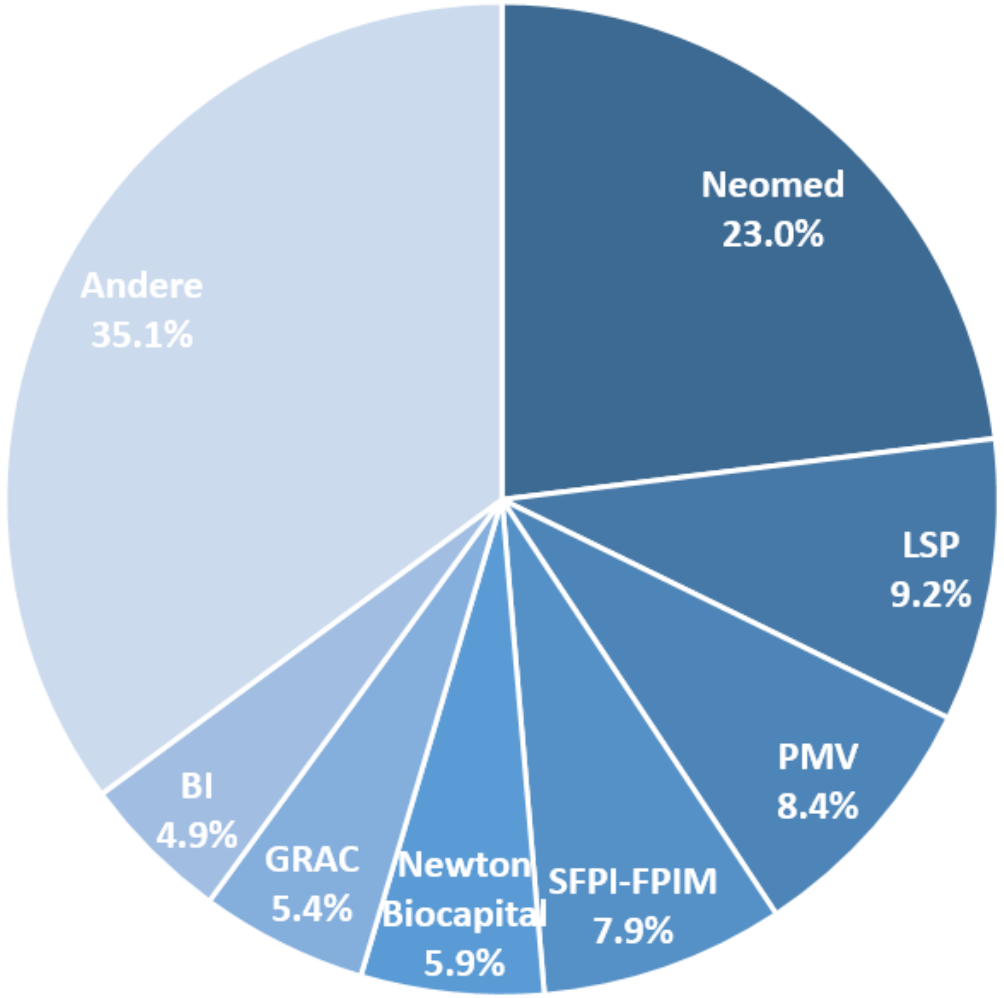
Note:

- **alfa**pump® is a registered trademark. DSR® and **alfa**pump DSR® are registered trademarks in Benelux.

Sequana Medical NV

- Opgericht in 2006
- Hoofdkantoor in Gent, België
- Productie in Zürich, Zwitserland
- ~50 werknemers
- Euronext Brussels: SEQUA

Aandeelhoudersstructuur en financieel overzicht

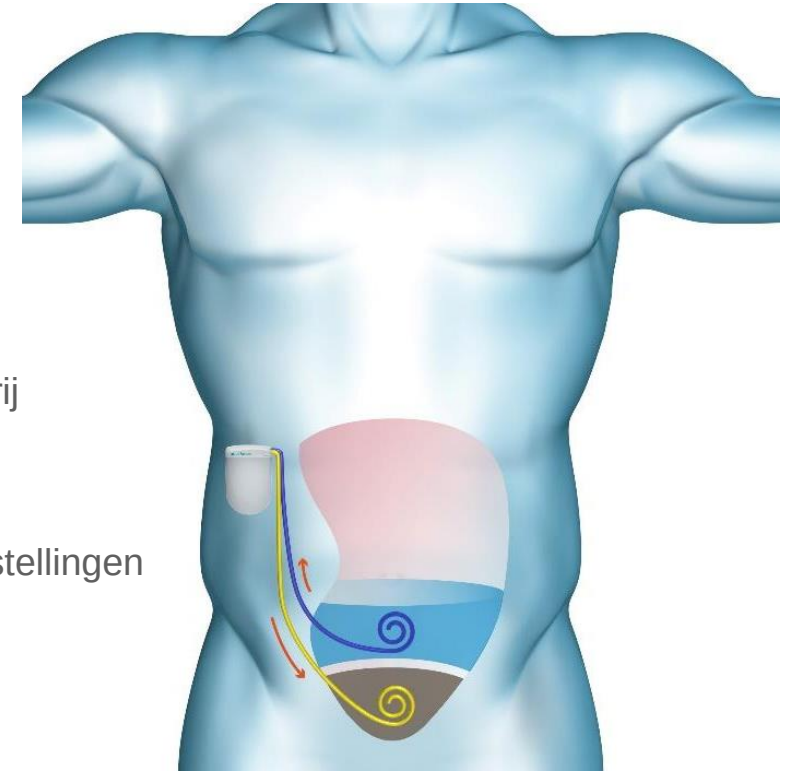


- Marktkapitalisatie: €165 M (~€9 / aandeel)
- Kaspositie (31 December 2020): €11,0 M
- Plaatsing van nieuwe aandelen (februari 2021): €22,5 M
- Cash runway tot in Q2 2022

alfapump® platform

Vochtoverbelasting behandelen via de blaas

- Volledig geïmplanteerd
- Automatische werking
- Draadloos opladen van de batterij
- Draadloos aanpassen van de instellingen
- Data monitoring van op afstand



- Eenvoudige implantatie
- Langetermijn implantatie & katheter doorgankelijkheid
- Verwijdert tot 4 liter vocht / dag
- Vrijwel geen verstoppingen
- Geen significante opwarming tijdens opladen en werking

Sterke IP door uitgebreide octrooiportfolio & knowhow

Twee belangrijke groeipijlers in grote afzetmarkten

alfapump®

Leverziekte (NASH)

CE markering / FDA Breakthrough Device

> 850 systemen geïmplanteerd

> €3 miljard / jaar marktopportuniteit(1)

POSEIDON pivotale studie in N-Amerika lopende

Eigen commercialisatieteam

alfapump DSR®

Hartfalen

Klinische proof-of-concept van
Direct Sodium Removal (DSR®)

> €5 miljard / jaar marktopportuniteit(2)

RED DESERT studie met herhaalde dosering lopende

Partnerschap na werkzaamheidsstudie in de VS

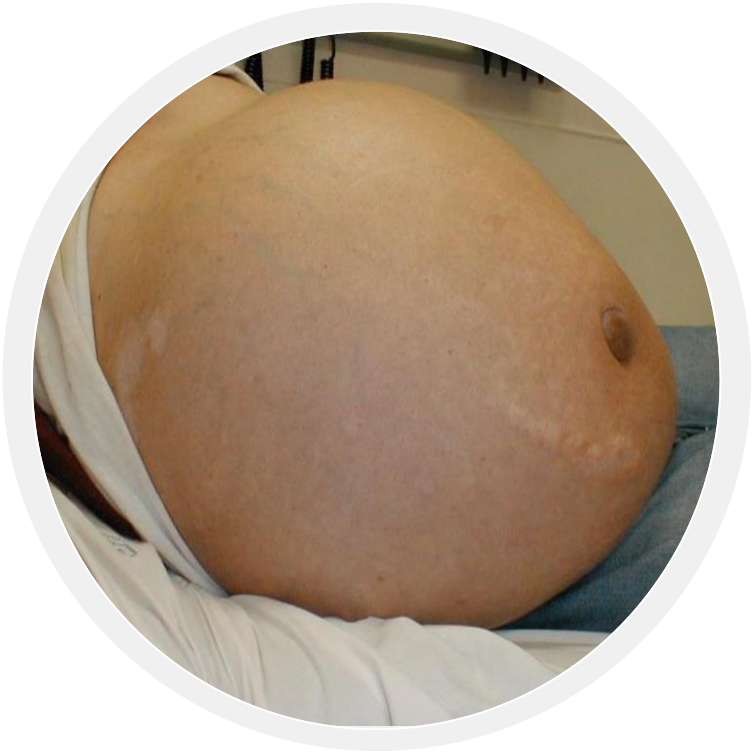
Gebouwd op bewezen Europese klinische & commerciële ervaring

Bron 1: Management inschatting voor de VS binnen 10-20 jaar, inclusief de geschatte groei in prevalentie voor NASH in de VS, gebaseerd op GlobalData Epidemiology Forecast to 2026
Bron 2: Management inschatting voor de VS & EU tegen 2026 gebaseerd op GlobalData Heart Failure Epidemiology Forecast to 2026; Costanzo et al. (2007). Kiglore et al (2017)

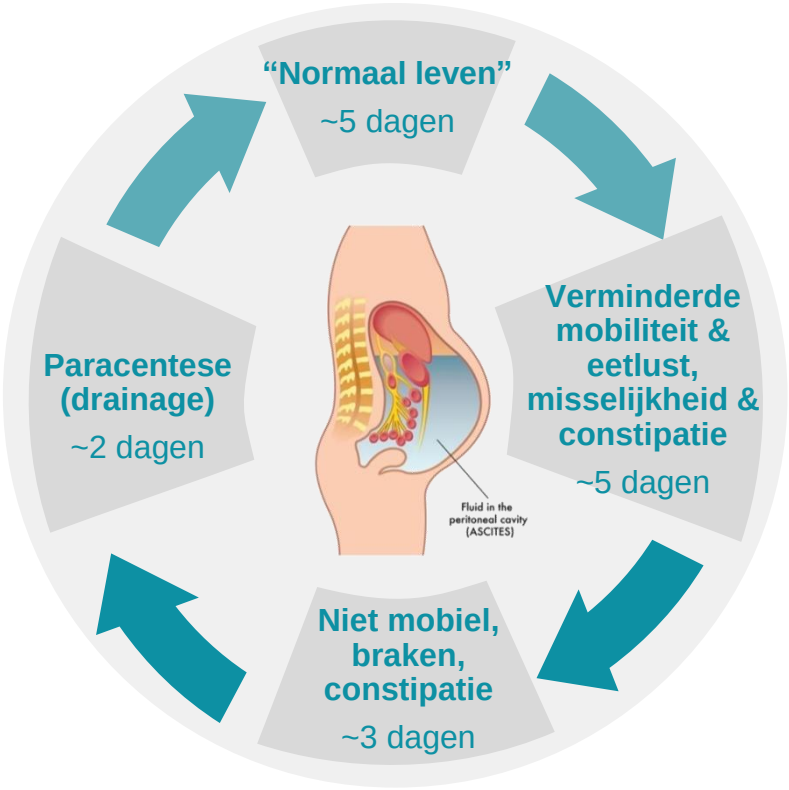
Levercirrose en refractaire ascites

Dramatische impact op de levenskwaliteit

- **Virale infecties** (Hepatitis B & C)
- **Alcoholische Leverziekte**
- **Niet-Alcoholische Steatohepatitis** (NASH)



Hoog sterftecijfer
Extreem ongemak

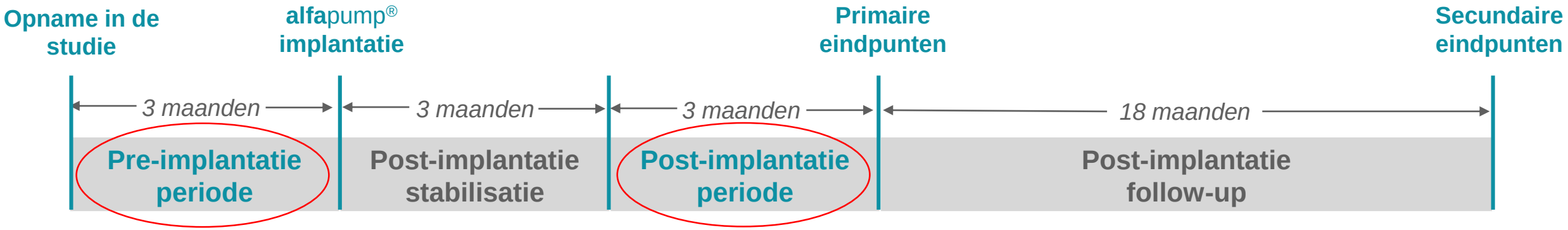


Typisch leven van een patient met refractaire ascites(1)

Bron 1: Presentatie van Dr. Rajiv Jalan op EASL in 2018, Behandelingscyclus voor grootvolume paracentese van refractaire ascites

POSEIDON pivotale studie voor goedkeuring in N-Amerika

Patiënten met terugkerende of refractaire ascites door levercirrose



- ***Pivotal Cohort: max 50 patiënten ⇨ analyse primair eindpunt***
- ***Roll-In Cohort: max 30 patiënten ⇨ tussentijdse data***

POSEIDON interim data van 13 Roll-In patiënten

Positief voor alle primaire eindpunten

WERKZAAMHEID

- ✓ Meer dan 90% vermindering in gemiddeld aantal paracenteses post-implant vs. pre-implant
  - ⇨ primair eindpunt: >50% vermindering
- ✓ Alle patiënten hadden >50% vermindering in gemiddeld aantal paracenteses per maand
  - ⇨ primaire eindpunt: >50% van de patiënten

VEILIGHEID

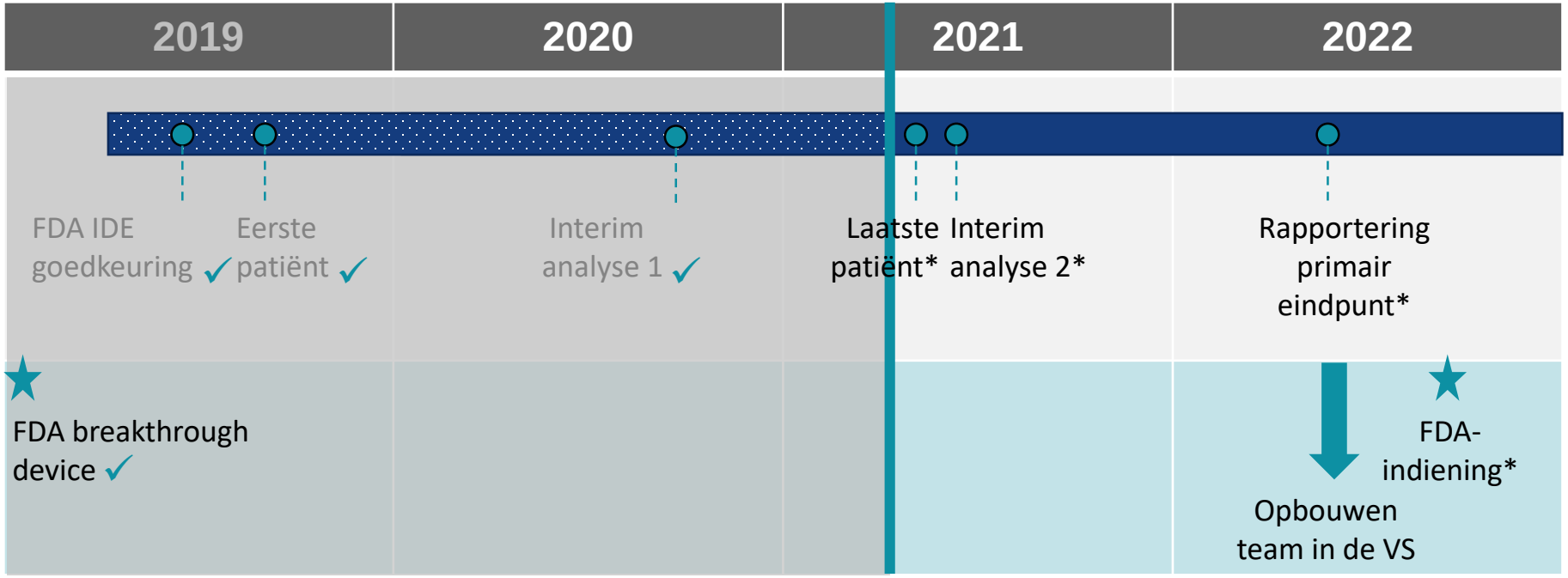
- ✓ Veiligheidsprofiel in lijn met de verwachtingen

LEVENSKWALITEIT

- ✓ Indicatie van snelle en blijvende klinisch relevante verbetering

Noot: Pre- and post-implantatieperioden voor deze analyse van het Roll-In Cohort verschillen van deze die zullen worden gebruikt voor de analyse van het Pivotal Cohort

Rapportering van primair eindpunt verwacht in Q2 2022



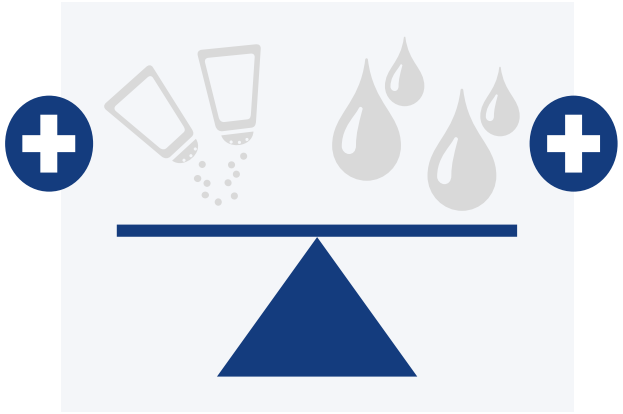
*Bijkomende initiatieven voor terugbetaling van Breakthrough Devices kunnen toegang tot **alfa**pump versnellen*

* *Onder voorbehoud van verdere ontwikkelingen gerelateerd aan de COVID-19 pandemie*

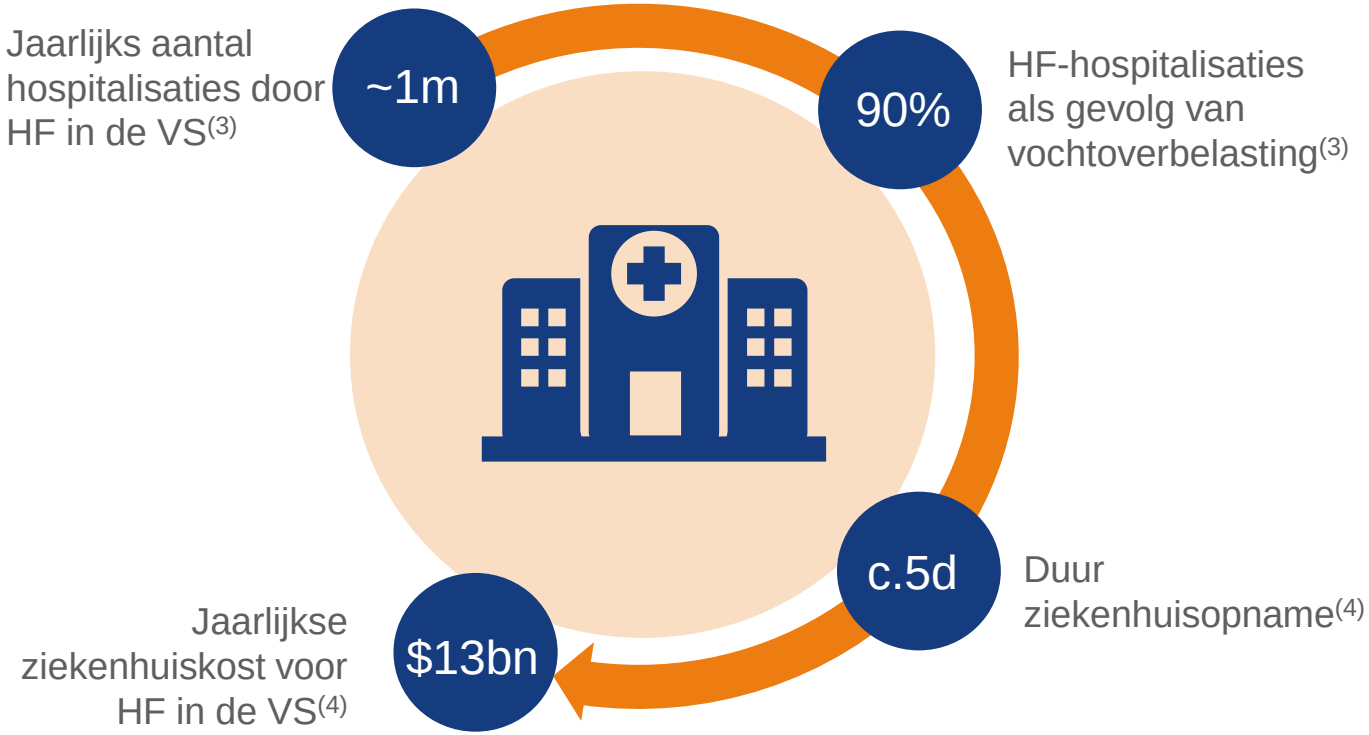
FDA: Food and Drug Administration (US); IDE: Investigational Device Exemption

Diuretica-resistente vochtoverbelasting bij hartfalen

Belangrijke klinische uitdaging en hoge medische kosten



Overtollig natrium leidt tot vochtoverbelasting



- *40% van patiënten met HF hebben een zwakke respons op intraveneuze lisdiuretica(1)*
- *24% heropnames binnen de 30 dagen(2)*

Bron 1: Testani, Circ Heart Failure, 2014 & 2016; Bron 2: Ross et al. (2010); Bron 3: Costanzo et al., J. Am. Coll., 2007; Bron 4: Kilgore et al. (2017)

Direct Sodium Removal (DSR®)

Gepatenteerde nieuwe methode voor behandeling van vochtoverbelasting

DSR-therapie verwijdert het overtollig natrium en lichaam herstelt vocht-natrium balans

DSR therapy directly removes the sodium

Body eliminates excess fluid

Preklinische en klinische proof-of-concept data van enkelvoudige dosis DSR-therapie gepubliceerd in toonaangevend cardiovasculair tijdschrift


Circulation

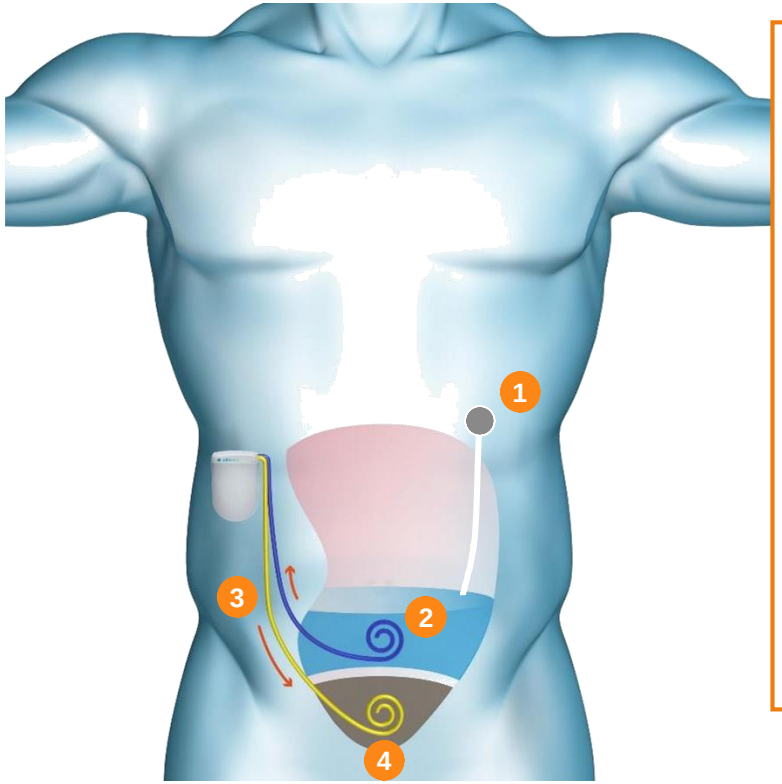
First in Human Experience with Peritoneal Direct Sodium Removal Using a Zero Sodium Solution: A New Candidate Therapy for Volume Overload

Veena S. Rao, Jeffrey M. Turner, Matthew Griffin, Devin Mahoney, Jennifer Asher, Sangchoon Jeon, Peter S. Yoo, Nabil Boutagy, Attila Feher, Albert Sinusas, F. Perry Wilson, ... Show all Authors

Originally published 8 Jan 2020 | https://doi.org/10.1161/CIRCULATIONAHA.119.043062 | Circulation. ;0:null

alfapump DSR®

Potentieel chronische therapie for diuretica-resistente patiënten met hartfalen en vochtoverbelasting

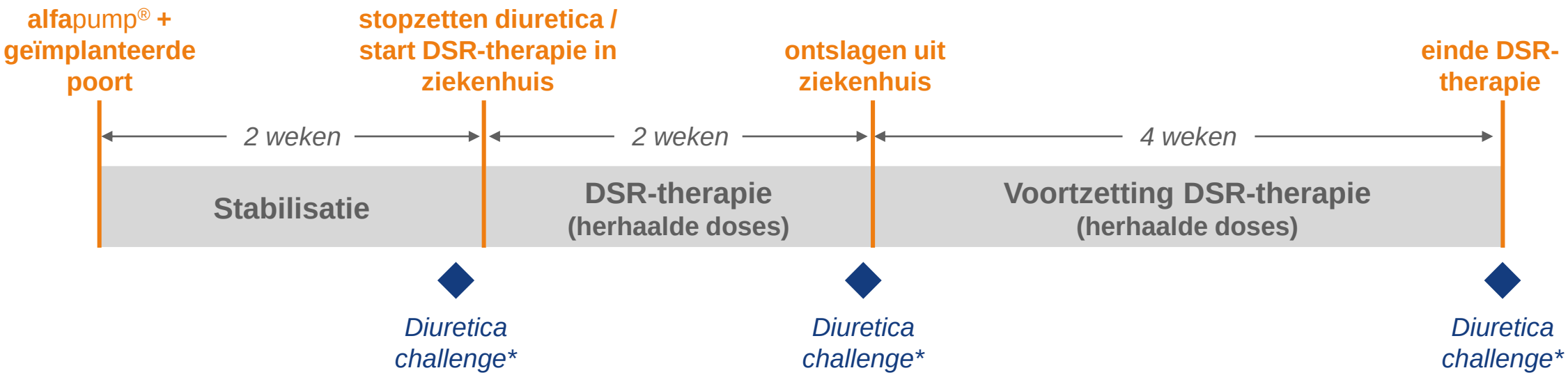


1. Toediening van natrium-arme oplossing (“DSR-infusate”) in buikholte via geïmplanteerde poort
2. Natrium uit circulatie diffundeert in het DSR-infusate
3. **alfa**pump pompt het natrium-rijk DSR infusate in de blaas
4. Lichaam verwijdert overtollig vocht via osmotische filtratie & urinatie

Fundamentele patenten om vochtoverbelasting in patiënten met hartfalen te verminderen, toegekend in de VS en Europa

RED DESERT alfapump® DSR proof-of-concept studie

Stabiele patiënten met hartfalen op hoge doses diuretica



** Eénmalige intraveneuze toediening van 40mg furosemide (= lage dosis diuretica) voor evaluatie van diuretische respons*

RED DESERT interim data van 5 patiënten

Positieve veiligheids- & werkzaamheidsresultaten na 6 weken alfapump **DSR® therapie**

VEILIG & GOED VERDRAGEN

Geen progressieve hyponatriëmie

Gerapporteerde bijwerkingen eenvoudig te behandelen

ZEER EFFECTIEF

Geen behoefte aan diuretica gedurende de 6-weken behandeling

Lagere doses DSR-therapie nodig bij de meeste patiënten

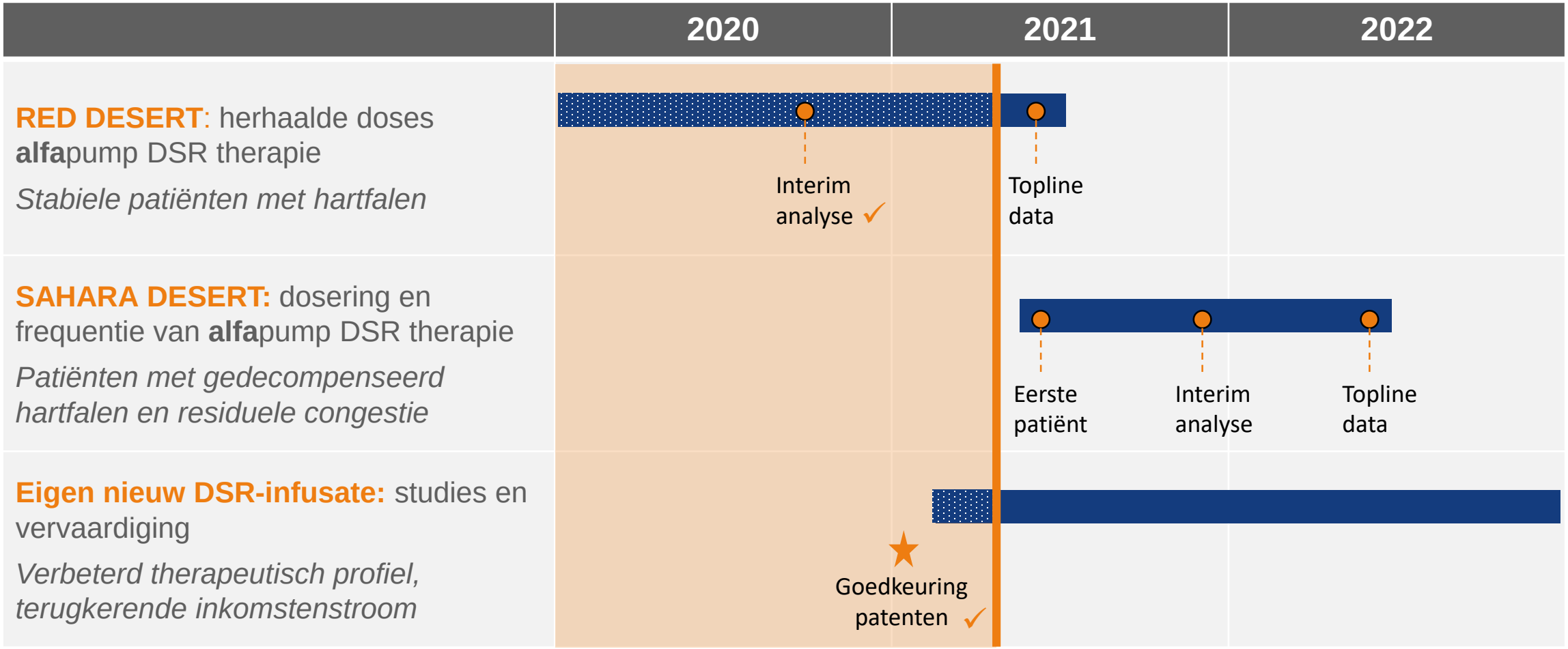
HERSTEL VAN DIURETISCHE RESPONS

Natriumuitscheiding meer dan verdubbeld na de studie

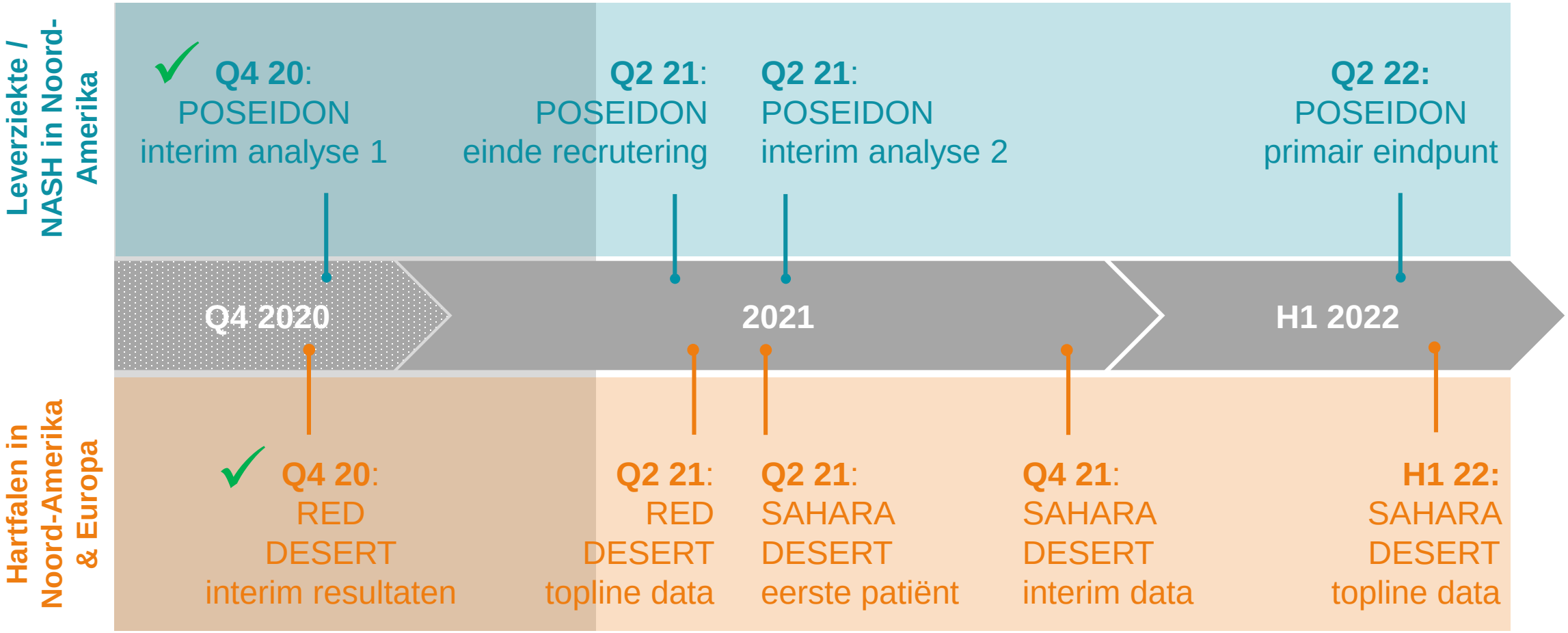
Drastische vermindering van dosis diuretica na de studie

- ***Indicatie dat DSR-therapie meer is dan juist een middel om natrium en water te verwijderen***
- ***Ondersteunt periodische dosering om natuurlijke respons van de nieren te herstellen***
- ***Mogelijke uitbreiding naar andere ziektes met vochtoverbelasting***

Uitbreiding klinisch onderzoek met alfapump DSR®



Belangrijke mijlpalen & vooruitzicht



Noot: Voorgestelde tijdslijnen zijn onder voorbehoud van verdere ontwikkelingen gerelateerd aan de COVID-19 pandemie

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