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POSEIDON 2nd interim analysis Roll-In Cohort

Webcast presentation – 1 July 2021

Today's presenters

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- 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 visit www.poseidonstudy.com.
- DSR® therapy is still under 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 currently not 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 operations accordingly.
- Sequana Medical has put in place mitigation plans to minimise delays. The impact of increased demands on the healthcare systems, limitations 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.

Positive results confirmed in larger Roll-In Cohort

POSEIDON - Second interim analysis of North American pivotal alfapump® **study**

- Interim data from 26 patients in the POSEIDON Roll-In Cohort reconfirm positive outcomes against all primary endpoints*
  - ✓ Over 90% reduction in mean frequency of therapeutic paracentesis versus baseline
  - ✓ All patients experienced at least 50% reduction in mean frequency of therapeutic paracentesis per month versus baseline
  - ✓ Clinically important improvement in quality of life maintained even up to 12 months post-implantation
  - ✓ Safety profile remains in line with expectations – three patients experienced a composite primary safety event
- Primary endpoint read-out from POSEIDON Pivotal Cohort expected in Q3 2022

** Note: Pre- and post-implant periods for this analysis of the Roll-In Cohort differ from those that will be used for the Pivotal Cohort analysis*

Recurrent and Refractory ascites

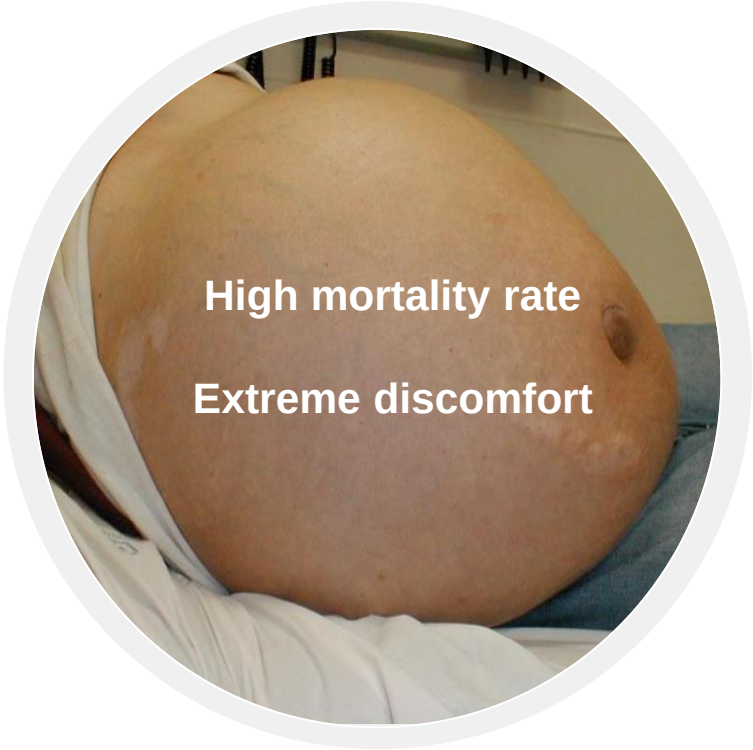
A key complication of liver cirrhosis, with a dramatic impact on quality of life

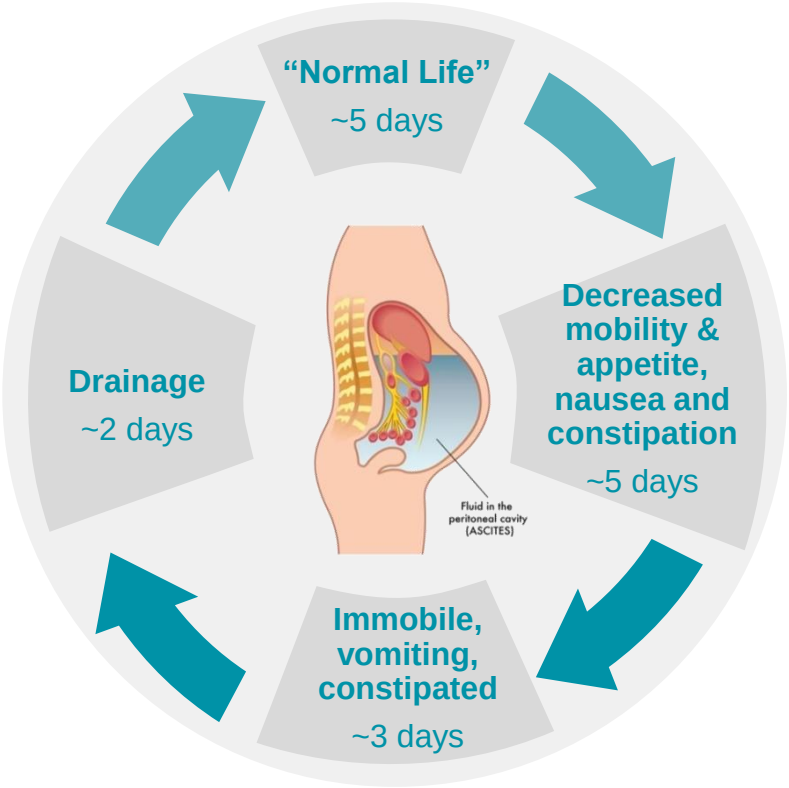
Viral infections (Hepatitis B & C)

Alcoholic Liver Disease

Non-Alcoholic Steatohepatitis (NASH)

Note : Prevalence of NASH in US is expected to increase by 63% between 2015-2030; Estes et al., 2018



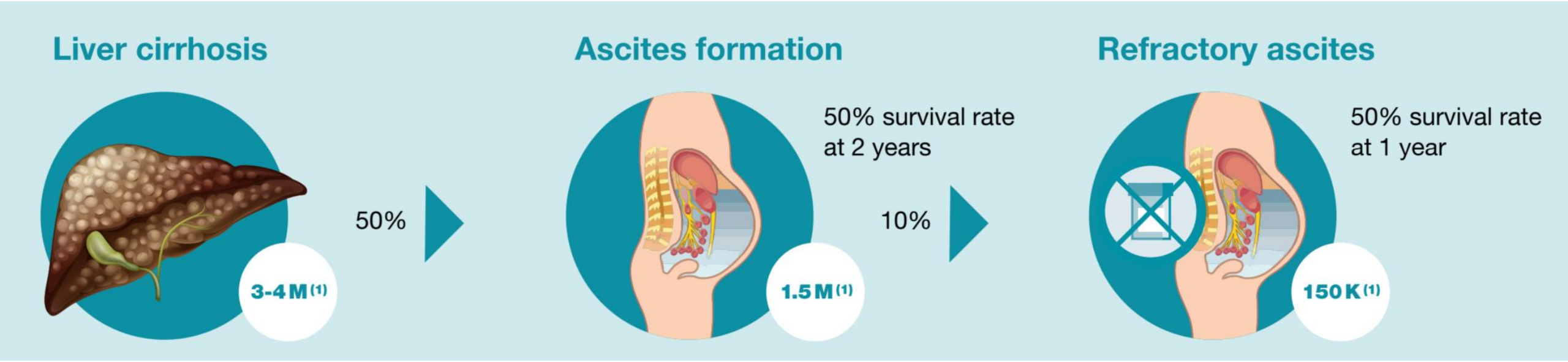


Typical patient life*

** Presentation of Dr. Rajiv Jalan at EASL in 2018, Paracentesis ("drainage") treatment cycle for refractory ascites*

US prevalence of NASH is large and growing

1 in 4 POSEIDON patients have ascites due to NASH

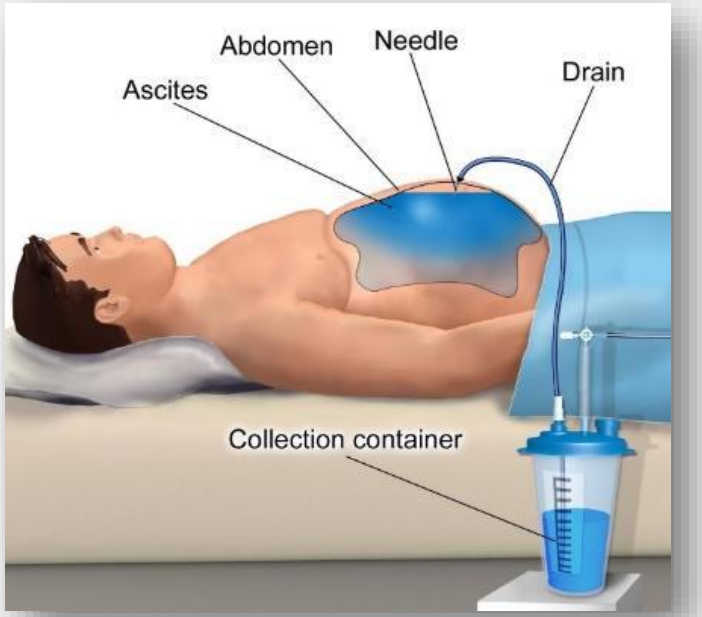


(1) US population forecast due to NASH

Sources: GlobalData Nash Epidemiology Forecast to 2026; Estes (2018); Runyon (2009); Ginès (2004); Fortune (2017); Perri (2013)

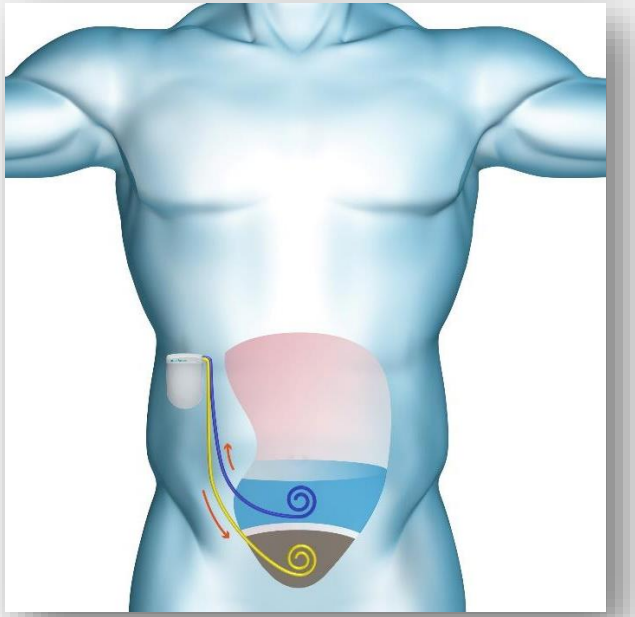
alfapump® – Reduce the need for Therapeutic Paracentesis (TP)

Therapeutic Paracentesis



- Painful
- Frequent hospitalisations
- Poor quality of life
- Short-term benefit

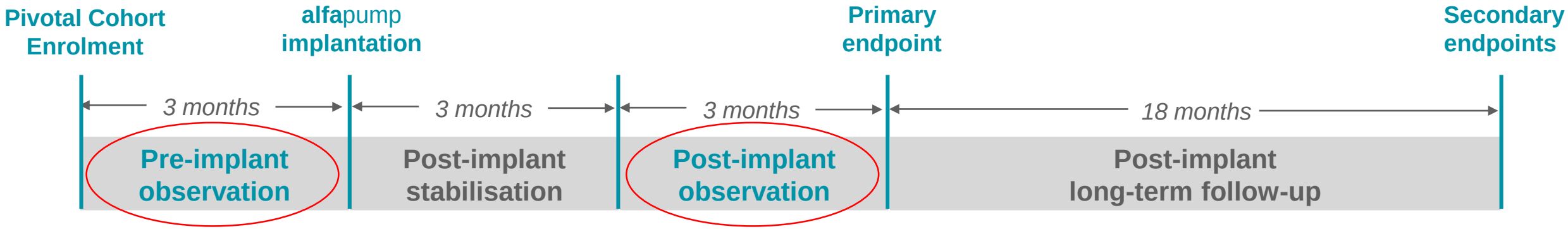
alfapump®



- ✓ Automatic and continuous removal of ascites
- ✓ Fully implanted and wirelessly battery charging
- ✓ FDA breakthrough designation / CE mark
- ✓ Over 850 implants to date

POSEIDON – study design

Pivotal study to support future marketing application of the alfapump® in the US and Canada



Two study cohorts with the same inclusion / exclusion criteria

- Pivotal Cohort – for primary and secondary endpoint analysis
- Roll-In Cohort – to familiarise new centres with **alfa**pump implantation

Recurrent or refractory ascites – patient profile

26 patients from the Roll-In Cohort in the POSEIDON study

Age (mean)	63 y
MELD score (mean ± SD)	10.3 ± 3.9
Cirrhosis etiology	
- Alcohol	- 50.0%
- NASH	- 23.1%
- NASH / Alcohol	- 3.8%
- Alcohol / Hepatitis	- 11.5%
- Alcohol / Primary Sclerosing Cholangitis	- 3.8%
- Hepatitis C	- 3.8%
- Budd Chiari Syndrome	- 3.8%
TP per month prior to study (mean ± SD)	3.8 ± 1.4

N. American patients are treated early in their disease

NASH is becoming a major driver of ascites market

Higher number of TP compared to Europe

MELD: *Model for End-stage Liver Disease;* ***SD:*** *Standard Deviation;* ***NASH:*** *Non-Alcoholic Steatohepatitis;* ***TP:*** *Therapeutic Paracentesis*

Roll-In Cohort: Substantial and durable reduction in Therapeutic Paracentesis (TP)

Mean values	Primary efficacy endpoint Pivotal Cohort	Interim data Roll-In Cohort (N = 26)
% reduction in monthly frequency of TP	> 50% (1)	> 90% (2)
% patients with >50% reduction in TP	> 50% (1)	100% (2)

(1) Monthly frequency of TP during 3-month post-implant observation period (month 4 to 6) vs 3-month pre-implant observation period

(2) Monthly frequency of TP during period up to 12 months post-implant vs one month prior to implant (medical history)

Substantial reduction in TP well beyond 6 months post-implantation with alfapump®

** Note: Pre- and post-implant periods for this analysis of the Roll-In Cohort differ from those that will be used for the Pivotal Cohort analysis*

TP: *Therapeutic Paracentesis*

Roll-In Cohort: Safety in line with expectations

Primary safety endpoint:

- Rate of **alfa**pump related re-interventions adjudicated by Clinical Events Committee (CEC)

Interim data Roll-In Cohort (N=26):

- No unanticipated adverse device effects
- Three patients experienced a composite primary safety event as adjudicated by CEC:
  - Hematuria after car accident – **alfa**pump explant — 1 in 1 patient
  - Wound dehiscence – **alfa**pump explant — 1 in 1 patient
  - Arterial injury during implantation – patient died — 1 in 1 patient

"Safety data reassuring for the potential of the alfapump as a long-term treatment in this fragile patient population" – Prof. Wong, Principal Investigator POSEIDON

Roll-In Cohort: Clinically important improvement in quality of life maintained up to 12 months

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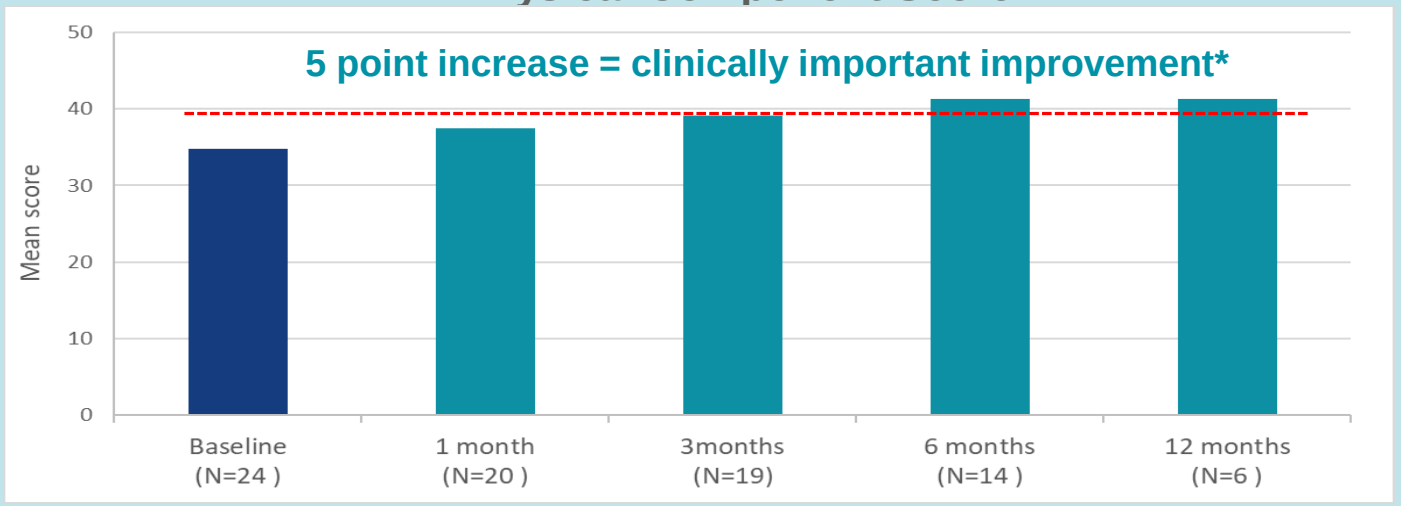
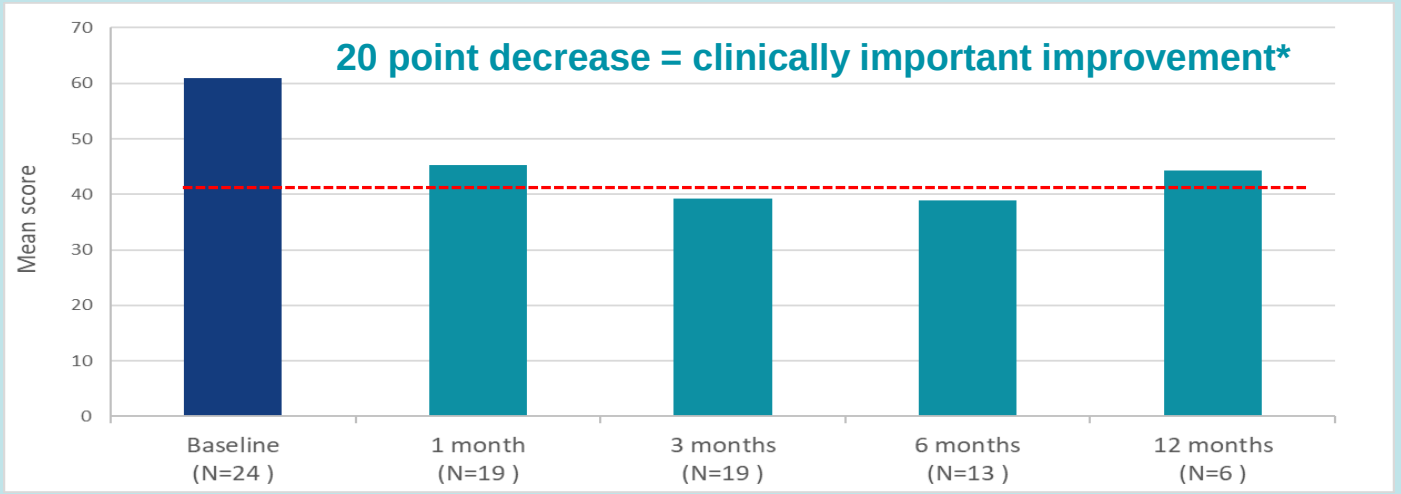
General health-survey questionnaire



Higher is better

Ascites Q

Specific health-survey questionnaire for ascites



Lower is better

** Clinically important improvement: exceeding the threshold for Minimal Clinically Important Difference*

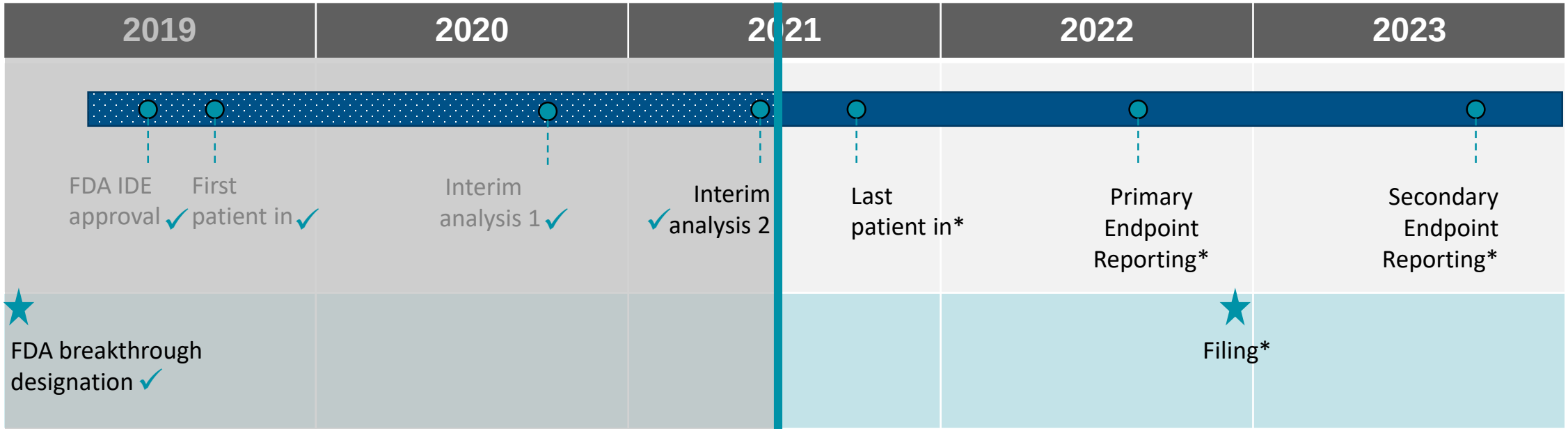
Pivotal Cohort: Additional patient recruitment

Completion of enrolment with approx. 10 additional patients in Pivotal Cohort is now expected in Q3 2021

- Pivotal Cohort patients are screened for inclusion / exclusion criteria at enrolment AND prior to planned **alfa**pump implantation (following 3 month observation period)
- Review revealed a higher rate of attrition between enrolment and planned implantation due to failing inclusion / exclusion criteria just prior to implantation, in many cases due to disease progression
  - Extended delay in **alfa**pump implantation due to COVID has been a significant factor
- As a consequence, approx. 10 additional patients will need to be enrolled in the Pivotal Cohort to ensure up to 50 patients are implanted with the **alfa**pump following the 3-month observation period

"The higher attrition rate is a reflection of how the condition of these patients continues to deteriorate, and underlines how important alfapump can be to these patients"

Targeting announcement of primary endpoint in Q3 '22



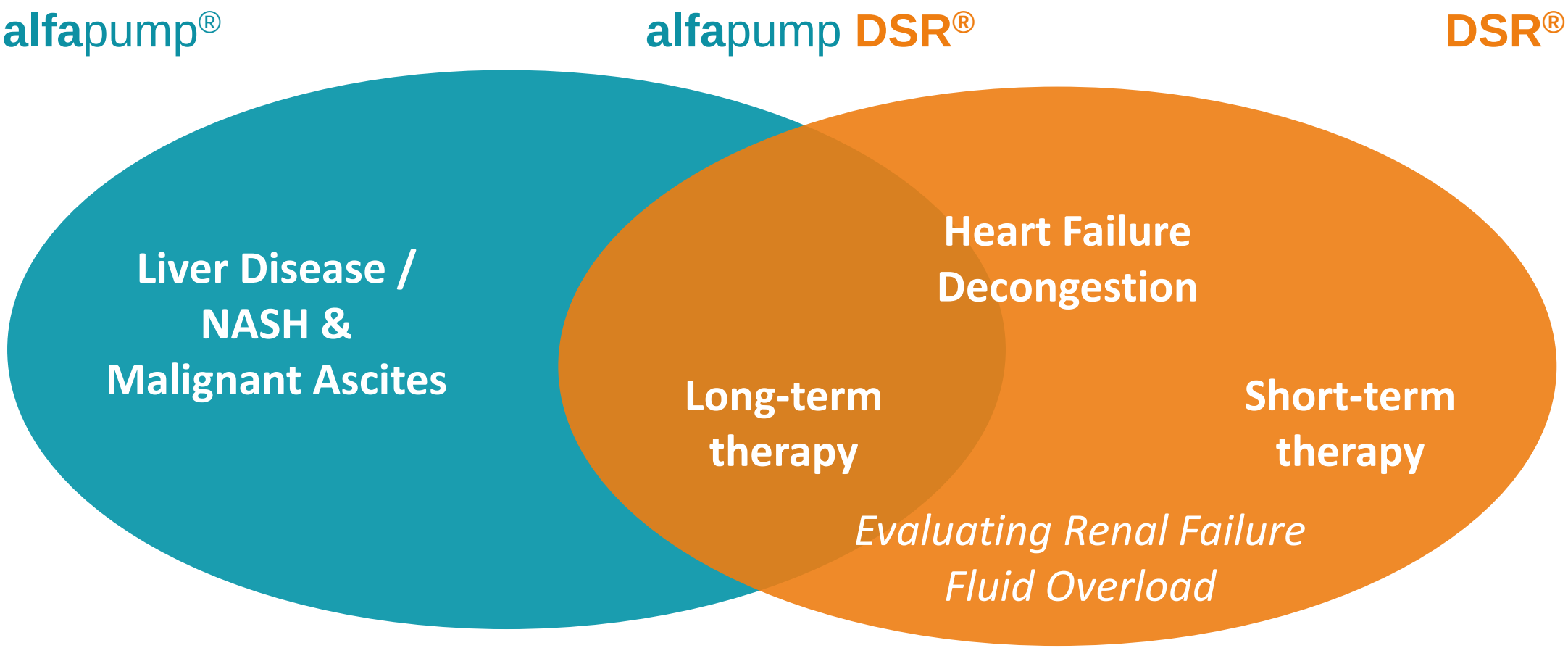
*MCIT & NTAP – CMS initiatives for breakthrough devices to further support coverage & reimbursement for the **alfa**pump*

** Subject to further developments related to the ongoing COVID-19 pandemic*

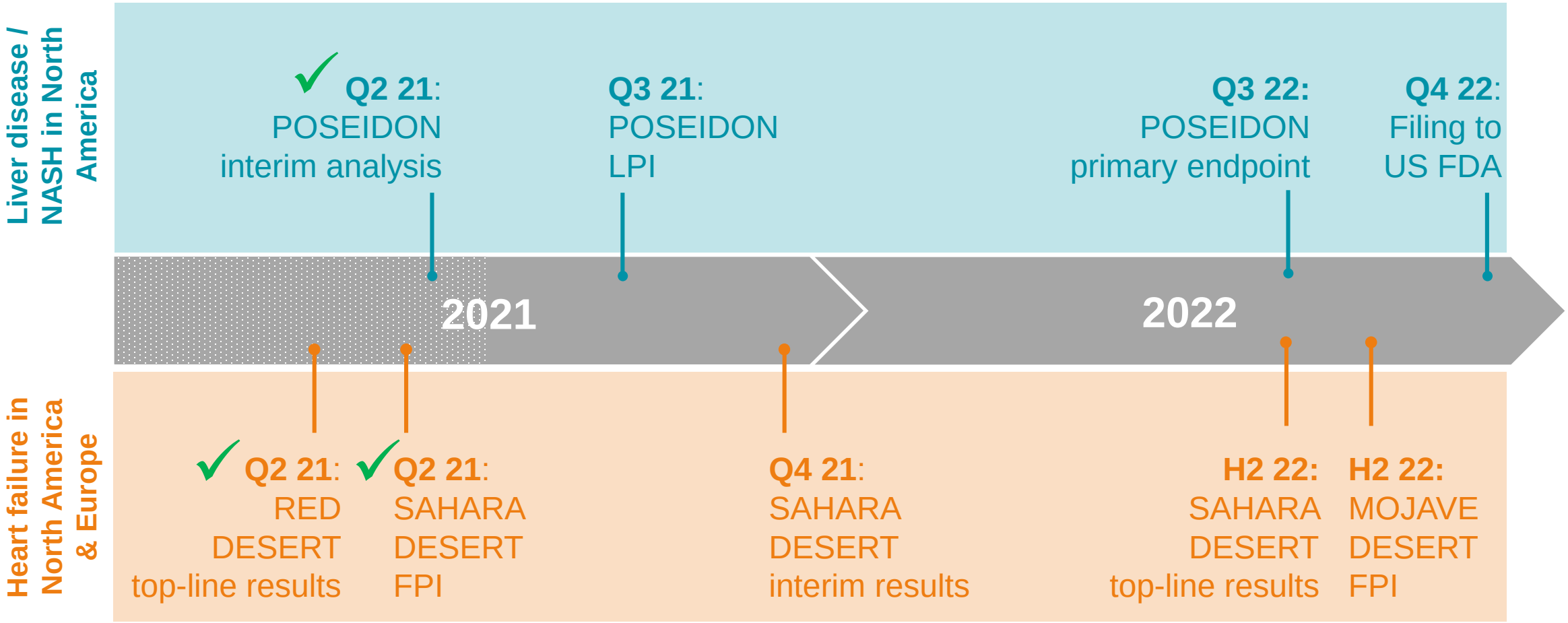
***FDA:** Food and Drug Administration (US); **IDE:** Investigational Device Exemption*

Building Sequana Medical on two technology platforms

Complementary approaches to diuretic-resistant fluid overload



Expected core value drivers & outlook



Note: Presented timelines are subject to further developments related to the COVID-19 pandemic

FPI: *First Patient In;* ***LPI:*** *Last Patient In*

Q&A