ESN CLEER

Early Market Access and Regulatory Assessment Report – ESN Cleer

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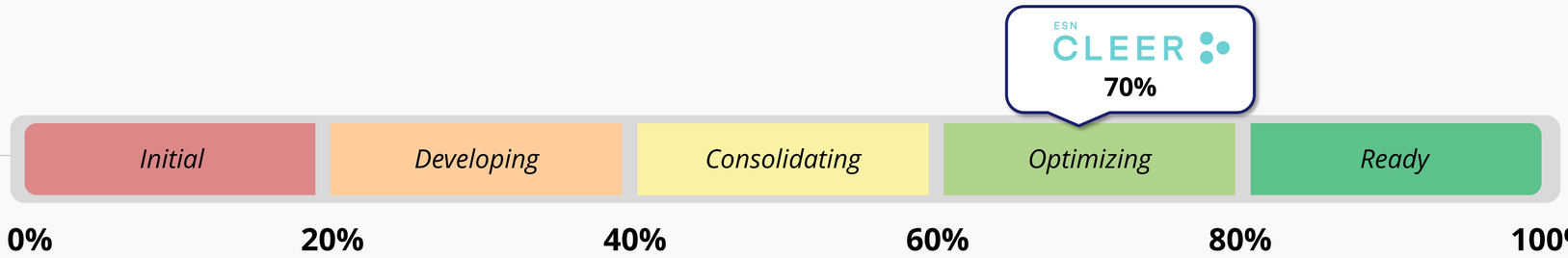
Maturity Assessment

All **insights and conclusions are based on the 1h interview** with the company team and review of the pitch deck. **No extra primary or secondary research** has been done to validate the conclusions

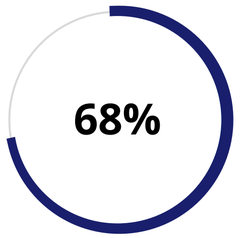
The company understands the regulatory and market access needs and is well prepared at this stage for the following investment rounds

Maturity Level

Overall Regulatory and Market Access maturity level

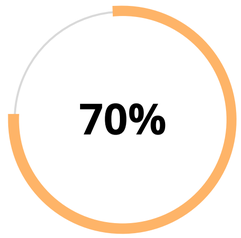


REGULATORY



- Considering early stage of development, the **solidity of the development** timelines is limited
- Although regulatory requirements are being contemplated, it is recommended that nonclinical and clinical development plan is **discussed with relevant health authorities** (EU EMA & US FDA) as soon as possible

MARKET ACCESS & PRICING

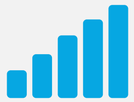
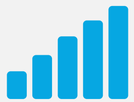
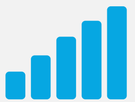
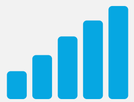


- ESN Cleer has a clear understanding of the specific **cardiomyopathies market and its unmet needs**. They aim to provide with a **targeted solution for these patients**
- The company should develop a **pricing strategy for the EU and assess market size** across all relevant markets. Additionally, they should **stress-test their value messages for the repurposed drug** to prevent payer uncertainty

Positive Aspects

All **insights and conclusions are based on the 1h interview** with the company team and review of the pitch deck. **No extra primary or secondary research** has been done to validate the conclusions

ESN Cleer has a good understanding of the regulatory and market access requirements needed to commercialize the product

	Relevance	*Description*	*Area*
Landscape assessment		▶ The company has a good understanding on the current **Heart Failure and specific cardiomyopathies landscape** (i.e. patient journey, SoC and current competitors)	
Unmet needs & coverage of unmet needs		▶ ESN Cleer has a good understanding of current unmet needs: there are **no specific treatments** for patients with restrictive cardiomyopathy and have a **poor management and QoL** ▶ The company's asset provides for a **specific solution** for patients with cardiomyopathies **(cardiac hemochromatosis and cardiac sarcoidosis)**	
Regulatory Requirements		▶ Despite current early stage of development of the drug, **nonclinical and clinical requirements are already being contemplated**. Preliminary strategies have been defined to meet them	
Regulatory Opportunities		▶ ESN CLEER is **aware of potential regulatory opportunities** that can be triggered to expedite drug development (e.g., Orphan Drug Programs)	

QoL: Quality of Life; SoC: standard of Care

Main Challenges and Key Actions

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There are some challenges that should be solved before moving into new phases of development to ensure success in regulatory and market access & pricing

	Challenge	Key Action
1	**Timelines**	▸ Current **proposed timelines can only be deemed to be tentative**. Plenty of uncertainties are still to be defined, considering early stage of development
2	**Regulatory Strategic Plan**	▸ Current clinical development plan looks interesting since some clinical data might be already generated from previous development. Nonetheless, the approach is not conventional; Meaning that **endorsement from regulatory authorities should be sought for both nonclinical and clinical development**. Before first in human (FIH) trials, discussion with health authorities should happen. Please note that in EU & US, drug developments are evaluated on a single indication basis. Indication prioritization should be done, considering future opportunities and constraints
3	**EU & US Strategy**	▸ A global development in US & EU is currently being considered. The company should be able **to leverage potential differences from US and EU Reg authorities in regard to clinical strategy** ▸ AH would recommend interacting with both agencies to anticipate potential differences that should be addressed

Relevance (+ / −)

	Challenge	Key Action
1	**EU Strategy Development**	▸ ESN Cleer is **focusing on the US market** as its primary commercial strategy and plans to address the EU market later. While the **EU market doesn't consider US pricing** in negotiations, therapeutic **positioning in the US** market is assessed in EU. The company needs to **develop an EU strategy** to define full market potential and associated risks
2	**Pricing study & market sizing**	▸ ESN Cleer needs to develop a holistic pricing strategy that includes the **product value proposition, a country launch sequencing strategy** (determining which geographies to prioritize and assessing the risk of external reference pricing, with a price corridor) ▸ In addition, ESN Cleer must understand the market potential by **assessing the addressable population to be treated** in all the markets in scope, not only the epidemiology
3	**Repurposed drug value message**	▸ Discussing a **repurposed drug could potentially cause confusion to payers**, as it might encourage associations with the generic market. Repurposed drugs are normally associated with a deep understanding of the clinical efficacy and safety profile, and if the active ingredient has not been marketed, this could generate confusion to payers

Relevance (+ / −)

AH: Alira Health; EU: European Union; US: United States

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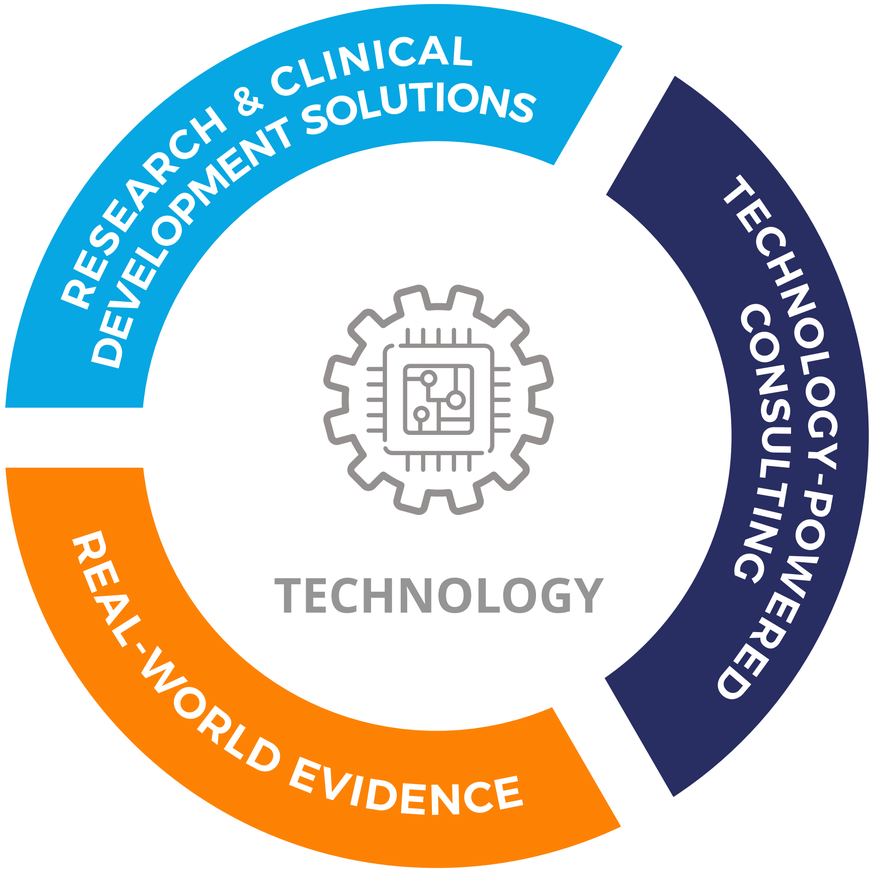

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- CMC Technical & GMP Training

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- Lifecycle Maintenance Support
- CMC Quality and Regulatory Affairs

CLINICAL

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- Site Selection and Feasibility
- Investigator Training
- Subject Recruitment & Retention
- Trial Management and Clinical Operations
- Pharmacovigilance

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- Biostatistics and Statistical Programming
- Statistical Consulting
- CDISC Conversion
- ISS/ISE Reporting
- Medical Writing
- Biometrics Optimization Solution (B.O.S)
- Centralized Biometrics

Technology Powered Consulting and Real-World Evidence Solutions

MANAGEMENT CONSULTING

Market Opportunity Assessment

Portfolio Management

Commercial / Vendor Due Diligence

Commercial Excellence

Corporate Strategy Planning

Commercial Strategy and Go-to-Market Model Development

Integrated Launch Planning

Healthcare Optimization

MARKET ACCESS

Global Market Access, Pricing and Reimbursement Strategy

Evidence Generation Strategy and Plan

Indication Prioritization

Value Communication

Mock Negotiations and Payer Consultations

Health Economics and Outcomes Research Strategy

Value Based Healthcare Pilots

Market Access Diagnostic MAP™

Accelerated Coverage Pathways for Innovation

PATIENT ENGAGEMENT

Patient Centricity Strategy

Patient Advisory Board

Patient Knowledge Center

Patient Mobilization Program

Patient Support Program

TRANSACTION ADVISORY

M&A Sell-Side

M&A Buy-Side

Business Development and Licensing

Carve-Out

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Data Strategy

Real-World Studies

Real-Time Data

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Thank You

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