



Norwegian Centres of Expertise

NCE **Blue Legasea**

MARINE FOR HEALTH

Nina Zisko, Project Manager

20. Nov 2019



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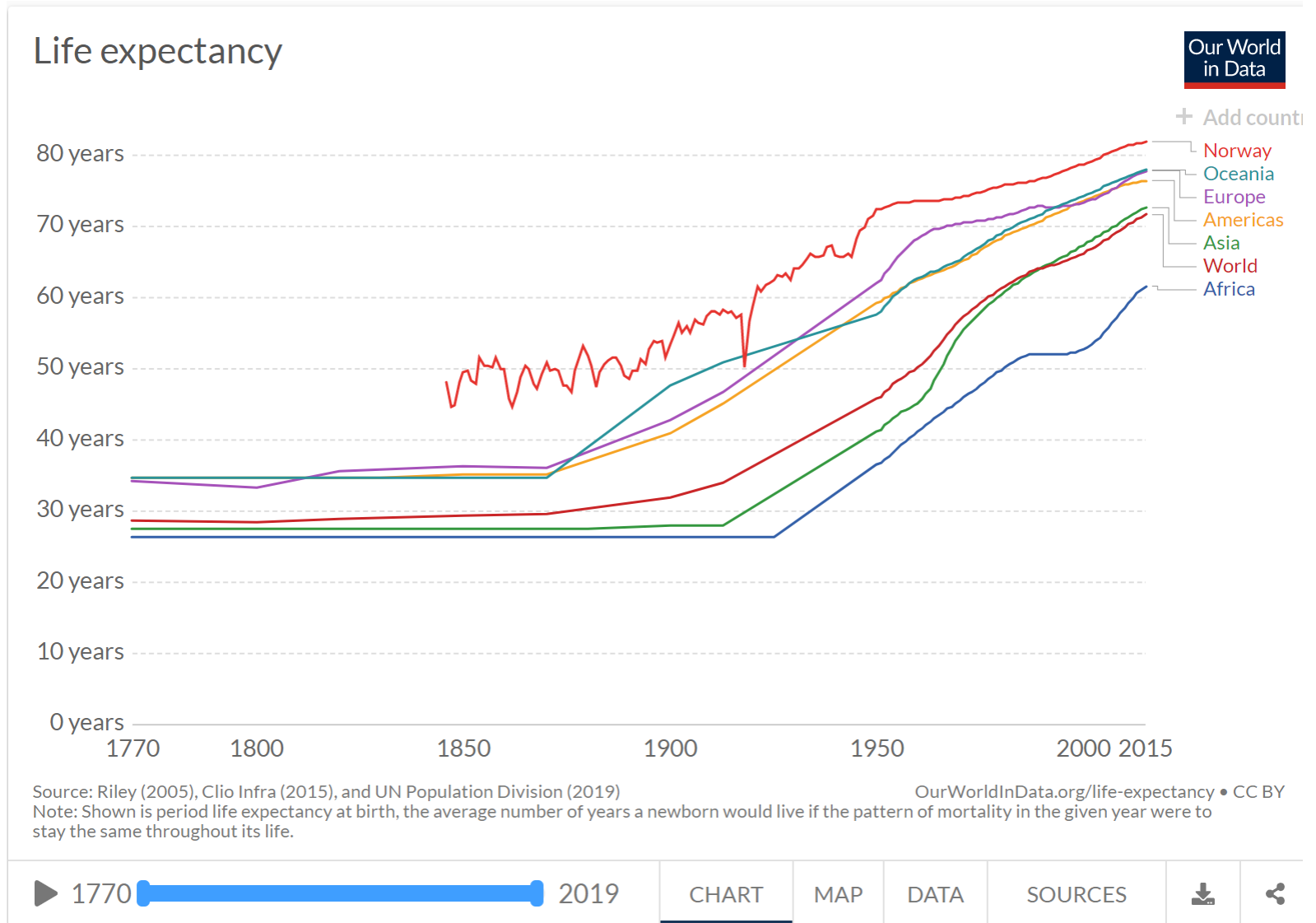
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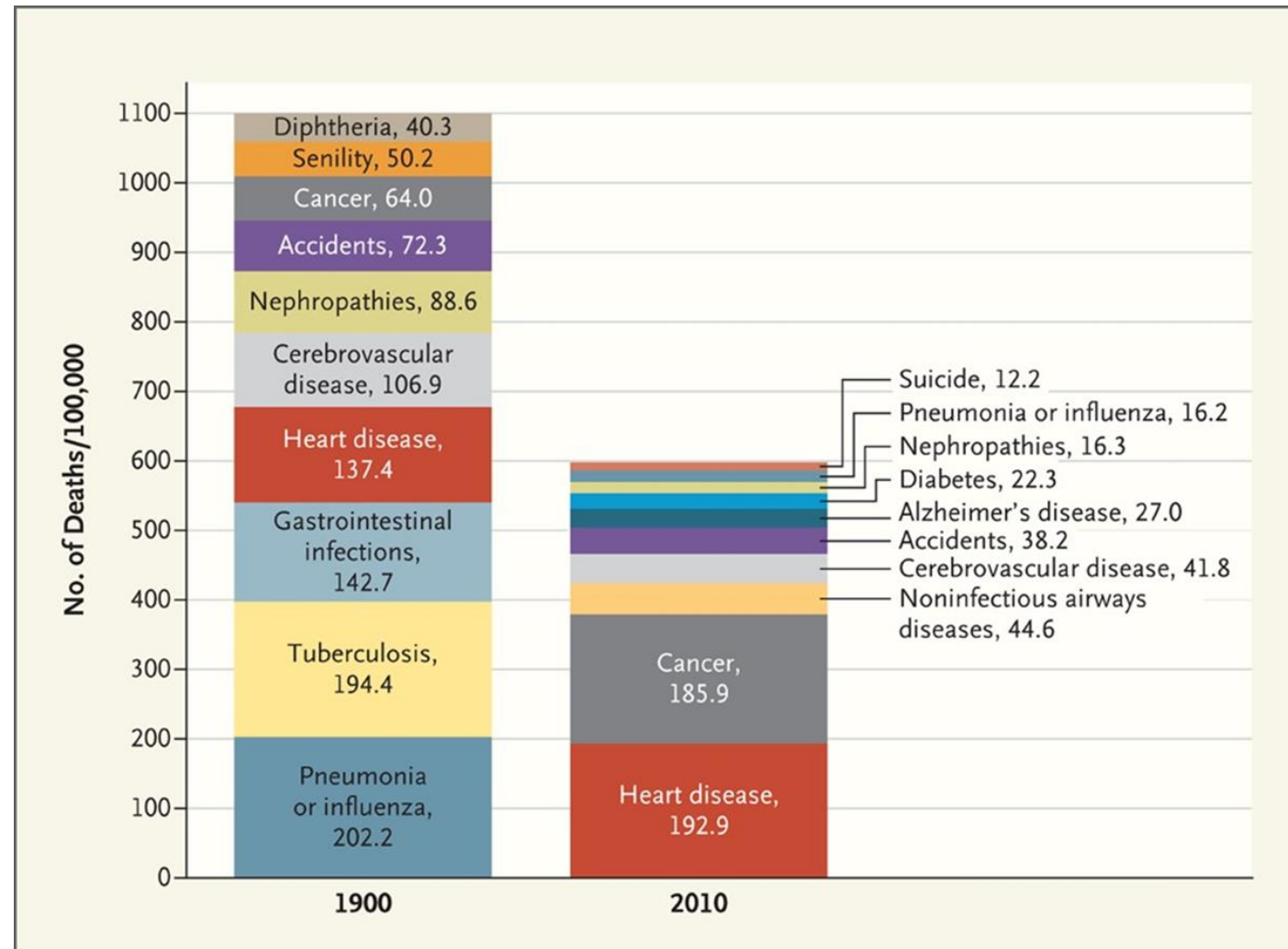
MARINE FOR HEALTH

FACTS

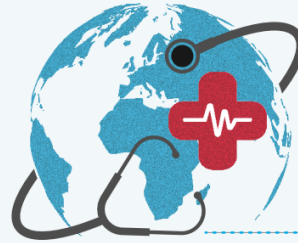
- Oceans cover $\frac{3}{4}$ of the Earth's surface, contain 97 % of the Earth's water, and represent 99 % of the living space on the planet by volume
- Over 3 billion people depend on marine and coastal biodiversity for their livelihoods
- Oceans contain nearly 200,000 identified species, but actual numbers may lie in the millions
- Oceans serve as the world's largest source of protein, with more than 3 billion people depending on the oceans as their primary source of protein



WHAT KILLS US? LEADING CAUSES OF DEATH FROM 1900 to 2010



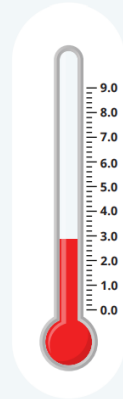
Global health care spending continues to increase dramatically



is projected to reach

\$10.059 trillion by 2022

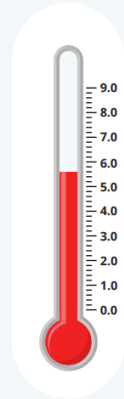
FACTS



Annual
growth
rate

2.9%

2013-2017



5.4%

2018-2022

Factors impacting health care costs

- life expectancy continues to climb—number of people aged over 65 globally is more than **668 million**, or **11.6%** of the total global population
- winning the fight against communicable diseases
- non-communicable diseases (NCDs)—most prominently, cancer, heart disease, and diabetes—continue to grow



Shifting the focus from *'sick'* care to one of *'health'* care, supported by:

Well-being

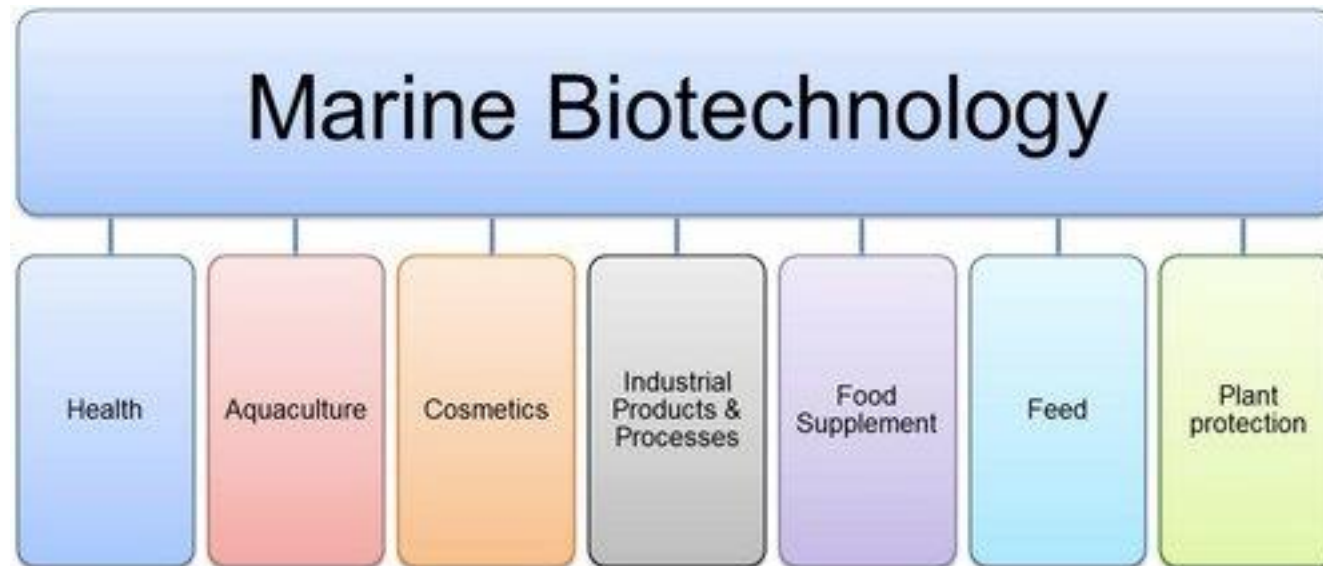
Prevention

Early intervention



MARINE FOR HEALTH

In the last 10 years, marine biotechnology was applied to different areas



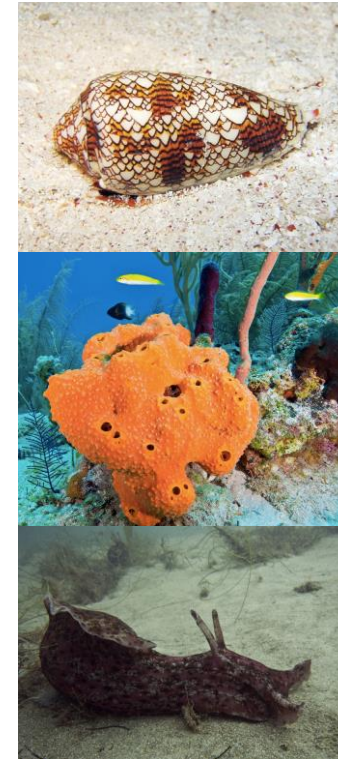


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Many promising pharmaceutical products developed from marine organisms for:

- cancer therapy (e.g. algae, sea hare)
- painkillers (e.g. venom in cone snails)
- antiviral drugs and anticancer agents (e.g. extracts from sponges)



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Approved Marine Drugs

Compound Name	Trademark	Marine Organism	Chemical Class	Molecular Target	US - Active Clinical Trials	Europe, Australia- Active Clinical Trials	Chinese - Active Clinical Trials	Disease Area	Company/ Institution
Plitidepsin**	Aplidin®	Tunicate	Depsipeptide	eEF1A2	None	[7+]	None	Cancer: Multiple Myeloma, Leukemia, Lymphoma	[Pharmamar]
Trabectedin (ET-743)	Yondelis® (2015)*	Tunicate	Alkaloid	Minor groove of DNA	[26+]	[29+]	None	Cancer: Soft Tissue Sarcoma and Ovarian Cancer	[Pharmamar]
Brentuximab vedotin (SGN-35)	Adcetris® (2011)*	Mollusk/ cyanobacterium	ADC(MMAE)	CD30 & microtubules	[56+]	[30+]	None	Cancer: Anaplastic large T-cell systemic maglinant lymphoma, Hodgkin's disease	[Seattle Genetics]
Eribulin Mesylate (E7389)	Halaven® (2010)*	Sponge	Macrolide	Microtubules	[45+]	[10+]	None	Cancer: Metastatic Breast Cancer	[Eisai Inc.]
Omega-3-acid ethyl esters	Lovaza® (2004)*	Fish	Omega-3 fatty acids	Trygliceride-synthesizing enzymes	[18+]	[1+]	None	Hypertriglyceridemia	[GlaxoSmithKline]
Ziconotide	Prialt® (2004)*	Cone snail	Peptide	N-TypeCa channel	[1+]	[1+]	None	Pain: Severe Chronic Pain	[Jazz Pharmaceuticals]
Vidarabine (Ara-A)	Vira-A® (1976)*	Sponge	Nucleoside	Viral DNA polymerase	[139+]	None	None	Antiviral: Herpes Simplex Virus	[Mochida Pharmaceutical Co.]
Cytarabine (Ara-C)	Cytosar-U® (1969)*	Sponge	Nucleoside	DNA polymerase	[293+]	[137+]	[11+]	Cancer:Leukemia	[Pfizer]

* FDA Years Approved ** Australia Dec 2018 Approved.



Malnutrition is a global challenge



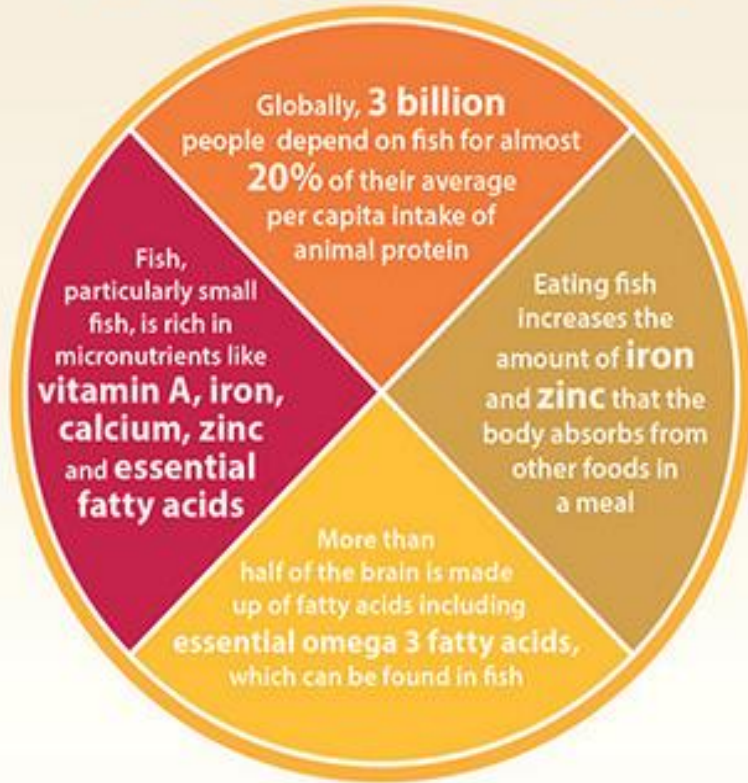
GLOBAL NUTRITION REPORT 2015

#NutritionReport

- One third of all food goes to waste
- 795 million people are regularly hungry
- 680 million people are obese
- Global economic cost of obesity is roughly **\$2 trillion or 2.8% of global GDP**
- A serious global challenge



A Nutritious Solution



30%
FISH & SEAFOOD
FOOD LOSSES

Collaboration from sea to market

Catch



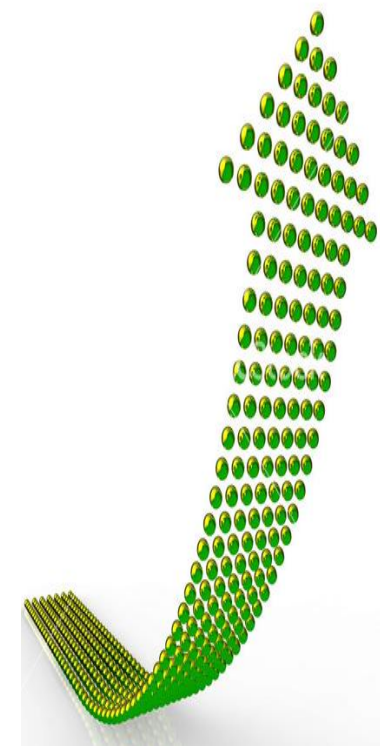
Processing



High Quality Products
For different Market segments



Profit



Opportunity in Healthcare

- 40-50% of drugs currently in use are from natural products (terrestrial plants, organisms, and microorganisms)
- 80% of life form is present only in oceans
- Prospect of new drug 300 to 400 times more likely than isolating one from the terrestrial ecosystem





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Ocean is an important but largely **untapped source** of natural products with **enormous potential** for pharmaceuticals, nutritional supplements, enzymes, pesticides, cosmetics and other novel products.



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MARINE FOR HEALTH

Knowledge hub on raw marine materials,
ingredients, and effects on health

- Established according to the industry's desire for regional expertise in health and nutrition
 - Faster and more efficient development and commercialization of high-quality products



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MARINE FOR HEALTH

Knowledge hub on marine raw material, ingredients and effects on health is based on four pillars

Regulation &
Documentation

Database of
Clinical Trials

Bio-marine
Analysis

Centers for
Clinical Trials



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Regulatory
competence and
need for
documentation

- Development of regulatory expertise to satisfy documentation requirements in various market segments
- Complex and comprehensive legislation that is constantly changing and varies from country to country
- Establish a portal in collaboration with other knowledge environments



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10. AND 11. DEC 2019



**SEMINAR ON
NEUTRACEUTICAL AND PHARMACEUTICAL**



Marine For Health Regulatory Seminar

10. December 2019

10:00-10:45 Registration

10. December 2019

10:45-11:00 **Wenche Uksnøy, Welcome and introduction**

Mari Lyyra, Regulatory Affairs Manager Food and Nutrition, Medfiles, Finland

11:00- 12:00 Novel food and health claim dossiers-A well done plan guarantees the best outcome

12:00-13:00 **Lunch**

Anders Mikael Sjödin, Professor, Division Nutrition, Exercise and Sports, University of Copenhagen, Denmark, EFSA Expert Panel
TBC

13:00-14:00 **Asim K. Duttaroy, Professor, Clinical Nutrition, University of Oslo, Norway**

14:00-15:00 Functional food regulations in Europe: A case study

15:00-15:20 **Break**

15:20-16:20 **Jim Lund, Research Institutes of Sweden (RISE), Sweden**
Marine research and business innovation platform-A pilot study

16:20-16:20 **Break**

16:40-17:40 **Maie Gall, CEO, Varanah Ventures, Switzerland**
Disrupting a health paradigm; Setting a new way of thinking

18:15-22:30 **Dinner**

11. December 2019

9:00-10:00 **Firoz Roshan, Pharmaceutical Regulatory Affairs Specialist, Sweden**
Role of regulatory affairs in clinical drug development

10:00-10:30 **Break**

10:30-11:30 **Jan Petter Akselsen, Leader, The Norwegian Medicines Agency Innovation Office, Norway**
Regulatory Requirements and Services in Drug Development

11:30-12:30 **Åsa S. Mjelva, Link Medical, Norway**
Development of your pharmaceutical – Do it right first time



MARINE FOR HEALTH

Database on
quality assured
clinical trials

- User-friendly and searchable database of scientifically published clinical trials relevant to the industry
- Currently working with partners for database development
- Allow companies easy access to relevant literature
- Opportunity to quickly respond to "fake news"



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Competence
within clinical
trials

- Formalize collaboration with relevant clinical environments for conducting clinical trials
- Anchored to Helse Møre and Romsdal in collaboration with national and international environment

Subject day "Cell, animal and clinical studies"

SEMINAR Marine for Health invites you to a professional day. Get a common understanding about using cell, animal and clinical studies to develop higher value products.





MARINE FOR HEALTH

Business-relevant analyses



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- Overview of relevant analyzes throughout the marine value chain - regionally, nationally and internationally
- Quick access to relevant analysis for documentation purposes



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Company-relevant marine analyzes

SEMINAR What kind of analysis is available in the biomarine industry today, what do we need and how do we solve the future analysis needs?





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FUTURE OF MARINE FOR HEALTH

We will continue to work actively with the industry partners as a resource for the commercialization of new high-quality marine products with well documented safety and efficacy.

ULTIMATE GOAL OF MARINE FOR HEALTH

Improve population health and quality of life through high quality marine products and in the process to help contribute to development of strong marine health industry in Norway.



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THANK YOU