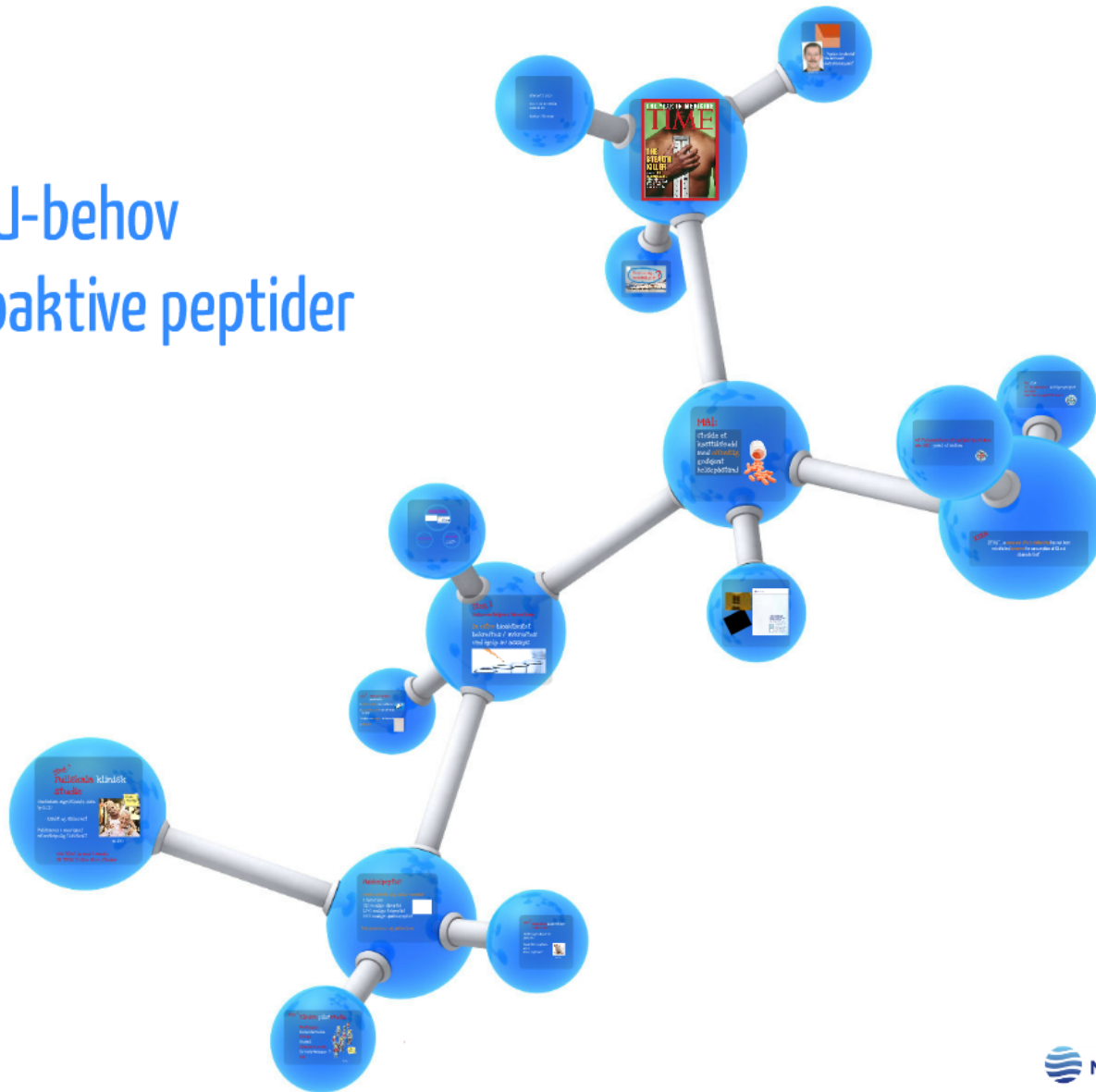
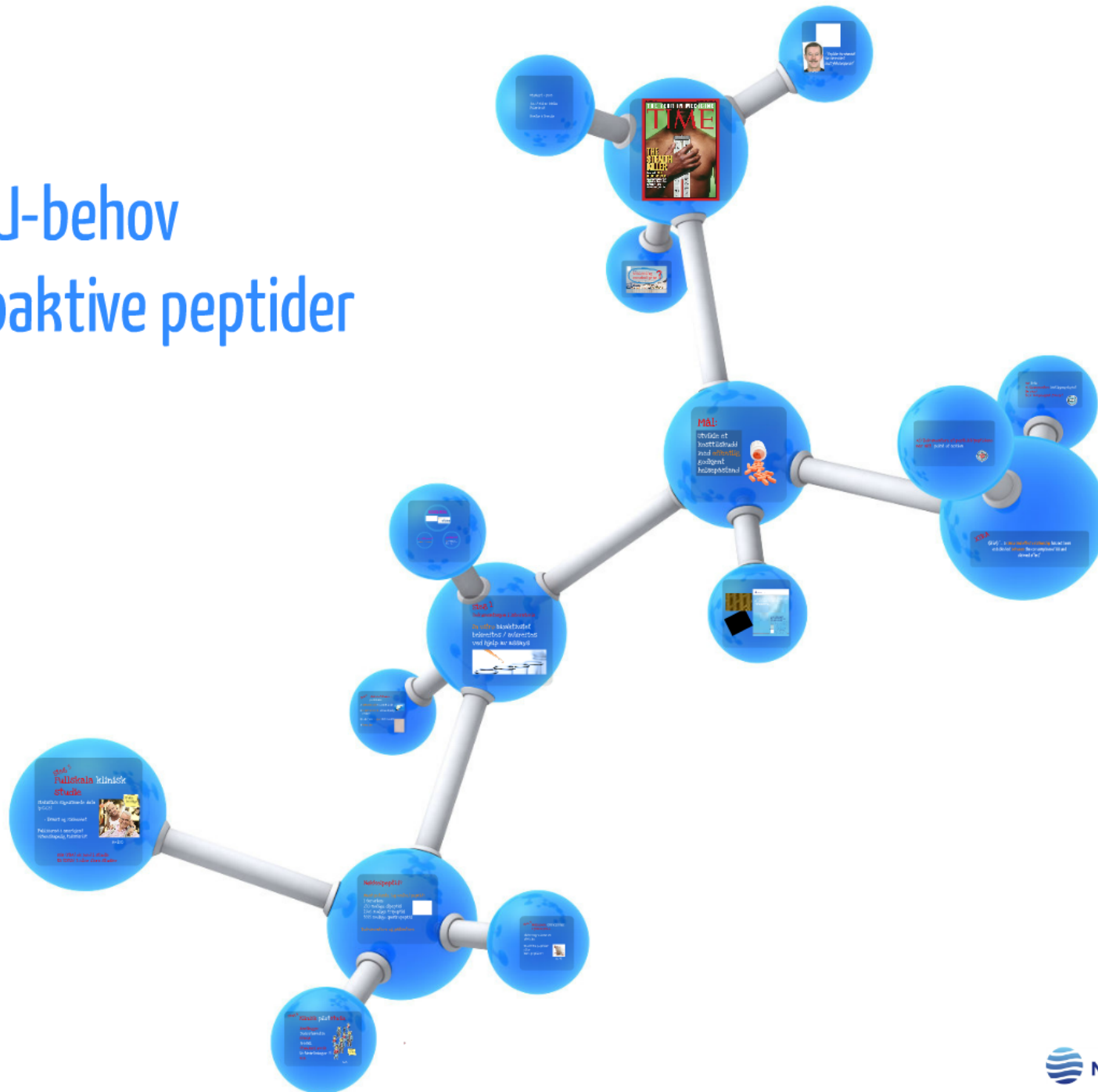


FoU-behov Bioaktive peptider



FoU-behov Bioaktive peptider





MAREALIS[®]

Etablert i 2008

100 % eid av Stella
Polaris AS

Kontor i Tromsø



2007:

5.000.000 kg

rekeskall pr år



**BREAKING
NEWS**



Asbjørn Gildberg, Nofima

*- "Peptider fra rekeskall
kan være svært
blodtrykksdempende!"*

THE YEAR IN MEDICINE

TIME

THE STEALTH KILLER

America's **HIGH BLOOD PRESSURE** crisis is spinning out of control. Learn about it, treat it—and maybe save your life



Mål:

Utvikle et
kosttilskudd
med offentlig
godkjent
helsepåstand



REGELVERK



#1) Sikkerhet

Ref. Novel Food / New Dietary Ingredient

#2) Effekt

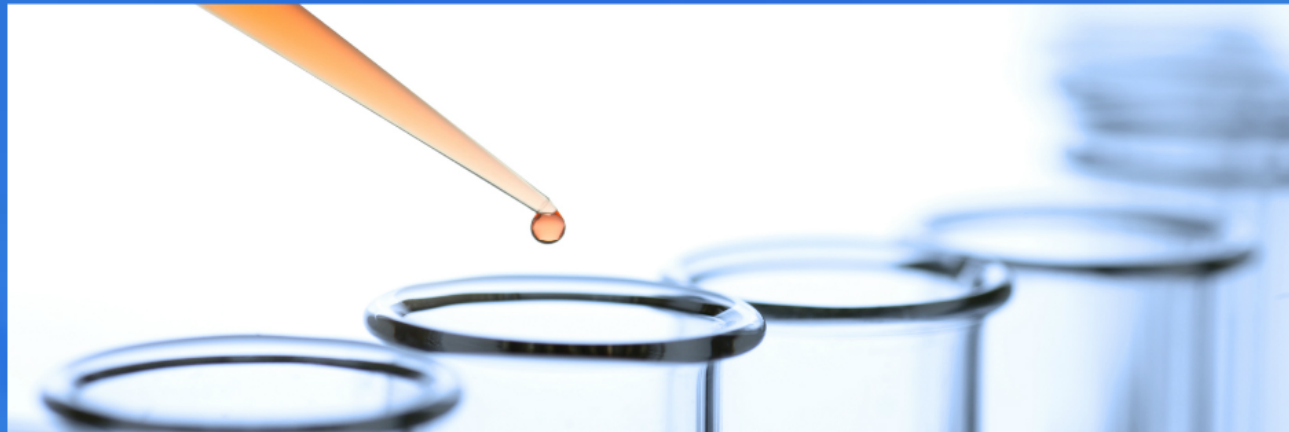
Ref. Helsepåstand

fx: "Promotes a healthy
blood pressure"

steg 1

Dokumentasjon i laboratorie

In vitro bioaktivitet
bekreftes / avkreftes
ved hjelp av assays



steg 2

Sikkerhetstudier - preklinisk

- 1) Akutt toksisk studie i musemodell (14 dg)
- 2) Langtids toksisk studie i rottemodell (90 dg)
(overdose)
- 3) Analyser av ev mutasjoner i bakteriemodeller
- 4) Allergistudier



steg 3

PREKLINISK EFFEKTSTUDIE I DYREMODELL

Aktiv ingrediens vs
placebo

Bioaktive peptider
eller
bare peptider?



n=50

steg 4

Klinisk pilotstudie

Kartlegge:

Dosestørrelse

Effekt

Frafall

Standard avvik

Ev bivirkninger (!)

mm



n=74

steg 5

Fullskala klinisk studie

Statistisk signifikante data
($p < 0,05$)

› Effekt og Sikkerhet

Publiseres i anerkjent
vitenskapelig tidsskrift



n=150

USA (FDA) ok med 1 studie

EU (EFSA) 3 eller flere studier



THE CLEAN, DEEP ARCTIC WATERS OF NORWAY BRING YOU **TENSIOTIN[®]**



A NOVEL AND SCIENCE BACKED NATURAL MARINE INGREDIENT FROM THE ARCTIC FOR MAINTAINING HEALTHIER BLOOD PRESSURE.

Tensiotin[®] is backed by extensive research and its effect of lowering blood pressure is currently being proven through an extensive clinical study to help. It is ideal for people looking for a natural alternative to manage blood pressure and to keep it within a normal and healthy range.



Unlike prescription and over the counter medication, Tensiotin[®] is 100% natural, safe and without any side effects. It is originating in the deep Arctic waters, and is backed by the highest scientific standards. Tensiotin[®] has a proven ACE-inhibiting effect that lowers the blood pressure and reduces the risk for cardiovascular disease.

www.marealis.com

See reverse for product details.

XTRA

(EFSA) "... a **cause and effect relationship** has not been established **between** the consumption of XX and claimed effect"

For EFSA:

#1) Dokumentere biotilgjengelighet
(in vivo)

(Ref. FHF-prosjekt D'Liver)



#2) Dokumentere at peptidet/peptidene
når sitt "point of action"

