

Outcome of NBF Co-creation workshop

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Introduction

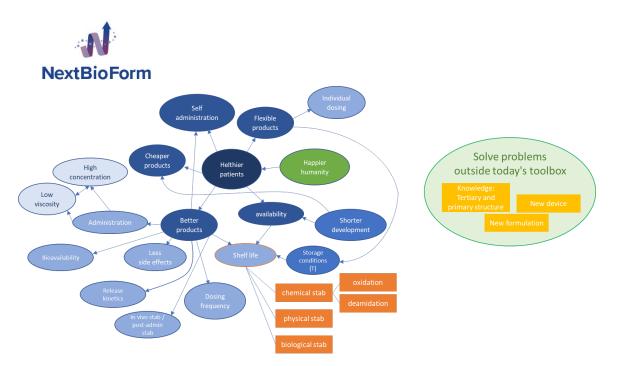
To fully leverage the potential of NextBioForm in context of healthcare system, life science industry and academia, an active innovation strategy is critical. The mission for NextBioForm is to be a gamechanger regarding more patient friendly available biological drug products:

- To have a focus on how to develop drug products that can be easily handled by the patient and in health care
- To improve the time to market for drugs for new break-through therapies

We have performed a workshop to renew or refine existing research areas as well as potential innovations that could be fulfilled by the research in the centre (academic or industrial) or would need another type of setting. The workshop will be led by RISE TTO (Tech Transfer Office) and the setup is called Co-Creation workshop.

In the NextBioForm centre life science (pharma, medical devices, probiotics and service providers), academia and health care collaborate to perform research in industrially relevant scientific areas. The research is mainly performed by academia and closely associated service providers. Industry provides input based on current needs in manufacture and characterization of products. However, the great potential of the centre could allow for a higher ambition with respect to innovation in the clinical treatment using biological drugs, including stabilization of drugs, dosing, manufacture, distribution and actual clinical use. NextBioForm is actively working to find better ways to focus its research in critical areas.

In order to focus the Co-Creation workshop effectively, areas with high innovation needs in this context has been identified in a pre-workshop by the pharma producing parties in NBF. Based on the mindmap below 9 primary needs were identified and conceptualized. These were currently further scrutinized and prioritized and was finally the basis for the scope of the CoCreation workshop (see table below).



The concepts were then ranked based on (monetary) value to the market (1-7) if achieved and complexity to achieve (1-3).

#	Title	Value	Complexity
1	New excipients designed for stabilization during drying	1	2,5
2	The interplay between active ingredients and excipients	2	1,5
3	Molecular understanding of protein stabilization	3	2
4	Room temperature stable liquid formulations	4	1
5	Increased humidity tolerance	4	2
6	Aggregation free protein formulations	5	2
7	Modified release for biologics	6	2
8	What happens after administration	6	3
9	Convenient administration – Flexible administration	7	2,5

Important to note is that the solutions that we seek in the coming workshop go beyond the current state of the art and should be sought outside today's toolbox. Solutions should not be limited to what can be achieved within NextBioForm project/consortium, but also include concepts that can be realized by individual partners, in extended collaborations or by other constellations.

CoCreation Workshop

A two-day workshop based on design methodology in the field of product and business development, aimed at providing an informed decision prior to commencing an innovation project. A concrete customer requirement was formulated and submitted before the workshop.

Responding parties (in the case of NBF this means industrial as well as academic researchers) were invited to attend the workshop for creative concept generation and structured assessment of implementability and profitability. To boost creativity a number of people from other areas as well as end-users can be invited as well. Deliverables from the workshop are a number of completed innovation concepts.

During the workshop we worked together in groups to refine and develop the topics selected from the pre-WS.



Workflow:

Day 1

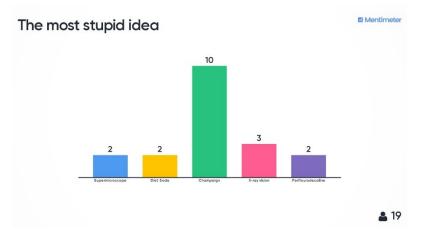
- 1. Introduction
- 2. Most stupid solution (Mentimeter test)
- 3. Brainstorming on solutions to needs A-I
- 4. Canvas production of solutions
- 5. Refine solutions canvases
- 6. Clustering of solution canvases
- 7. Rating of solutions by heart and by brain

Day 2

- 8. Concept portfolio production based on solutions
- 9. Balancing the Concept portfolio

Outcome from the workshop

In order to get our brains going we started with a brainstorming session on the most stupid solution that we could come up with to meet the need of a healthier patient. The mentimeter system was tested by voting on five potential solutions. The winning solution was to drink champagne in order to not feel sick!



The 9 different needs identified during the pre-workshop were introduced in short form (see Appendix 1). Individual and group brain storming led to several ideas that within each group were refined into solution canvases. The solution canvas should have a title, and pros and cons for the idea was listed here.

In the next session each idea was discussed, and improvements suggested from other groups were added. The solutions were then grouped with similar ideas and numbered according the original needs. All workshop participants were then allowed to vote for the five best ideas by, and by brain.



 Mentimete NextBioForm: Best Proposals by BRAIN NextBioForm: Best Proposals by HEART h1 b3 a g6 i5 d1 b1 a6 d4 a3f1 f3_{a1} d3 q1 i4 e1 f1 b3 h1 **a** 16 **a** 16

Based on the voting, the solutions were ranked with 1, 2 or 3 stars (golden stars for heart, and silver stars for brain).

New groups were formed and in the following session each group chose solution ideas that they were inspired by and worked them into concept canvases. 17 concepts were produced in power point format (see Appendix 2). The concept was summarized with a synopsis and a short potential project description based on necessary steps was given in the canvas. In addition, some preliminary estimates of effort needed, business and patient value of the concept was given. Also, critical partners needed, potential financing and regulatory concerns were considered.

In the final session the concept portfolio was evaluated using the mentimeter tool. Both complexity/cost, that is how hard it would be to and how much economical effort would be needed, as well as value/impact the solution would have if it could be achieved was estimated. The most beneficial concepts would ideally be the ones having high value/impact and low complexity/cost, and within the centre we should aim for a balance between the different kinds of projects.

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NBF Portfolio



1: Formulation web portal
2: Sourcing novel drying protectants
3: Protein traps
4: Making the unwanted wanted
5: Using the secret of the tardigrades
6: Live Shelf-Ilife
7: New surfactants to avoid aggregation
8: Sweet as sugar
9: Forced degradation – follow the few
10: Iformulation – Lajuid state
11: Iformulation – Lajuid state
12: Local Microbe Bioplant for Good Gut Health
13: Challenging Freeze Drying Standards
14: New excipients
15: The cool solution to room temperature problem
16: Vaccine for me
17: Controlling aggregation

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Concept	Complexity/Cost	Value/Impact
1: Formulation web portal	5,2	6,1
2: Sourcing novel drying protectants	5,0	6,0
3: Protein traps	5,8	5,5
4: Making the unwanted wanted	6,2	6,8
5: Using the secret of the tardigrades	6,3	5,6
6: Live Shelf-life	6,4	8,0
7: New surfactants to avoid aggregation	5,4	6,4
8: Sweet as sugar	5,8	6,9

Mentimeter

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9: Forced degradation – follow the few	5,3	5,8
10: iFormulation – Solid state	7,6	6,7
11: iFormulation – Liquid state	6,3	6,8
12: Local Microbe Bioplant for Good Gut Health	7,3	7,6
13: Challenging Freeze Drying Standards	5,2	6,3
14: New excipients	5,6	7,8
15: The cool solution to room temperature problem	4,5	6,8
16: Vaccine for me	8,9	8,4
17: Controlling aggregation	6,1	5,5

Finally, the workshop participants voted on their 3 most preferred solutions. However, since this voting only reflects the ranking of the participants and not of the whole NBF consortium it should not be taken as a final ranking of the concepts.

Mentimeter

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Next NBF Action



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The concepts will be considered in the process of establishing a new project portfolio for the next phase of NBF. Concepts alredy included in part or as a whole in project portfolio of NBF are marked with the NBF logo (Appendix 2). The outcome of the workshop is open to public and concepts that the NBF consortium are not able to utilize should ideally be broadcasted in general or pitched to potentially interested parties.

List of Appendices

Appendix 1: Short needs

Appendix 3: Concept portfolio

New excipients to preserve function during drying

The stability of proteins and bacteria is tightly linked to their interaction with water in their natural environment. Thus, drying is very stressful and often the structure is changed when the possibility to bind water disappear. Could new excipients, that will stabilize proteins or bacteria during drying, be chemically designed?

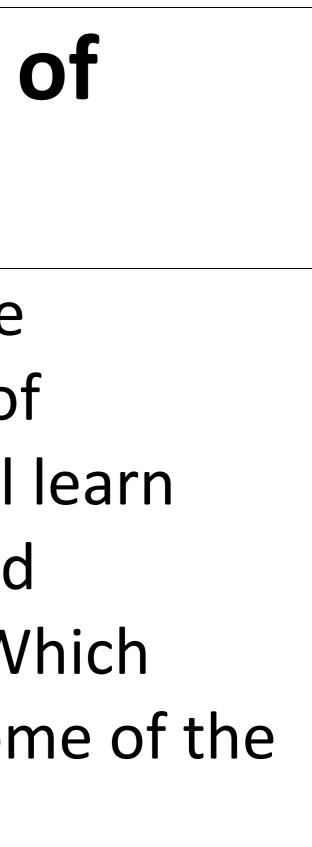


The interplay between active ingredients and excipients

Understanding is needed in order to design better, more stable, formulations that will allow higher patient flexibility. Water is also an excipient and play an important role in dry formulations.

Molecular understanding of protein stabilization

Through better understanding of the interaction between different type of molecules in the formulation we will learn how to distinguish a bad from a good formulation early in development. Which measures are relevant for the outcome of the formulation?



D Room temperature stable liquid formulations Reduced reaction rates for detstabilising reactions would increase stability.

Increased humidity tolerance in dry formulations

Dry formulations are more stable than solutions, but not always enough. Control of the water molecules and how they are moving is needed. Where is the water, and how can it be managed?

Aggregation free protein formulations

High concentration formulations are desired to lower dose volume or frequency, compensate for quick breakdown in body or for low therapeutic effect (potency), but may lead to increased risk of protein aggregation during storage. Preservatives often interact with proteins and their presence increase the risk of aggregation but are required in multidose formulations.

Modified release for biologics

There are numerous controlled release formulations for small molecules and peptides, but not for biologics. Could any of the intrinsic properties as oligomerization or reversible aggregation, fibrillation, be utilized? Ultimate goal is oral delivery.

What happens after administration

What is the fate of the API after administration? Can we affect what happens in the body with the formulation? How do we know?

Convenient administration – Flexible administration

What is convenient for the patient? What makes the patient feel less like a patient? Is oral delivery the holy grail or are there other dosage forms that would work even better?





NextBioForm Proposal Portfolio

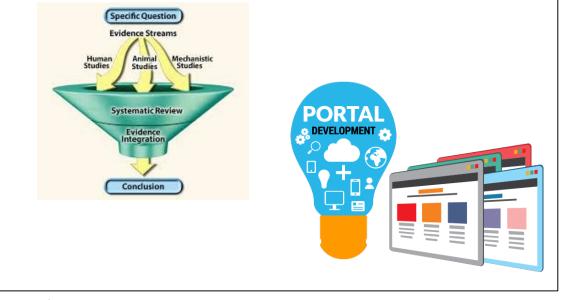
LET'S PUT OUR HEADS TOGETHER TO KEEP AHEAD.



1: Formulation web portal (A3)

Synopsis

- Mine existing data for a defined area (e.g. proteins, bacteria)
- Perform a systematic review of the mined data
- Develop and beta-test a reporting web portal within NBF
- Go public with the web portal
- Present portal to external users and provide incentive for upload data.



Project Proposal Description Systematic review of existing data Set-up a web portal for negative (and positive) results

Step

1

2

3

4

5

6

Preliminary Estimations

R&D Effort			500 K € 5 Years Simple Medium High cost…					
Business Ca	ase/Other Val	ue High v	High value, big market Middle Smaller					
Patient Valu	е	Positiv	Positive Neutral Negative					
Critical Part	ners	Web c	Web designer					
Financing		Vinnov	Vinnova?					
Regulatory (Concerns	No	No					
	Rating							
Value/Impact	6,1	Complexity	mplexity 5,2 Priority					





2: Sourcing novel drying protectants (A2)

Synopsis

- Use existing chemicals/compounds libraries produced by combinatorial chemistry and the synthesis of compound libraries to screen for lyoprotective effects.
- Confirm effects in experimental studies
- Use labeling techniques of identified protective compounds to find the interaction site
- Study the interaction mechanism
- Design or discover novel excipients





Project Proposal Description Step Screen with libraries 2 Experimentally confirm effects 3 Interaction characterization Design or discover novel excipients 4 Validate the new excipients 5 **Preliminary Estimations** X € | 5-10Years | Simple | Medium | High **R&D** Effort cost... **Business Case/Other Value** High value, big market | Middle | Smaller Patient Value Positive | Neutral | Negative **Critical Partners** Research lab with libraries Vinnova? Formas? Financing Yes - new excipients will have to be **Regulatory Concerns** thoroughly tested and registered Rating 6.0 5.0 Priority Complexity Value/Impact



3: Protein traps (F2)

Synopsis

- Trap structure during drying in order to avoid phase separation and local high protein concentration. Gel structure will dissolve upon dissolution (pH, salt, temperature, etc.)
- Trap proteins in microgels, can work as sustained release formulations.
- Protect proteins by encapsulation from moisture, aggregation, deamidation.
- Add water absorbing material (i.e. Upsalite, mesoposous silica) to dry formulations as water activity sink
- Competitive parallel reactions (scavenger excipients)



	Project Proposal										
Step -				I	Descriptio	n					
1	Literature study										
2	lde	ntify feas	sible "trap	os", choic	e of mode	els					
3	Exp	periment	al studie:	s on diffe	rent princi	ples	for protectior	ı			
4											
5											
6											
			Prelin	ninary	Estim	atic	ons				
R&D Eff	ort			2 Year	s (post-do	oc)					
Busines		ise/Othe	r Value	•	High scientific value (potential business value if concept is proved)						
Patient	√alu	е		Neutra	Neutral						
Critical F	Partr	ners		NBF c	NBF consortium						
Financin	ng			NBF o	r public fu	Indin	g				
Regulate	Regulatory Concerns No Yes – if new excipients are needed										
				Ra	ting						
Value/Impa	act	5,5	Сс	mplexity	5,8		Priority				

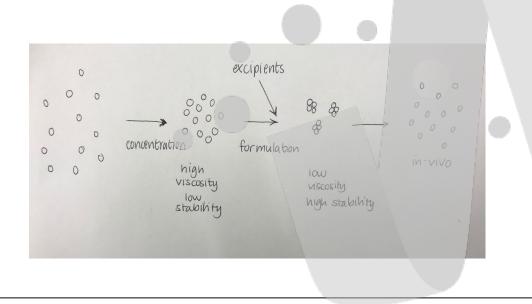


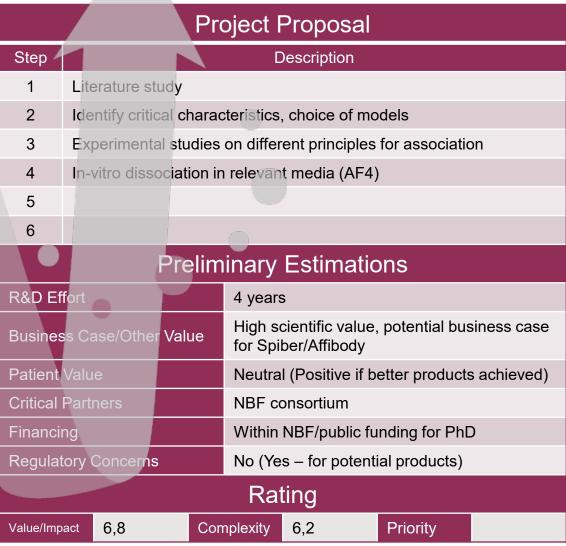
4: Making the unwanted wanted; controlled protein association (G1)

<u>Synopsis</u>

Aggregates would allow higher concentration and give lower viscosity. Higher ordered structure may also protect proteins from chemical and physical degradation.

- Various ways of compacting protein structures in solution
 - reversible oligomerization/aggregation
 - bind proteins reversible to synthetic spider silk or other polymers
- Knowledge about what triggers irreversible aggregation will be gained as well







5: Using the secret of the tardigrades (A1)

<u>Synposis</u>

Various organisms are surviving under extreme conditions. Other industries (e.g.food) have a long history of drying and re-suspending protein structures.

- Learning from nature
 - Bacteria/spores, orgasims living under extreme conditions, tardigrades (björndjur)
- Interdisciplinary learning, e.g food industry



Project Proposal											
Step /	Step Description										
1	1 Literature study on mechanisms, identification of concepts										
2	2 Proof of concept for therapeutic or model proteins										
3	3 Regulatory aspects for potentially new excipients needed.										
4											
5											
6											
Preliminary Estimations											
R&D Ef	fort			2 Year	s (post-doc)						
Busines	s Ca	ase/Other	Value	High s	High scientific value (potential						
Patient	Valu	le		Neutra	Neutral						
Critical	Part	ners		NBF c	NBF consortium						
Financi	ng			NBF o	r public fundir	ıg					
Regulat	ory	Concerns		No Ye	es – if new ex	cipients are n	eeded				
				Ra	ting						
Value/Imp	act	5,6	Со	mplexity	6,3	Priority					



6: Live Shelf-life (D2)

Synopsis

Dynamic expiration date

- Adapt expiration date depending on time-temp experience of the product (hard upper and lower temp limits and end of shelf-life based on time)
- Patient information interface (both direct by color code on the package/device and by an app explaining why the color code and/or how to treat the medicine based on the situation)



Project Proposal Step Description Identify technology and stakeholders 1 2 Freedom to operate study 3 Advice from regulatory body Design of stability studies (temp profiles/freeze-4 thaw/light/humidity/transport at different times) Predictive model based on stability study 5 Validation of model 6 **Preliminary Estimations R&D** Effort 4,5 Years **Business Case/Other Value** High patient value, unclear business value **Patient Value Highly Positive Critical Partners** Modelling, app, sensor Financing New funding **Regulatory Concerns** Yes – new concept Rating 0,8 Complexity 6,4 Priority Value/Impact



7: New surfactants to avoid aggregation (F4)

<u>Synopsis</u>

Using liberies of excipients to understand their interaction with proteins

Key interesting surfactants are

-Sugar based

-Charged sugar based

-Amino acid based surfactants

-Polypeptide based headgroups

-Phospahtedylcoline

Could be interesting to look at the numbers of tails

Set up HTS method for mapping

Set up calorimetric or other methods for further studies

Using x-rays and neutrons to understand key systems

Would lead to next generation surfactants tailor made for functionality

Project Proposal											
Step /			۵	Descriptio	n						
1	Identifying p	Identifying proper surfactant liberies									
2	Identify HTS	6 methods									
3	Identifying o	compleme	ntary me	ethods							
4	Data mappi	ng and ch	emornet	rics to ev	aluate						
5	Developme	nt of new	surfacta	nts							
6											
Preliminary Estimations											
R&D Ef	fort		4 year	project							
Busines	s Case/Othe	r Value	High s	cientific a	nd commercial potential						
Patient	Value		Better	safer drug	g products						
Critical	Partners		Tools a	Tools and safety							
Financi	ng			research i panies.	in nextbioform- Development						
Regulat	tory Concerns	5	Yeas s	afety							
			Ra	ting							
Value/Imp	oact 6,4	Con	nplexity	5,4	Priority						

NextBioForm

8: Sweet as sugar – the development of new sugar based excipients (D4)

Synopsis

To replace PEG-based chemistry with sugar based one

Today PEG based chemistry is used

- For surfactants to stabilize emulsions, <u>increase stability of proteins</u>, solubilization,
- For peg based polymers, co-solvent, bulking agent
- PEG attachment to proteins for increased in-vivo stability
- In the NextBioform we could work both with mapping unmet needs
- In NextBioform work with proof of concept for sugar surfactants

				Pro	oject l	⊃ropo	sal				
Step -					۵	Descriptio	on				
1	Ma	Mapping of unmet needs									
2	lde	ntifying p	orope	r carl	oohydra	te structu	ires				
3	De	velop sui	table	biote	echnolog	gy toold f	or pr	oduction of ex	kcipients		
4	Pro	of of for	mulat	ion c	oncept						
5	Sca	ale up an	id sel	I							
6											
Preliminary Estimations											
R&D Ef	fort		Γ		5-10						
Busines	ss Ca	ase/Othe	r Valı	le	High c	igh commercial potential					
Patient	Valu	е			Better safer drug products						
Critical	Partı	ners			Tools and safety						
Financi	ng							extbioform- De competence o	•		
Regulat	tory (Concerns	5		Yeas s	afety					
					Ra	ting					
Value/Imp	act	6,9		Con	nplexity	5,8		Priority			



9: Forced degradation – follow the few (?)

<u>Synopsis</u>

- Combine force degradation with labeling to be able to follow what happens with the proteins when introduced in pristine solution
- Labeling would include
 - Label first degradation and then follow
 - Degradation that can be followed- to follow
 - Labeling through degradation to follow
- What to follow would
 - Aggregation
 - Adsorption
 - Reversible quaternary structure
 - Population differences in conformational structure
- Especially interesting for Neutrons
- Could be linked to what happens in- vivo

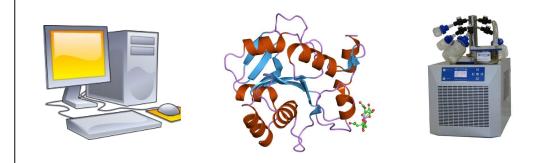
	Project Proposal										
Step /			۵	Description							
1	Design labling principle										
2	Understand methods how to follow the population										
3	3 Understand and develop methods for forced degradation										
4	Used to stu	dy differen	nt pheno	mena							
5	5										
6											
Preliminary Estimations											
R&D Ef	fort		X€ 1	-2 years for m	ethod dev						
Busines	s Case/Othe	r Value	High v	alue research							
Patient	Value										
Critical	Partners										
Financi	ng		Within	NextBioform							
Regulat	tory Concerns	\$	No								
			Ra	ting							
Value/Imp	act 5,8	Con	nplexity	5,3	Priority						



10: iFormulation – Solid state (B2)

Synopsis

- Molecular dynamic simulation of protein formulations in solids.
- Simulate systems with low water content.
- Focus will be in on the modeling
- Challenge will be the time needed for the simulation and methods to speed up time to equilibrium
- The gain would be new modeling tools that could
 - Understand mechanism of protein excipient and water interaction
 - Understanding properties of excipients
 - Using the model to optimize freeze drying





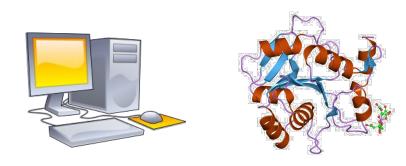
Project Proposal

Step				C	Description				
1	Dev	Developing methodology							
2	Cor	Compare experimental data with models							
3	Und	Understand mechanism of protein surfactant interaction							
4	Usi	ng the model	to op	otimize fr	eeze drying				
5	Usi	ng verify the	conce	ept					
6	Edu	Educate industry on how to use the tools							
Preliminary Estimations									
R&D Ef	ffort			X€ 5-	-10 High cost				
Busines	ss Ca	ise/Other Vali	Je	High value for both research and if implement for industry					
Patient	Value	e		In the long run more efficient drug development					
Critical	Partr	ners							
Financi	ng			Other financing (e.g. VR or EU), will be pursued by NBF partners outside NBF					
Regulat	tory C	Concerns		No					
				Rat	ting				
Value/Imp	bact	6,7	Con	nplexity	7,6	Priority			

11: iFormulation – Liquid state (B2)

<u>Synopsis</u>

- Molecular dynamic simulation of protein formulations in liquid state
- Use and refine existing methods to study aggregation and excipient interaction
- Focus will be in on comparison between models and experiments
- Challenge will be the time needed for the simulation and methods to speed up time to equilibrium- Realistic and universal force fields
- Possibility to model chemical reactions with quantum dynamics
- The gain would be understanding of
 - Understand mechanism of protein excipient interaction
 - Understanding aggregation
 - Using the model to optimal
 - Linking structure to chemical degradation





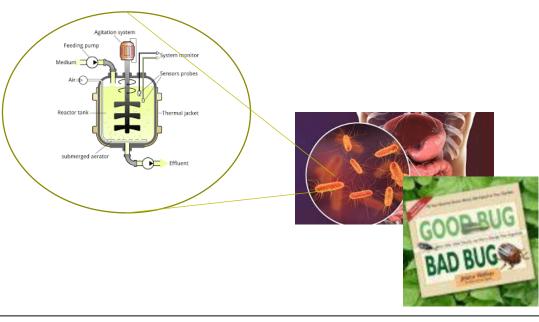
	Project Proposal										
Step		Description									
1	Fin	Find collaborators									
2	Со	mpare experi	ment	al data w	/ith mode	els					
3	Un	derstand med	chanis	sm of pro	otein surf	actar	nt interaction				
4	Us	ing the mode	l to op	otimize d	esign of	excip	pient				
5	Us	ing the mode	l to co	ompare v	vith expe	rime	ntal data				
6	Ed	ucate industr	y on ł	now to us	se the too	ols					
	Preliminary Estimations										
R&D Ef	ffort			5-10							
Busines	ss Ca	ase/Other Val	ue	High value for research/hig value							
Patient	Valu	e		In the long run more efficient drug development							
Critical	Part	ners		Theoretical chemists							
Financi	ng			Joint N	lextBioFo	orm o	ther financing	g – EU SSF			
Regula	tory	Concerns		No							
	Rating										
Value/Imp	bact	act 6,8 Complexity 6,3 Priority									



12: Local Microbe Bioplant for Good Gut Health (I1)

<u>Synopsis</u>

- Technologies from Biogaia and Ilya Pharma will be combined to produce microorganisms that will produce API proteins to treat Inflammatory bowel disease (local treatment) to start with, could be expanded later.
- Present treatment today is to give systemic treatment for a local disease (via IV). This leads to severe side effects to the patient. Solution would be to have an oral "drug" that is a "microbe-bioplant" that will produce the API "in situ" in the gut.



Project Proposal

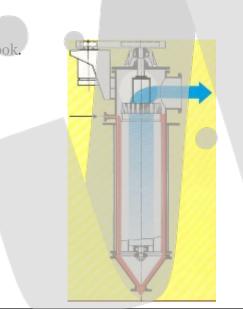
Step				C	Description					
1	Inve	Investigate regulatory aspects.								
2		Try to find a protein sequence that have gone off patent to test in project. Agree on protein and define vector for cloning, for example Anti-TNF. Absorptions levels in gut should be low?								
3		Identify good bacteria strain that is robust and meet the needs cloning, safe, host (need to colonize and stay)								
4	Clon	e sequence into the	bacteria	a.						
5	Prod	luction and formulati	on (free	ze drying?)						
6	Perf	orm testing (Ferring	have dif	ferent mode	els). Identify good mo	odels				
Preliminary Estimations										
R&D Ef	fort			4 years total /6 man years						
Busines	ss Ca	ase/Other Val	ue	Novel approach, large patient group						
Patient	Valu	е		Positiv	e					
Critical	Parti	ners		Ferring, Biogaia, Ilya pharma						
Financir	ng			Extern	al, with Nextbi	ioform collabo	oration			
Regulat	ory (Concerns		Need to investigate						
				Rat	ting					
Value/Imp	act	7,6	Corr	nplexity	7,3	Priority				



13: Challenging Freeze Drying Standards (B1)

Synopsis

- Replace conventional freeze drying with other alternatives.
- Investigate different parameters, including "controlled collapse".
- Different drying options:
 - Speed up freezing process using for example flash freezing.
 - Use vacuum drying (continuous,falling film, thin film) instead of freeze drying.
 - Ultrasound, etc.
- Design vials to optimize drying.
- Final result stable product with uniform look.



Project Proposal					
Step -		Description			
1	Define model substance (proteins, bacteria)				
2	Identify optimum drying process by concidering all alternatives.				
3	Investigate diffe	erent parameters, methods for drying process			
4					
5					
6					
Preliminary Estimations					
R&D Eff	ort	Two post docs?			
Busines	s Case/Other Va	Alue Can reduce drying time – economic. Science.			
Patient \	/alue	positive			
Critical F	Partners	Linked to WP2 NBF			
Financin	g	Within NextbioforM			
Regulato	ory Concerns	Low, Need to be confirmed.			
Rating					
Value/Impa	/Impact 6,3 Complexity 5,2 Priority				

14: New excipients – helping the authorities help us (A2)

Project Proposal

<u>Synopsis</u>

- Introducing new excipients to market is currently extremely complicated and costly
- This complicates formulation work and inhibit innovation
- These issues can be addressed by:
- Possibility to form consortia so cost for new api can be shared (and all get share of profit)
- Educate authorities so they understand the need. Risk mitigation. Stop regarding excipients as non-active ingredients
- Reduce refine animal testing acceptance of in-vitro/in-silico modelling tox data. Use learnings from cosmetics industry – it is now animal test free and still introduce new materials. Especially 'simple' wellknown species such as sugar, often excipients should not have to be tested repeatedly. Repurposing substances for other areas. Flexibility of regulatory framework. Authorities could share their vast information in a searchable database.





Project Proposal					
Step	Description				
1	Mapping – stakeholders (existing groups, authorities)				
2	Identification of key unmet needs for new excipients				
3	Identify and form relevant groups/consortia /workstreams				
4	Collect learning from cosmetic industry – minimize animal testing				
5	Stream a – educate authorities – show need Stream b – assess /improve in-vitro methods				
6	Together with authorities agree n new framework for new excipients				
Preliminary Estimations					
R&D Effort More than 1 billion € 5 Years High effort					
Business Case/Other Value		High value, big market			
Patient Value		Positive			
Critical Partners		Ingredient manufacturers, authorities, big pharma			
Financing		External additional funding to WP5			
Regulat	tory Concerns	Yes – by definition!			
Rating					

5.6

Complexity

Priority

7.8

Value/Impact

15: The cool solution to room temperature problem (D1)

Synopsis

- Chargeable smart minifridge, USB and solar cell
- App is consumer-centric. Gives info like: temp too high, container empty, time to take medicine. Connected and able to log temp no of doses
- AI built in to this medical device? Regulatory?



Project Proposal

Step	Description				
1	Freedom to operate study				
2	Involve device manufacturer				
3	Proof of principle (prototype)				
4	patent				
5					
6					

Preliminary Estimations

R&D Effort		Mediur	Medium cost			
Business Ca	ase/Other Value	Mediu	Medium value, small market			
Patient Valu	e	Positiv	Positive			
Critical Part	ners		Device manufacturer and app programmer patient groups			
Financing		Extern	External (patient groups)			
Regulatory (Concerns	Yes –	Yes – medical device class 2			
Rating						
Value/Impact	6,8	Complexity	4,5	Priority		



16: Vaccine for me (I3)

Synopsis

- Preventing immunological disease such as rheumatism by screening for early markers and discovery at pre-disease stage
- Outcome: Personalized medicine and possibly cure.
- Decision: which diseases to screen for
- Health economic aspects
- Learn from similar approaches ongoing for insulin screening (Skåne)
- Who takes cost for screening

Project ProposalStepDescription1Identification of the need-market-desease2Identification of the possible disease markers3Development of rapid screeing method for the desease marker4Establishment of production system (doctor/producer/patient)56

Preliminary Estimations

R&D Effort	1 B€ 15 years High cost				
Business Case/Other Value	High value, big market Middle Smaller				
Patient Value	Positive				
Critical Partners	Drug manufacturere-Healthcase athorities				
Financing	External (patient groups/healthcare authorities)				
Regulatory Concerns	Yes – approval needed				
Rating					
Value/Impact 8,4 Col	omplexity 8,9 Priority				



17: Controlling aggregation by using Intrinsically disordered protein as chaperon (F3)

Synopsis

- IDP is a class of proteins that lack fixed or ordered 3-dimensional structure.
- It has been observed in nature that this type of proteins exists in some desiccated species and protects them from being damage in the desiccated condition.
- One of the hypothesis is that the IDP bind to the protein and form a chaperon upon drying and thus protect the protein from aggregation in the dry state.
- Outcome: molecular understanding of IDP protein interaction.

Project Proposal							
Step /			۵	Descriptio	n		
1	Literature study and selection of IDP models						
2	Feasibility s	tudy for m	nodel pro	teins			
3	Structural a	nd dynam	ical char	acterizati	on at large scale facilit	ies	
4	Simulation s	study					
5	Proposed m	echanism	n of chap	eron form	nation		
6							
Preliminary Estimations							
R&D Effort 200k € 2 year Simple Medium High cost							
Busines	Business Case/Other Value High value, big market Middle Smaller					er	
Patient	Patient Value Positive						
Critical Partners Within				/ithin NextBioForm			
Financi	Financing Vinnova, VR, NextBioForm						
Regulatory Concerns No							
Rating							
Value/Impact Complexity 5,2 Priority							

