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"ACS Webinars updates and encourages me as a recent graduate in diverse fields of pharmaceutical science. This webinar specifically helped come across members coming from relatable background and my desired career path. I hope to get in touch with them for guidance!"

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Fan of the Week

Kirti Shetty
MSc (Pharmacology),
King's College London

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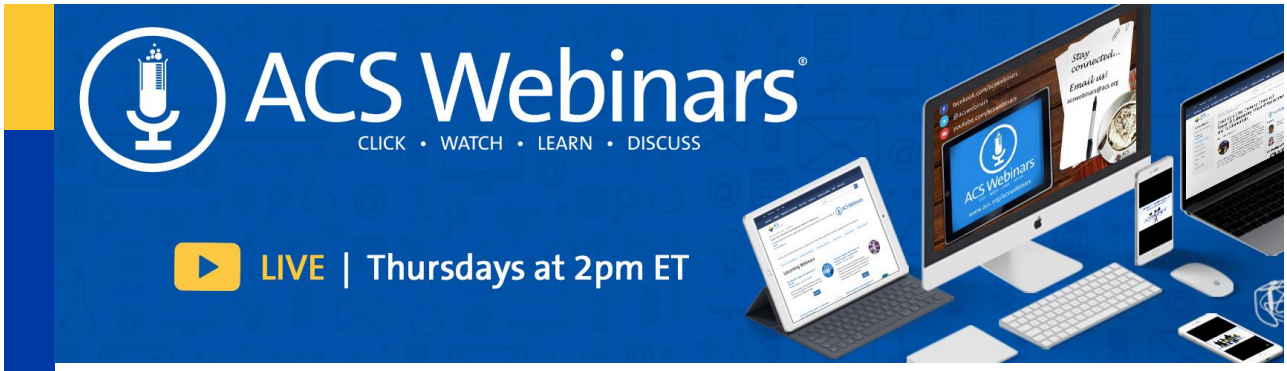

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Celebrating 4 years & 40 Drug Discovery Webinars!

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2014

1. Drug Discovery Series #1 - Current Drug Discovery and Development Process
(DDS #1) Watch this overview of the drug discovery and development process to learn the stages and challenges in every step.
2. Primer in Drug Target Classes
(DDS #2) Listen in on a discussion on the big four druggable families and the difference between small molecule and biotherapeutic targets.
3. Key Concepts in Identifying Drug Leads
(DDS #3) Discover how drug-likeness is a deceiving concept, explore the Rule of Five, and show how lessons from the past may guide the present.
4. Lead Optimization - Building Efficacy & Safety
(DDS #4) Learn strategies on how to effectively optimize small molecule hits and rapidly assess your findings.
5. Tips for Filing IND and Starting your Clinical Trials
(DDS #5) What do you need to know when filing for Investigational New Drug submissions to the United States Food and Drug Administration?
6. The Role of Chemistry in Clinical Trials: The Big Expense & Lessons Learned
(DDS #6) Learn how the properties of the candidate impact decisions in the discovery process.
7. Pharmacoeconomics and IP Strategies in Drug Development
(DDS #7) Review the basic principles of Pharmaco-economics in drug development strategies as well as its role in determining health insurance coverage of drug products.
8. Future of Drug Discovery - Challenges, Risks and Rewards
(DDS #8) Explore how how risks and challenges will be dealt with in the future and the key skill sets required of future medicinal chemists.

Co-Produced By

aaps American Association of Pharmaceutical Scientists

Division of Medicinal Chemistry

2015

- Designing Better Drug Candidates
(January) Learn various factors that can be used to improve candidate quality from Dr. Paul Leeson.
- Strategies to Improve Solubility of Drug Candidates
(February) Learn a number of different strategies for improving drug solubility through structural modification.
- Fragment-Based Drug Design Strategies
(March) Finding the right drug target is becoming increasingly difficult. Learn how focusing on the smaller picture can have big results.
- Screening Strategies
(April) Learn the pros and cons of different screening strategies.
- Avoiding PAINS (pan-assay interference compounds)
(May) Jonathan Baell shares some tips on how to avoid the dead ends of drug discovery.
- Accelerating CNS Positron Emission Tomography (PET) Ligand Discovery
(June) Join Lei Zhang as he lays out a set of preferred parameters for which has yielded successful PET ligands and reduced resources and timelines.
- X-ray Crystallography in Drug Discovery
(July) Jon Mason and Miles Congreve describe what protein-ligand X-ray data can do for you.
- Choices and Trends in Solid Dosage Form Selection
(August) Discover the pros and cons of the different solid state forms and what to consider when selecting.
- Delivery Options to Support Dose Escalation in Preclinical Toxicology and Pharmacodynamic Activity Studies
(September) Gain an understanding of acceptable drug delivery approaches to support preclinical dose escalation.
- Pharmacokinetic Considerations in Drug Design and Development
Learn about key pharmacokinetic concepts including clearance, volume of distribution, half life and protein binding.
- Prodrugs in Drug Discovery
(November) John Higgins shares the utility of prodrugs, their general properties and prerequisites for optimal performance.

2016

2017

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Upcoming ACS Webinars

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Thursday, April 5, 2018

Creating New Models to Combat Neglected Disease Through, Industry, Government, and Public-Private Partnerships

Co-produced with ACS Infectious Diseases

Experts

Michael Pollastri
Northeastern University

Félix Calderón
GlaxoSmithKline

Thursday, April 12, 2018

NSF's Big Ideas: *Understanding the Rules of Life and The Quantum Leap*

Co-produced with ACS External Affairs & Communications

Experts

Angela K. Wilson
National Science Foundation

Cynthia J. Burrows
University of Utah

Theodore Goodson III
University of Michigan

Glenn Ruskin
American Chemical Society

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- **Clinical Pharmacology**
- **Manufacturing & Bioprocessing**
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YouTube video:
https://www.youtube.com/watch?v=1DOxLBg0Ouw

Website: www.aapspharmsci360.org

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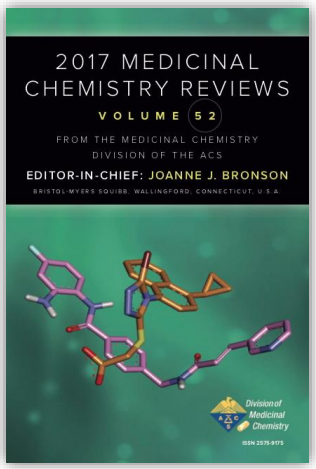

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A Nanomedicine Overview for mRNA Delivery: Innovative Methods Using Lipid Nanoparticles

Session 3 of the 2018 Drug Design and Delivery Symposium

Dennis Leung
Senior Scientific Manager, Genentech

Marianna Yanez Arteta
Senior Scientist and Physical Chemist Formulator, AstraZeneca

Slides available now and an invitation to view the recording will be sent when available.

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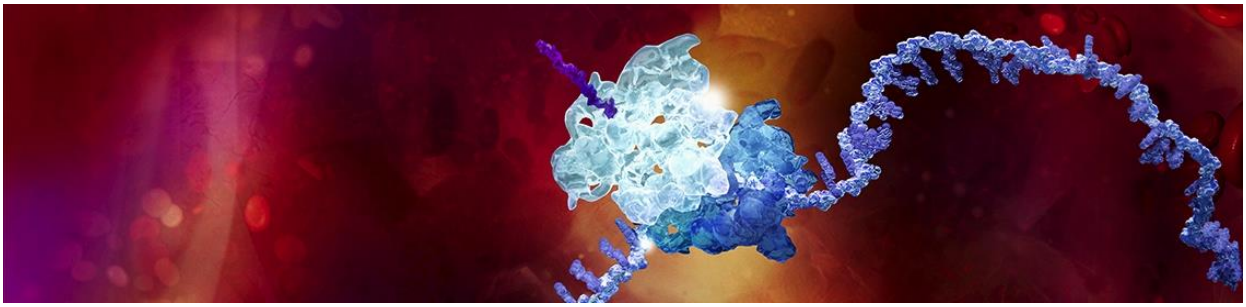
AstraZeneca

A Nanomedicine Overview for mRNA Delivery: Innovative Methods Using Lipid Nanoparticles

Marianna Yanez Arteta

ACS Webinar: Drug Design and Delivery Series 2018 29 March 2018



What will you learn in this webinar?

1	Nanomedicines for drug delivery
2	mRNA therapeutics: Promises, Challenges and Advances
3	Lipid Nanoparticles (LNPs) for RNA delivery
4	A (brief) background on Small Angle Scattering
5	LNPs for mRNA delivery: Characterization and Performance
6	Summary and Future Perspectives

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Why do we need nanomedicines?

Drugs are changing and their delivery requirements are changing.

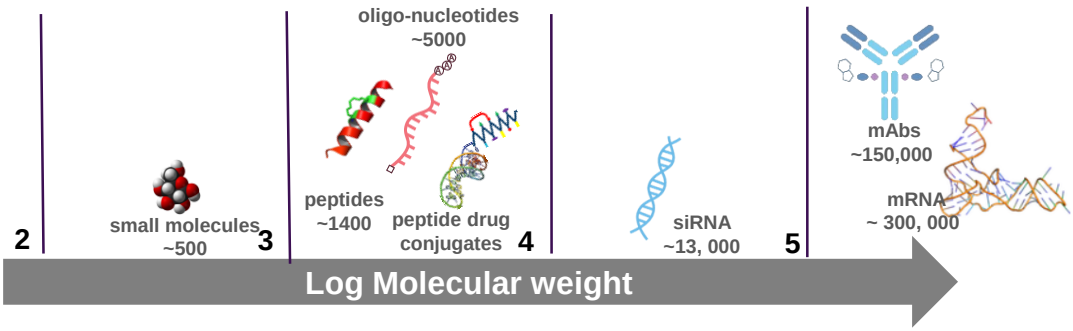

Figure courtesy of Marianne Ashford

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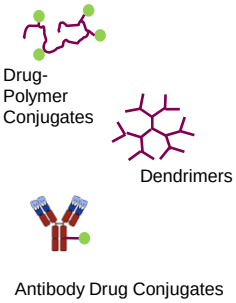
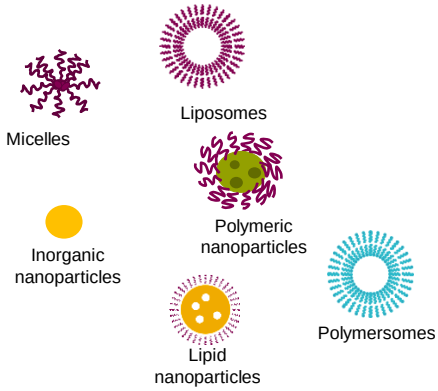
Nanomedicines for drug delivery

- Nanoparticles of drugs or biologics between 1-100 nm.





solid drug nanoparticles

drug chemically linked to a carrier

drug encapsulated in a carrier

Figure courtesy of Marianne Ashford

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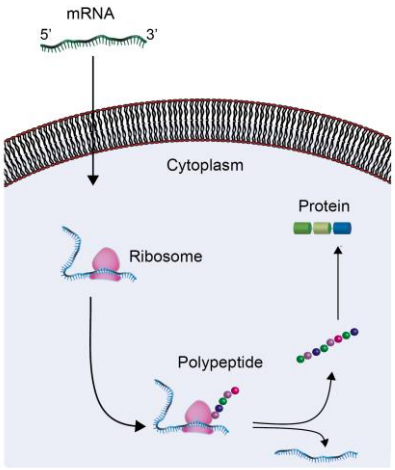
Promises and Challenges of *mRNA* therapeutics

- **Promises:** Production of proteins *in vivo* by administrating *mRNA*

- **Challenges:**

1. Crossing cell membrane for the long negatively charged *mRNA*.
2. Enzymatic degradation of *mRNA* before reaching target.
3. Finding a biocompatible vehicle.



Schematic representation of the mechanism of in vitro-transcribed mRNA translation and protein replacement.
(Image courtesy of Kristina Friis)

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Audience Challenge Question

ANSWER THE QUESTION ON BLUE SCREEN IN ONE MOMENT

How many mRNA therapeutic treatments have been granted FDA approval?

- None
- 1
- 3
- 7
- 10

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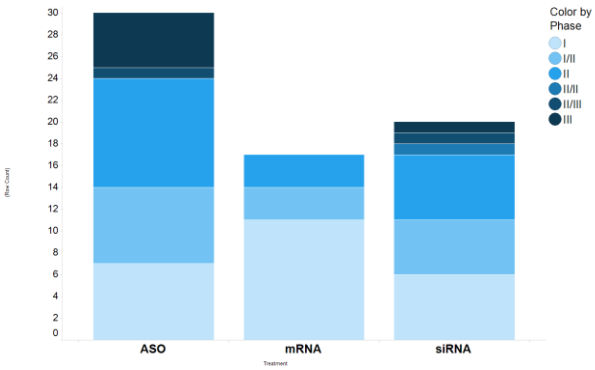
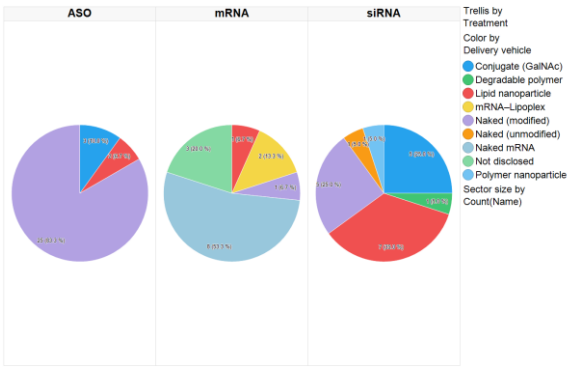
Clinical trials for RNA and delivery systems

Clinical trials involving RNA delivery by treatment and clinical phase



Clinical trials involving RNA delivery by treatment and delivery vehicle



Data taken from Kaczmarek et al. Genome Medicine 2017 and collated by Arpan Desai

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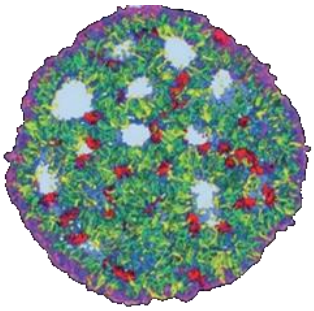
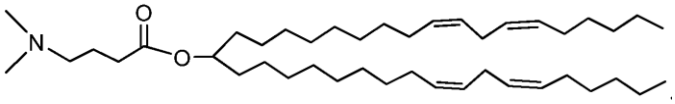
Lipid Nanoparticles (LNPs) for RNA delivery

LNPs: cationic ionizable lipid (CIL), cholesterol (Chol), distearoylphosphatidylcholine (DSPC) and a poly(ethylene glycol lipid).



Representation of LNP containing siRNA based on molecular simulations
(Rozmanov et al. Faraday Discussions 2014)



CIL: Dlin-MC3-DMA

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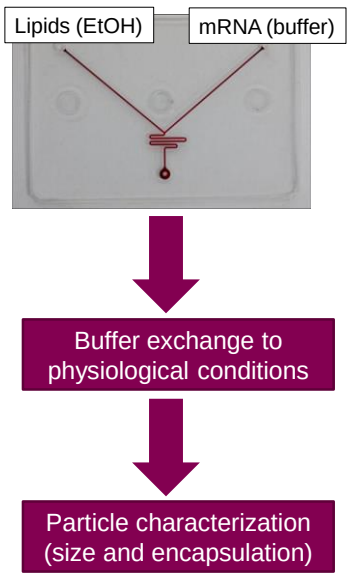
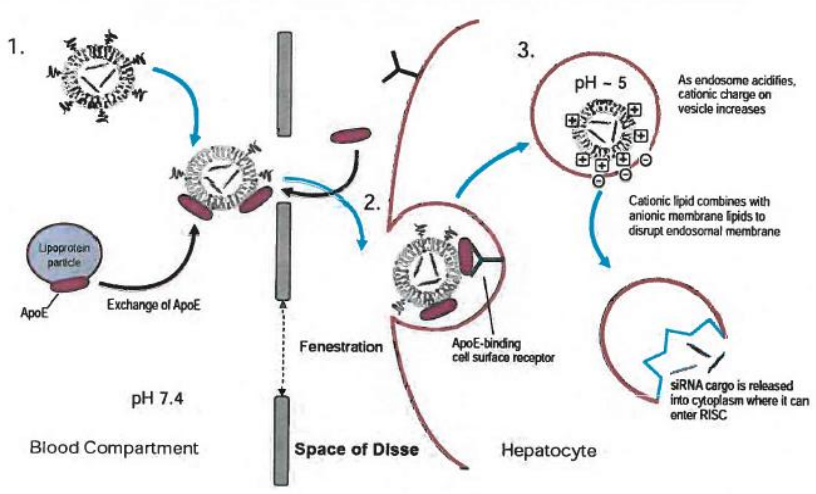
LNPs preparation approach: Using microfluidics



Easily produced with a microfluidic mixer with a high encapsulation efficiency (> 90%).

22

LNPs proposed mechanism of action for IV delivery to hepatocytes



Akinc et al., (2010) *Mol. Ther* 18:1357-1364

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Some examples of the use of LNPs in RNA drug discovery

- Alnylam Pharmaceuticals reported successful on Phase III clinical trials of Patisiran™, siRNA delivered using LNPs for hATTR amyloidosis.

- Moderna has completed clinical trials in Phase I/II for Zika vaccination using LNPs.

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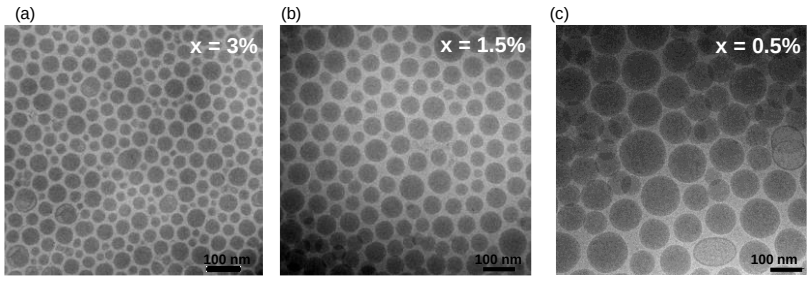
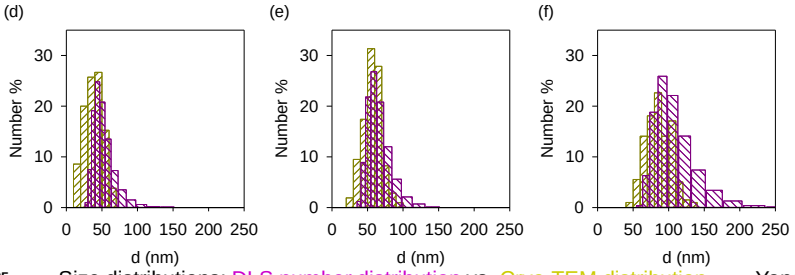
Controlling the size of the LNPs





Standard approach:
CIL:Chol:DSPC:PEG-lipid in a 50:40-x:10:x mole ratio.

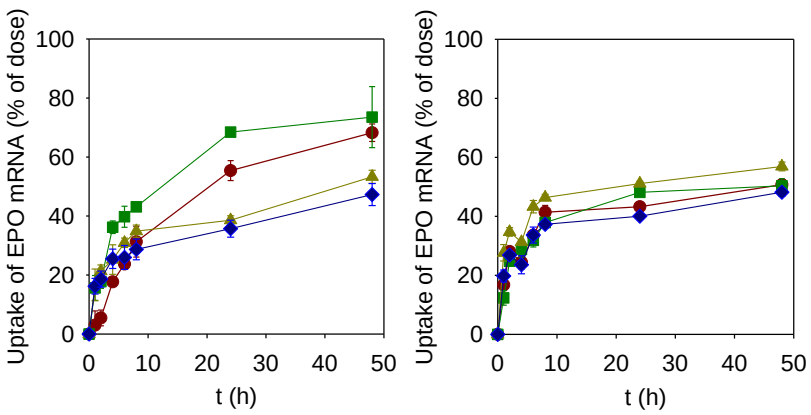
43 nm

62 nm

89 nm

25 Size distributions: DLS number distribution vs. Cryo-TEM distribution Yanez Arteta et al. *PNAS Just accepted*

In vitro uptake of LNPs of different size



Tracking of LNPs containing ^{3}H labelled DSPC.

43 nm

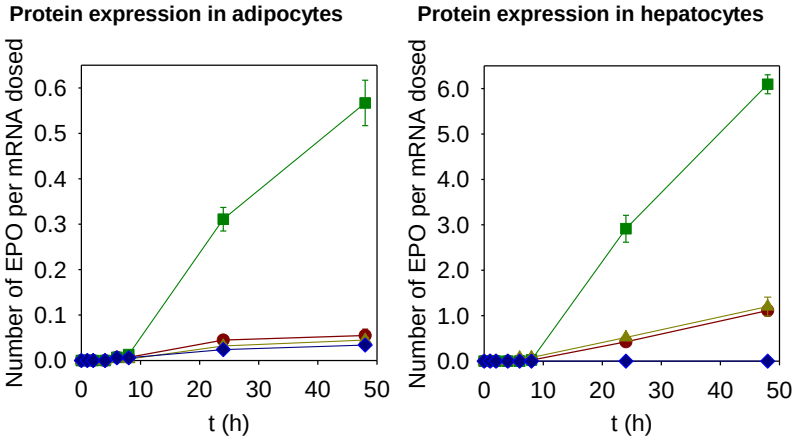
62 nm

89 nm

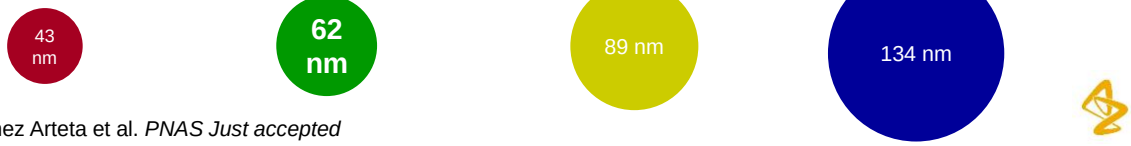
134 nm

26 Yanez Arteta et al. *PNAS Just accepted*

Expression of EPO mRNA *in vitro* for LNPs of different size



Why do LNPs of 62 nm have a higher transfection efficacy?



27 Yanez Arteta et al. *PNAS Just accepted*

Audience Challenge Question

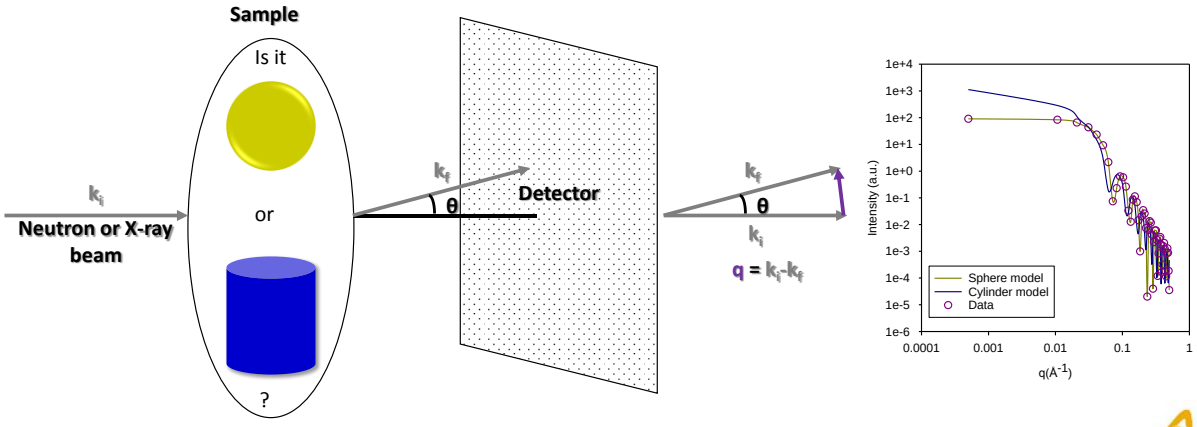
ANSWER THE QUESTION ON BLUE SCREEN IN ONE MOMENT

Have you performed small angle scattering experiments?

- I have measured small angle X-ray scattering (SAXS)
- I have measured small angle neutron scattering (SANS)
- I have vast experience in small angle scattering measurements
- I do not have experience with this technique

A (brief) background on Small Angle Scattering

Small angle scattering allows us to understand the shape and the size of nanomedicines:



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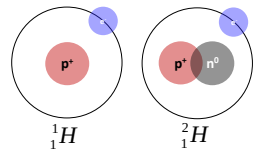
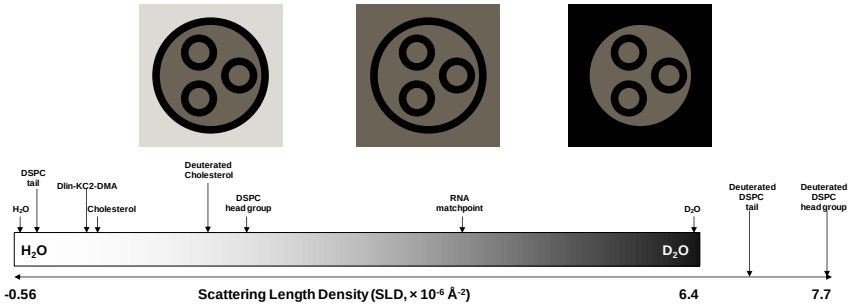
Why do we use neutron scattering?

Selective deuteration of lipids and/or solvent produce different scattering profiles.



b: Scattering length



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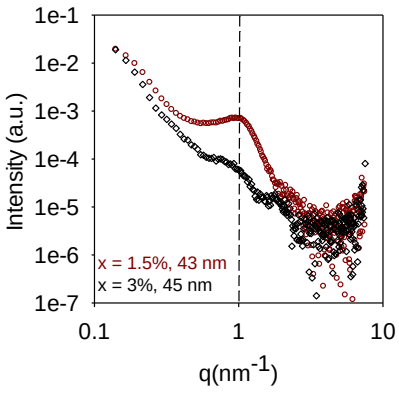
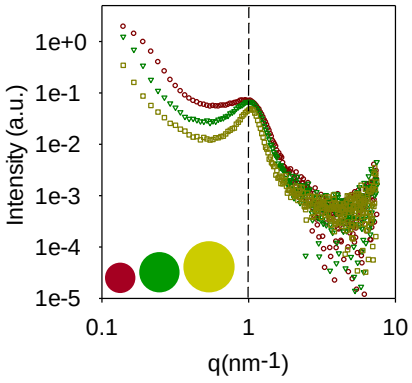
LNPs containing mRNA have a structured core

mRNA-LNPs have a “structured core” with a 6 nm correlation distance.

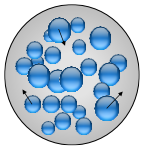
SAXS of mRNA LNPs vs. *Empty LNPs*



SAXS of mRNA LNPs of different sizes

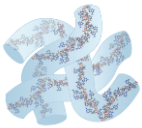


- Inverted micellar phase? (Literature)



- Onion?

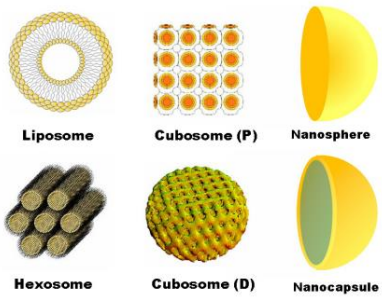
- Wormlike micelles?



31 Yanez Arteta et al. *PNAS Just accepted*

Why do we care about the structure of LNPs?

- LNP transfection efficacy is very low, 1-2% (Gilleron et al. (2013) *Nat. Biotech.* 31:638-646)
- Which type of structures will facilitate endosomal escape?



Géral et al., (2013) *Pharmaceutics* *5*:126-167

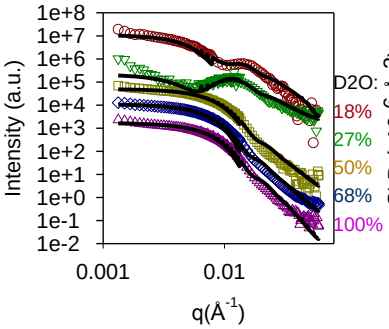
CAM2032: Fluid crystal © formulation for prostate cancer Phase II.

camurus.

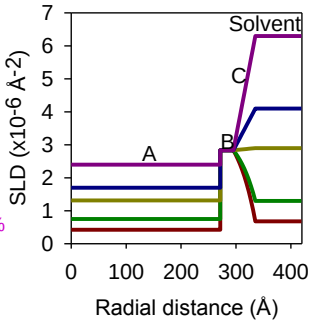
32

Location of lipids within the LNPs obtained by SANS

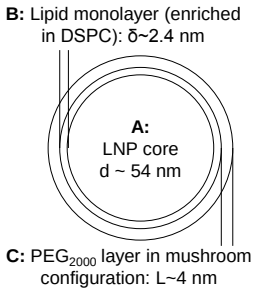
SANS of LNPs with deuterated DSPC and Chol in buffer with different H_2O/D_2O ratio



SLD profiles corresponding to the fits to the core-shell model



Schematic representation of the lipid distribution in the LNPs

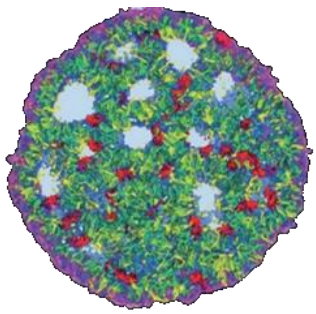


A. LNP core:

- Cationic ionizable lipid (CIL)
- Cholesterol (CHOL)
- 24% water
- mRNA

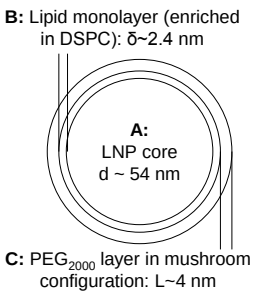
33 Yanez Arteta et al. *PNAS Just accepted*

Location of lipids within the LNPs: Comparison with previous models



Representation of an LNP containing siRNA : CIL, Chol, DSPC and PEG-lipid. Based on molecular simulations
(Rozmanov et al. Faraday Discussions 2014)

Schematic representation of the lipid distribution in the LNPs



A. LNP core:

- Cationic ionizable lipid (CIL)
- Cholesterol (CHOL)
- 24% water
- mRNA

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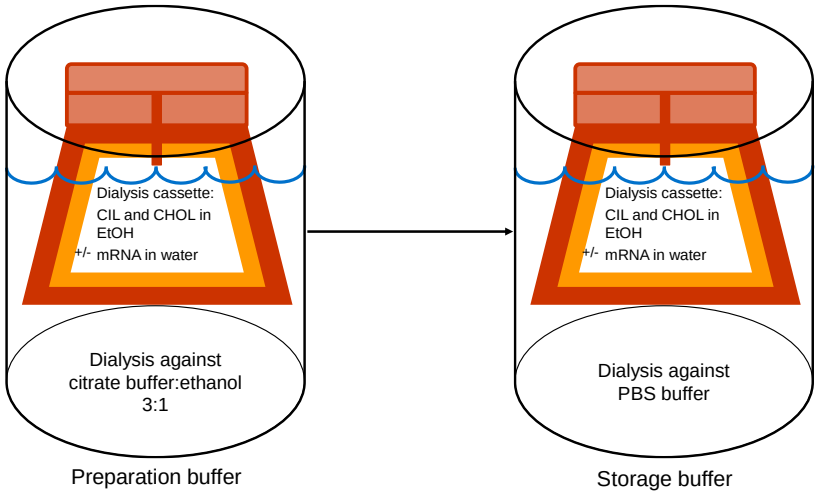
Further exploration of the LNP core



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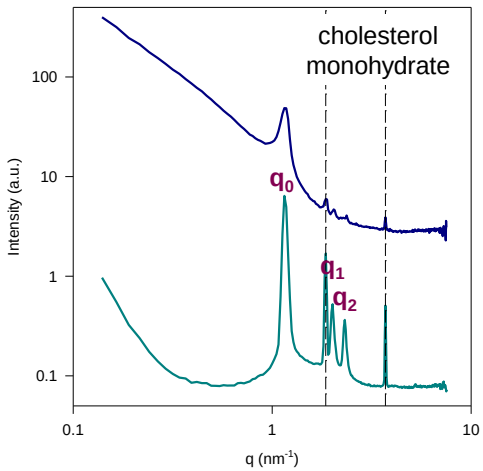
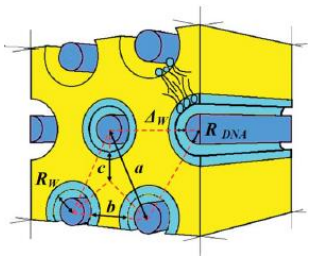
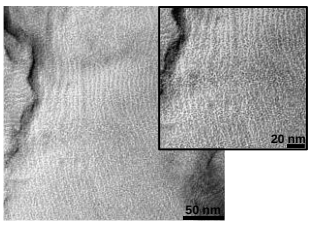
SAXS of the core phase: citrate:ethanol 3:1 phase

Small angle x-ray scattering (SAXS) for empty and polyA LNP bulk phases (pH 3, 25% EtOH)





Schematic representation of a reversed hexagonal phase structure. (Bilalov *et al.* Soft Matter 2011)



Freeze fracture micrograph of the LNP core phase in citrate:ethanol 3:1 phase

Reversed hexagonal phase (water or water/RNA rigid cylinders):

- $q_1=\sqrt{3}*q_0$
- $q_2=\sqrt{4}*q_0$

Center-center distance a=6.2 nm

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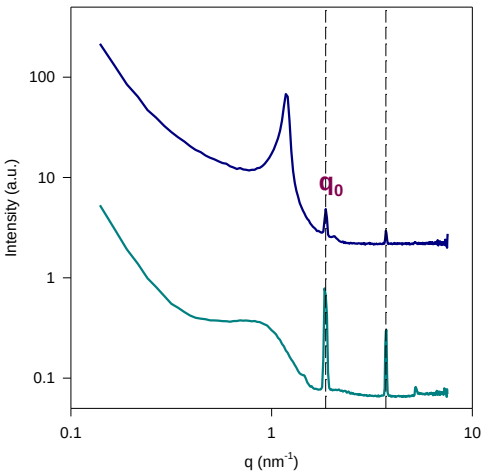
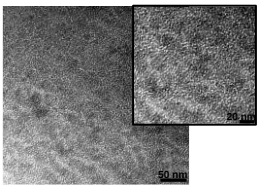
SAXS of the core phase: PBS buffer and comparison with LNPs

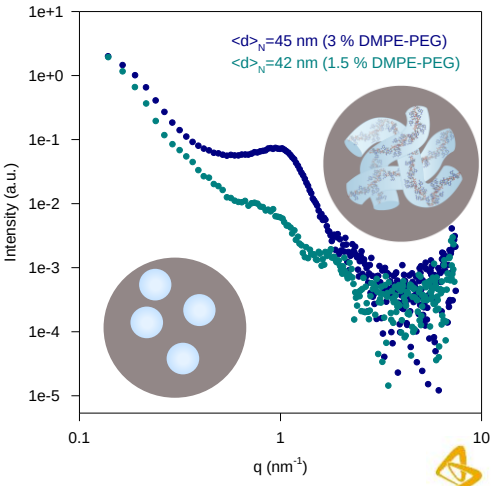
Small angle x-ray scattering (SAXS) for empty and polyA LNP bulk phases (pH 7.4)





Freeze fracture micrograph of the LNP core phase in PBS

Small angle x-ray scattering (SAXS) of mRNA LNPs vs empty LNPs



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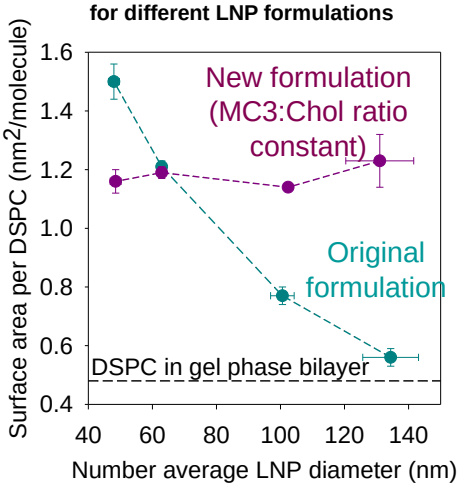
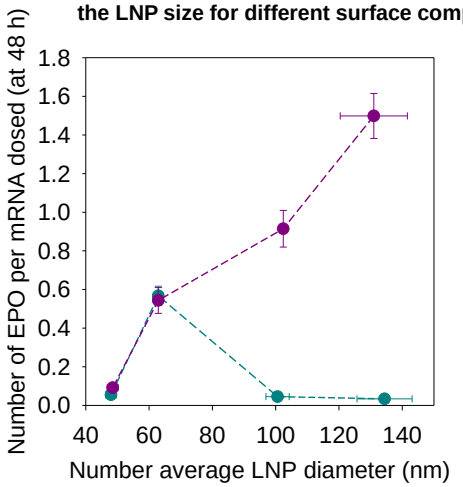
Reprograming cell protein production by modifying LNPs surface

Area per DSPC as a function of size for different LNP formulations



Protein expression in adipocytes as a function of the LNP size for different surface compositions



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Summary and Future Perspectives

- LNPs are potential candidates for the delivery of *mRNA*.
- Small angle scattering provides a tool to characterize nanomedicines.
- The transfection efficacy of LNPs containing *mRNA* is size and surface composition dependent.
- Can these characterization methods lead towards the optimization of other LNP formulations for *mRNA* delivery?

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Session 3 of the 2018 Drug Design and Delivery Symposium

Dennis Leung
Senior Scientific Manager, Genentech

Marianna Yanez Arteta
Senior Scientist and Physical Chemist Formulator, AstraZeneca

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(DDS #3) Discover how drug-likeness is a deceiving concept, explore the Rule of Five, and show how lessons from the past may guide the present.
4. Lead Optimization – Building Efficacy & Safety
(DDS #4) Learn strategies on how to effectively optimize small molecule hits and rapidly assess your findings.
5. Tips for Filing IND and Starting your Clinical Trials
(DDS #5) What do you need to know when filing for Investigational New Drug submissions to the United States Food and Drug Administration?
6. The Role of Chemistry in Clinical Trials: The Big Expense & Lessons Learned
(DDS #6) Learn how the properties of the candidate impact decisions in the discovery process.
7. Pharmacoeconomics and IP Strategies in Drug Development
(DDS #7) Review the basic principles of Pharmaco-economics in drug development strategies as well as its role in determining health insurance coverage of drug products.
8. Future of Drug Discovery - Challenges, Risks and Rewards
(DDS #8) Explore how how risks and challenges will be dealt with in the future and the key skill sets required of future medicinal chemists.

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- Designing Better Drug Candidates
(January) Learn various factors that can be used to improve candidate quality from Dr. Paul Leeson.
- Strategies to Improve Solubility of Drug Candidates
(February) Learn a number of different strategies for improving drug solubility through structural modification.
- Fragment-Based Drug Design Strategies
(March) Finding the right drug target is becoming increasingly difficult. Learn how focusing on the smaller picture can have big results.
- Screening Strategies
(April) Learn the pros and cons of different screening strategies.
- Avoiding PAINS (pan-assay interference compounds)
(May) Jonathan Baell shares some tips on how to avoid the dead ends of drug discovery.
- Accelerating CNS Positron Emission Tomography (PET) Ligand Discovery
(June) Join Lei Zhang as he lays out a set of preferred parameters for which has yielded successful PET ligands and reduced resources and timelines.
- X-ray Crystallography in Drug Discovery
(July) Jon Mason and Miles Congreve describe what protein-ligand X-ray data can do for you.
- Choices and Trends in Solid Dosage Form Selection
(August) Discover the pros and cons of the different solid state forms and what to consider when selecting.
- Delivery Options to Support Dose Escalation in Preclinical Toxicology and Pharmacodynamic Activity Studies
(September) Gain an understanding of acceptable drug delivery approaches to support preclinical dose escalation.
- Pharmacokinetic Considerations in Drug Design and Development
Learn about key pharmacokinetic concepts including clearance, volume of distribution, half life and protein binding.
- Prodrugs in Drug Discovery
(November) John Higgins shares the utility of prodrugs, their general properties and prerequisites for optimal performance.

2016

I - Time: The Fourth Dimension in Drug Discovery
1. The Importance of Drug Target Kinetics in Drug Design
Robert Copeland - Epizyme, Inc
Dan Erlanson - Carmot Therapeutics
2. Long-Acting Injectable Medications: Strategies and Mechanistic Considerations
Jules Remenar - Alkermes
Annetta Bai - Merck
3. Modified Release Formulations for Solubility Starved Compounds
Mangowi Hu - Merck
John Morrison - BMS
4. The Medicinal Chemist of Tomorrow (Special Topic)
Joe Barrish - Achillion
Ravi Nargund - Merck
Molly Schmid - Tech Coast Angels

II - Beyond Traditional Small Molecules
5. Design of Deliverable Macrocycles
Scott Lokey - UC Santa Cruz
Nicholas Meanwell - BMS
6. Dreaming Big and Thinking Small: Applying Medicinal Chemistry Strategy to Antibody-Drug Conjugates
L. Nathan Tumey - Pfizer
Peter Senter - Seattle Genetics
7. Nucleic Acids Therapeutics: Making Sense of Antisense Oligonucleotides
Punit Sach - Ionis
Richard Olson - BMS
8. Crystallography as a Drug Design and Delivery Tool (Special Topic)
Robert Wenslow - Crystal Pharmatech
Vincent Stoll - Abbvie
Andreas Brunskill - Merck

III - Pharmacology Revisited
9. Dealing with Reactive Drug Metabolites in Drug Discovery: Can We Predict Toxicities of Drug Candidates that form Reactive Metabolites?
Deepak Dalvie - Pfizer
Frederick Peter Guengerich - Vanderbilt University
10. Rational Design of Small Molecules Targeting RNA
Matt Disney - Scripps Fl Florida
Amanda Garner - University of Michigan
11. Cell Penetrating Peptides to Improve Cellular Drug Uptake
Dehua Pei - The Ohio State University
Scott Hart - Bristol-Myers Squibb

2017

I - Fighting Cancer
1. Fighting Cancer: Targeting CNS Malignancy with Kinase Inhibitors
Timothy P. Heffron - Genentech
Mark Wittman - Bristol-Myers Squibb
2. Fighting Cancer: Epigenetic targets for Oncology
Stuart Conway - Oxford
Sharan Bagal - AstraZeneca
3. Fighting Cancer: Allostery and Targeting Cancer Cell Metabolism
Stefan Gross - Agios
Scott Edmundson - AstraZeneca

Special Broadcast
4. Cystic Fibrosis: Discovery of CFTR Modulators
Peter Grootenhuis - Vertex
Nick Meanwell - Bristol-Myers Squibb

II - Anti-infectives
5. Anti-Infectives: Rational Approaches to the Design and Optimization
Jason Sello - Brown University
Courtney Aldrich - University of Minnesota
6. Tuberculosis: An Introduction for Medicinal Chemists
Carl Nathan - Weill Cornell Medicine
Christopher Boyce - Merck
7. Viral Hepatitis: The Search for a Cure
Mike Sofia - Arbutus Biopharma
Stephen Mason - CaridGen Corporation

Special Broadcast
8. Spinal Muscular Atrophy
Kevin Hodgetts - Harvard Medical School
Alyson Weidmann - ACS Publications

III - Immunology
9. Psoriasis: Treatment and Novel Approaches
Frank Narjes - AstraZeneca
John Morrison - Bristol-Myers Squibb
10. Lupus: Treatment and Novel Approaches
Laurence Menard - Bristol-Myers Squibb
Mary Struthers - Bristol-Myers Squibb

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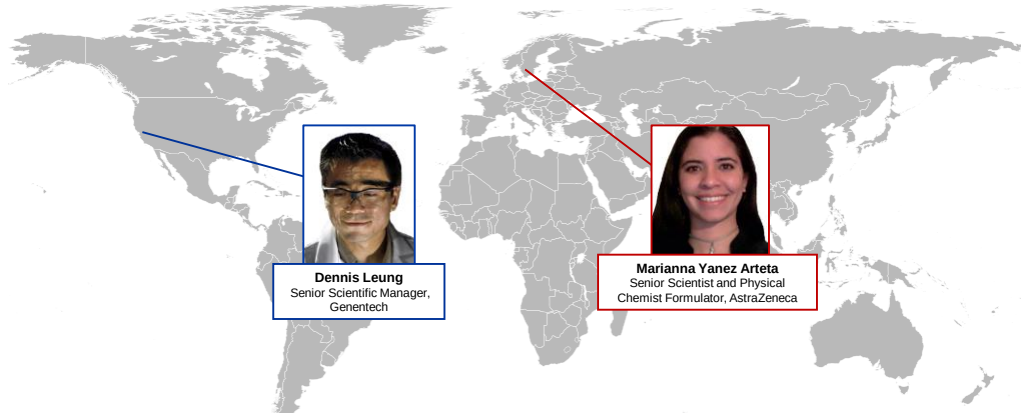

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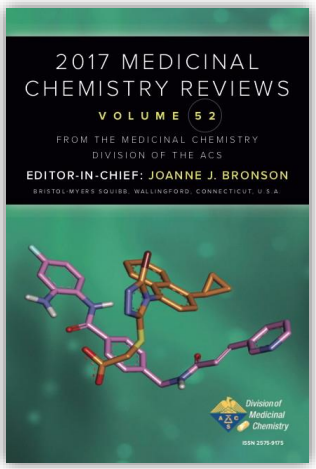

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