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"Many many thanks! Very clear description of clearance and volume of distribution. I learned a lot about PPB but will have to study this on my own."

In reference to DDDS10 "Pharmacokinetic Considerations in Drug Design and Development"

Fan of the Week

Paul R. Carlier
Professor, Department of Chemistry &
Center for Drug Discovery, Virginia Tech

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Upcoming ACS Webinars®

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Thursday, December 3, 2015

"Chemistry & the Economy: Global Outlook 2016"

Paul Hodges, Chairman, International eChem (IeC)
David Harwell, Asst. Director of Industry Member Programs, ACS

Thursday, December 10, 2015

"Outsmarting the Shortage: The Emergence of Base Metal Catalysis in Pharma"

J. Chris McWilliams, Director of Process Chemistry, Pfizer
David Constable, Director of the Green Chemistry Institute, ACS
Joseph Fortunak, Professor of Chemistry, Howard University

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2015 Drug Design & Delivery Symposium

#ACSWebinars

Co-produced by
ACS Division of Medicinal Chemistry
American Association of Pharmaceutical Scientists (AAPS)

Module 1: Improving Drug Design Efficiency and Efficacy		
Jan 29	Designing Better Drug Candidates	*Dr. Paul Leeson*
Feb 26	Strategies to Improve Solubility of Drug Candidates	*Dr. Michael Walker*
Module 2: Activity/Potency Screening for Drug Lead & Candidate Optimization		
Mar 19	Fragment-Based Drug Design Strategies	*Dr. Dan Erlanson*
April 30	Screening Strategies	*Dr. David Swinney*
May 28	PAINS (Pan-Assay Interference Compounds)	*Dr. Jonathan Baell*
June 25	Positron Emission Tomography (PET) Labeling in Drug Discovery & Development	*Dr. Lei Zhang*
July 30	X-Ray Crystallography in Drug Discovery	*Dr. Jon Mason & Dr. Miles Congreve*
Module 3: Enabling Drug Discovery		
Aug 27	Choices and Trends in Solid Dosage Form Section	*Dr. Scott Trzaska & Dr. Ron Smith*
Sept 24	Delivery Options to Support Dose Escalation in Preclinical Toxicology and Pharmacodynamic Activity Studies	*Dr. Evan Thackaberry*
Module 4: Pharmacokinetics		
Oct 29	Pharmacokinetic Considerations in Drug Design and Development	*Dr. Punit Marathe*
Nov 19	Prodrugs in Drug Discovery	*Dr. John Higgins*

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Join us January 28, 2016 for our continued Drug Discovery Series!

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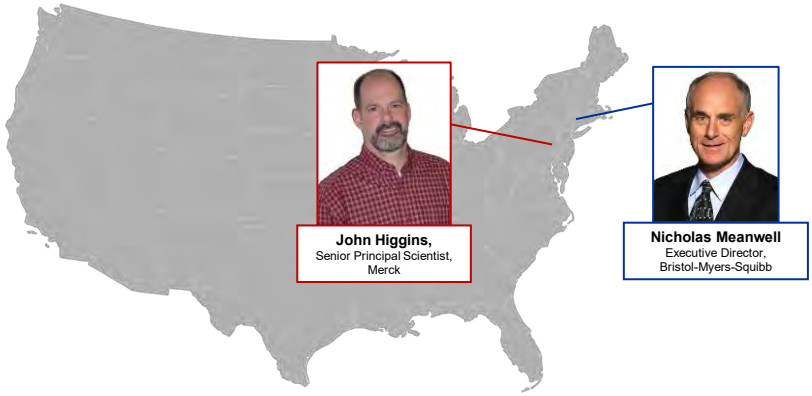
"2015 Drug Design and Delivery Symposium:

Prodrugs in Drug Discovery"



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The 2015 Drug Design and Delivery Symposium is co-produced by the ACS Medicinal Chemistry Division and the AAPS

Contents

1. **Prodrugs:** Definition and impact in Pharma

2. **Prodrug challenges to be met:**
   - Formulation, *in vivo* stability & bioconversion
   - The regulatory pathway

3. **Example prodrug handles and subsequent functional prodrugs**

4. **A prodrug program Research Operating Plan** (ROP)
   - Prioritizing activities on identifying and characterizing prodrug leads

5. **Case Study: Permeability Enhancement Via a Prodrug Strategy**
   - An ambitious example of a prodrug strategy to increase colonic absorption to enable a CR formulation for QD dosing

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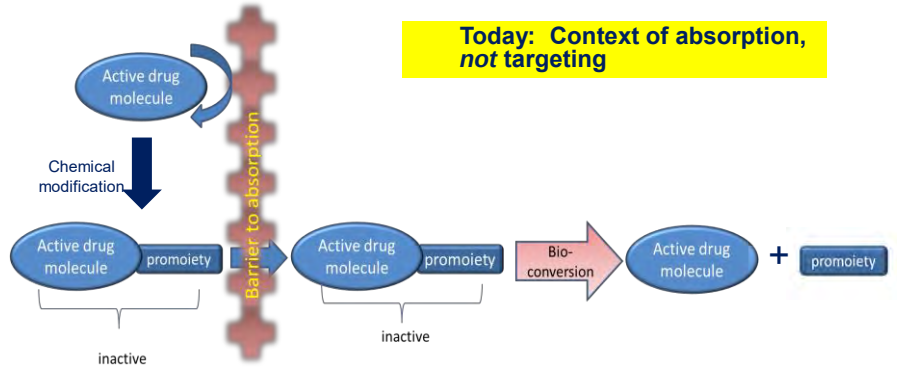
What is a prodrug?

A bioreversible derivative of an active drug compound:

- **Undergoes *in vivo* enzymatic or chemical transformation to release active parent drug compound**



Today: Context of absorption, *not* targeting

Adapted from Rautio, J et al. Prodrugs: design and clinical applications, Nature Reviews, 2008, 7, 255-270

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Audience Survey Question

ANSWER THE QUESTION ON BLUE SCREEN IN ONE MOMENT

Which can NOT be influenced by a Prodrug?

- Cell permeability
- Administration route
- Half life
- Intellectual property
- None of the above

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What Benefits Can a Prodrug Provide?

- **Improved properties related to ADME**
  - **⇧ aqueous solubility**
  - **⇧ permeability**
  - **⇧ chemical stability**
  - **⇩ pre-systemic metabolism**
- **New/ improved delivery options**
  - **Oral ⇨Topical**
- **Life cycle management**
- **Targeted delivery (another day's topic)**
- **Additional intellectual property (IP)**


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When to Engage a Prodrug Strategy?

The Discovery Debate on a candidate with sub-optimal physchem properties:

- **Fix it now** *via* a prodrug? ⇨ More complex synthesis, tox, regulatory pathway
- **Fix it later** *via* an enabled formulation? ⇨ Longer/more costly & complex dosage form development

Real life observation:

- Insoluble, highly crystalline candidate was advanced as a **low drug-load amo dispersion** ⇨ led to nightmarish, dose limited, high-cost formulation
- Later on, a soluble prodrug was identified…probably to late!

The prodrug conversation must be had EARLY by the Lead Ops team!


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Prodrugs:
Recently Overheard in Discovery Hallways

Comment: *Let's fix our bioavailability problems with a prodrug!*

Responses:

- *"No; I love my parent compound and you formulators can fix it through drug delivery."*
- *"No, prodrugs are the last resort for poor medicinal chemistry efforts."*
- *"Prodrugs are for losers."*


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Audience Survey Question

ANSWER THE QUESTION ON BLUE SCREEN IN ONE MOMENT

What percentage of the Top 100 Blockbuster Drugs are actually Prodrugs?

- Less than Two percent
- About Five percent
- About Fifteen percent
- About Twenty percent

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Prodrugs: More Common Than You Think!

The Pharma Industry:

- ☑ **15% of the 100 blockbuster drugs are prodrugs*!***

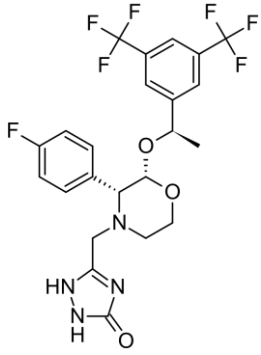
Some Blockbuster Prodrugs:

- ☑ **Omeprazole, Prilosec®, proton pump inhibitor: permeation**
- ☑ **Acyclovir, Zovirax®, anti-viral: liver targeting**
- ☑ **Enalapril maleate, Vasotec®, ACE inhibitor: permeation**
- ☑ **Simvastatin, Zocor® , HMG-CoA reductase inhibitors: liver targeting**

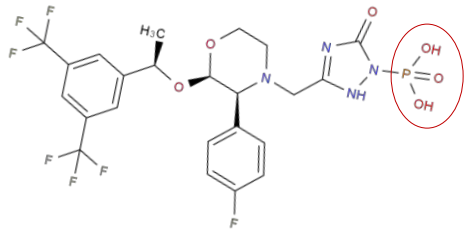
Clas et al., 2013; Landis, 2013.

Aprepitant (Emend®) Example

A poorly soluble compound: Two Enabling methods for two administrations routes



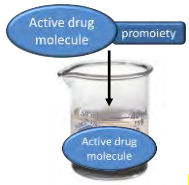
Oral Dosage Form
Nanoparticles



IV Solution
Phosphate Prodrug

Prodrugs Do Have Potential Challenges

Poor formulation stability
- Converts to parent



Poor stability in stomach
- Converts to parent

All this must be interrogated

Prodrug too stable *in vivo*
- No bioconversion to parent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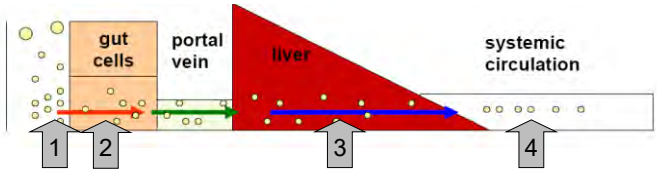
Potential Assays to Probe Bioconversion



1. ***In vitro* stability & solubility**
   - Biological Media: Simulated GI fluids (SGF, FaSSIF) with and without digestive enzymes
   - Buffers (formulation & serum conversion prediction)
2. ***In vitro* permeability assays (Caco-2, LLC-PK1…)**
3. ***In vitro* stability in hepatocytes and plasma**
4. ***In vivo* PK and bioconversion**
   - Look for circulating prodrug and parent in plasma
   - Rat and/or dog most common preclinical species
   - Beware of species differences (i.e. high metabolism in rat; Esterase activity is species dependent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Audience Survey Question

ANSWER THE QUESTION ON BLUE SCREEN IN ONE MOMENT

What are the toxicology and regulatory considerations for Prodrugs?

- Circulating prodrug levels
- Bioconversion
- Regulatory input
- All of the above
- None of the above

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Prodrugs' Toxicology & Regulatory Considerations

Prodrugs still require thorough safety evaluation

Circulating prodrug levels

Bioconversion

- Species differences
- By-product characterization (i.e. formaldehyde)

Regulatory input

Prodrug Development to FIH is typically same as any new chemical entity even when parent molecule is already approved

TOX STUDIES MUST BE REPEATED: CASE FOR CONSIDERING EARLY IN THE DISCOVERY PHASE!

28 Public

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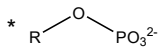
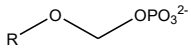
Common "Prodruggable" Handles and Subsequent Functional Prodrugs

Parent Handle	Prodrug Examples
Alcohols	Esters (incl. amino acids (AAs)); Phosphates/Phosphonates*
Amines	Amides, Phosphates/Phosphonates Sulfenamides*
Carboxylic Acids	Esters (incl. AAs)
Phenols	Esters (incl. AAs); Phosphates/Phosphonates
Thiols	Thioethers/esters

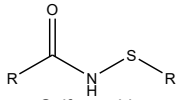
- **⇧ Solubility: ⇧ ionization/polarity, ⇩ lipophilicity (log D)**
- **⇧ Permeability: The opposite of above**



Phosphate



oxymethylphosphate



Sulfenamide

Stella, *Prodrugs: Challenges & Rewards*, **2007**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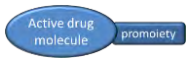
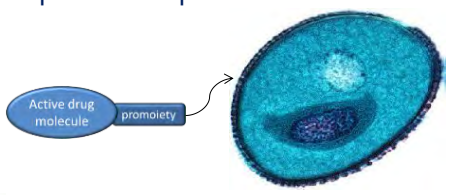
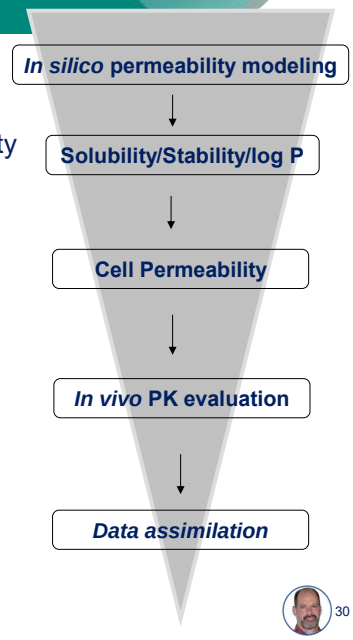
Example ROP: A Prodrug Strategy for Enhancing Permeability



- Promoieties selected to increase lipophilicity
- *in vitro* screening for prodrug viability:
  - Solubility, log P,
  - Chem Stability (GI, formulation)
  - Cell permeability
- *In vivo* PK and bioconversion studies in preclinical species





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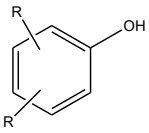
Case Study:
Prodrug to Enable a CR Formulation

- **Compound A:** Short half-life (1.5h) required BID dosing ⇨ *QD preferred*
  - Low permeability although good intestinal absorption observed
- **Controlled release formulation for once daily (QD) dosing?**
  - NO: Poor permeability led to poor colonic absorption, which makes controlled release (CR) formulations impossible
- **Compound A contained an ionizable phenol that contributed to poor permeability (pKa 6.7)**
  - ✓ Also a prodrug handle…

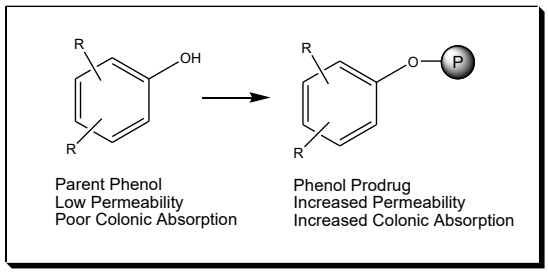
Compound A



Parent Phenol
Low Permeability
Poor Colonic Absorption

Prodrug Strategy to Enable Colonic Absorption and a CR Formulation

Can a prodrug that masks phenol ionization increase permeability and colonic absorption to enable a CR QD formulation?



Parent Phenol
Low Permeability
Poor Colonic Absorption

Phenol Prodrug
Increased Permeability
Increased Colonic Absorption

A modified release dosage form to bypass the intestine (good absorption there) also would be required…(colonic delivery…another day's topic)

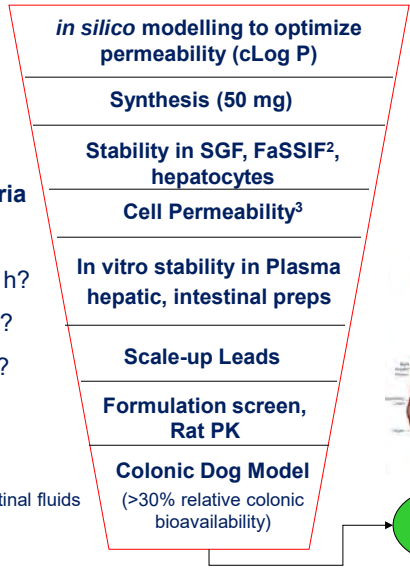
Ref. Sophie-Dorothee Clas, Becky Nofsinger, Abbas Walji

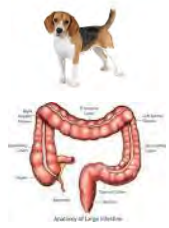
Case Study: Colonic Prodrug ROP

- Modelled >80 prodrug structures for calculated Papp (cLog P)[1]
- Selected 20 for synthesis

Candidate Selection Criteria

1. P_{app} ≥ 10x Parent?
2. Bioconversion ≥ 90% in 1h?
3. Formulation stability ≥ 3h?
4. >30% colonic absorption?





[1]Accelrys Cerius2 Software
[2]Simulated gastric and fasted intestinal fluids
[3]Cell line: [1]LLC-PK1

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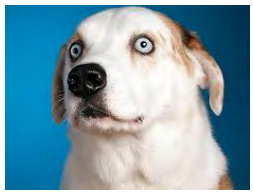
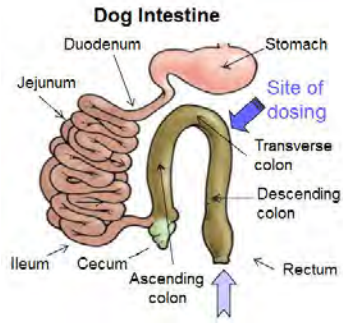
Dog Colonic Absorption Study: Retrograde Catheter Dosing in Beagle dogs

- **Experiment is based on % relative absorption: Colonic AUC/Oral AUC**
- **Predictive of human colonic absorption**





Administer catheter here

Nofsinger, et.al. *Pharmaceuticals*, **2014**, *7*, 207-219 **2015**, *10*, 245 – 252

Public

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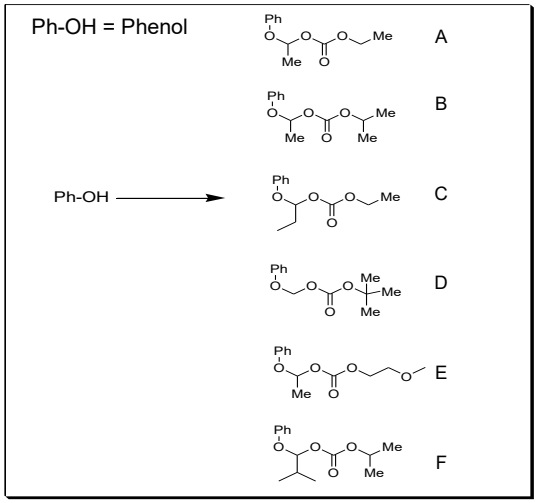
Case Study:
Lead Carbonate-ester Prodrug Structures



Walji, ChemMedChem **2015**, *10*, 245 – 252

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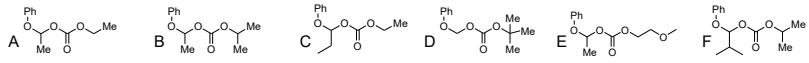
Carbonate Ester Physchem Properties

Compound	cLogP[1]	Solubility in SGF[2] (mg/mL) 1hr	Solubility FaSSIF[3] (mg/mL) 1hr	Stability in SGF[2] (1hr) %Claim	Stability in FaSSIF (5hr) %Claim	Hepatocyte parent conversion <1h?
Parent	-0.7	0.01	0.50	98.36%	99.40%	n/a
Prodrug A	0.9	0.37	0.33	93.80%	90.97%	Yes
Prodrug B	1.3	0.02	0.03	100.02%	99.92%	Yes
Prodrug C	1.5	0.04	0.25	99.32%	98.27%	Yes
Prodrug D	1.3	0.06	0.06	100.14%	101.61%	Yes
Prodrug E	0.4	6.6	0.60	95.50%	96.27%	Yes
Prodrug F	2.2	0.02	0.04	91.32%	98.45%	Yes



[1] Apparent octanol/water partition coefficient (cLogP) calculated using Accelrys Cerius2 Software

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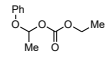
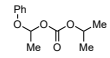
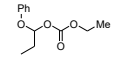
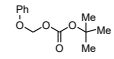
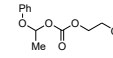
Carbonate Ester cLogP and Permeability

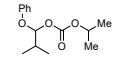
A 

B 

C 

D 

E 

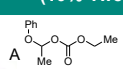
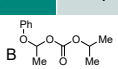
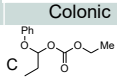
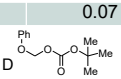
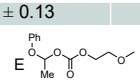
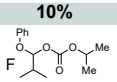
F 

Compound	cLogP	LLC-PK1 Papp (*10^{-6} cm/sec)
Parent	-0.7	11.6
Prodrug A	0.9	5.8
Prodrug B	1.3	8.9
Prodrug C	1.5	11.9
Prodrug D	1.3	11.9
Prodrug E	0.4	1.7
Prodrug F	2.2	15.4

cLog P does NOT correlate well with cell permeability…?

Colonic Dog Study Results

Compound Dosed (solution vehicle)	Dose (mpk)	Dosing Route	nAUC$_{0\text{-}24hr}$ (μM*hr/ mpk)	Dog Colonic Absorption (vs. oral, n = 3)
Parent (3% Tween)	4	Oral	2.92 ± 0.48	-
		Colonic	0.30 ± 0.26	9%
Prodrug A (3% Tween)	4	Oral	**1.91 ± 0.12**	-
		Colonic	0.76 ± 0.21	40%
Prodrug B (10% Tween)	1	Oral	**0.94 ± 0.05**	-
		Colonic	0.40 ± 0.13	43%
Prodrug C (10% Tween)	1	Oral	**0.77 ± 0.13**	-
		Colonic	0.24 ± 0.04	31%
Prodrug D (30% Captisol®)	4	Oral	**2.4 ± 0.14**	-
		Colonic	0.72 ± 0.07	30%
Prodrug E (10% Tween)	0.7	Oral	4.35 ± 1.3	-
		Colonic	0.24 ± 0.15	5%
Prodrug F (10% Tween)	1	Oral	0.75 ± 0.02	-
		Colonic	0.07 ± 0.13	10%

A  B  C  D  E  F 

Conclusions

- **Prodrugs are prevalent in the industry and an effective means of improving physchem properties**
- **Need to consider early in Discovery phase before it's too late**
- **Need to be aware of specific tox and regulatory challenges**
- **Case study: Demonstrated that a lipophilic prodrug can increase colonic absorption**
  - Of note: The cLog P and LLC-PK1 permeability did not correlate well with subsequent colonic absorption
  - Interplay between several physchem attributes and oral bioavailability
  - Next comes a formulation challenge to deliver prodrug to the colon….another day's topic

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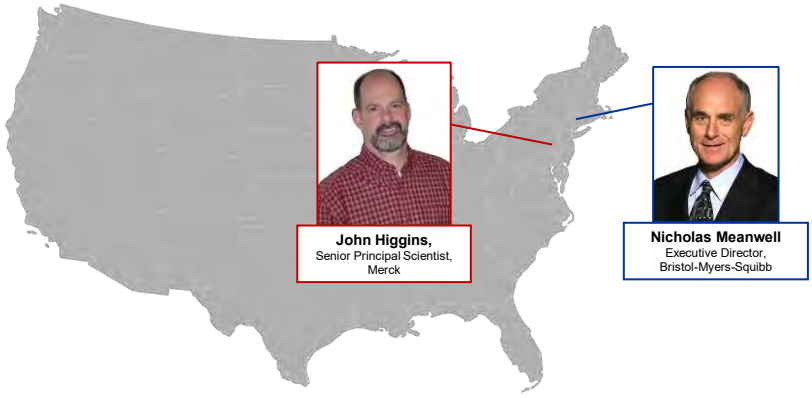

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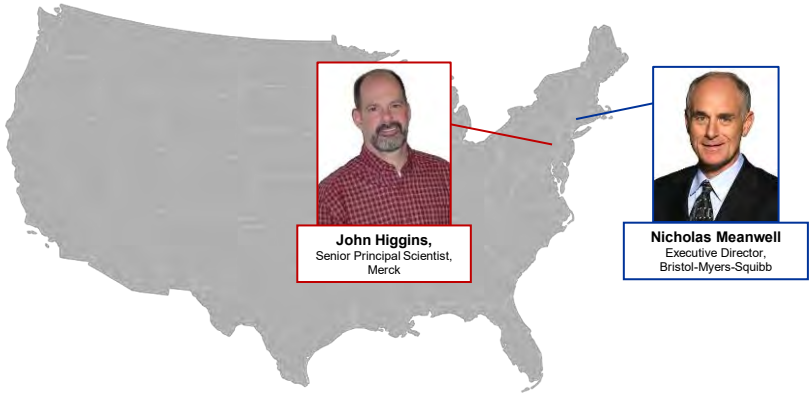

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