



# ATTENTION WITH DIMENSION

Capabilities and Sample Work

# WHO WE ARE

We bring our expertise and passion for marketing communications to our clients with an entrepreneurial spirit. As a virtual agency, we are best positioned to bring a customized team of professionals, deeply steeped in healthcare to each and every project in an affordable, efficient and nimble manner.

- Tightly-knit team of talented, creative professionals with over 20 years working together
- Specialize in corporate branding—bringing a fresh approach to marketing
- Agency quality without the agency overhead
- Dedicated to creating personalized teams to bring the right mix of experts to every program
- Relationship-building that sets us apart from other agencies
- Strategic, positive, responsive and flexible

# CAPABILITIES

## Branding/Advertising

- Marketing Plans
- Brand Positioning & Messaging
- Logo Development
- Stationery/Business Cards
- PPT Template/Refinement
- Clinical Trial Branding
- HCP and Patient Collateral

## Interactive/Digital

- Digital Strategy
- Website Design/Implementation
- Animation/Multimedia
- Clinical Trial Patient Recruitment, Search Engine Marketing (SEM)
- Video Production
- SEO/PPC Campaigns
- Web Tracking/Data Analysis/Reporting

## Other

- Annual Reports
- Convention Exhibits/Activities
- Photography
- Infographics
- Medical Illustration
- Internal Campaigns/Employee Communications
- Community Programs/Events
- Packaging



# SAMPLE WORK – CORPORATE BRANDING

# Corporate Branding

## Nimbus Therapeutics

<https://www.nimbustx.com>

**nimbus**  
THERAPEUTICS

ABOUT SCIENCE PIPELINE NEWS CULTURE & CAREERS

## SMALL MOLECULE LUMINARIES

World-class expertise.  
Leading-edge technologies.  
Record-breaking success.  
We're taking medicine to new heights.

**nimbus**

ABOUT SCIENCE PIPELINE NEWS CULTURE & CAREERS

## DESIGN WITH INTENTION

At Nimbus, exquisite selectivity is at the core of everything we do. From people to targets to molecules to partners, our meticulous choices enable us to successfully design and develop high-quality small molecule medicines capable of significantly improving people's lives. And we have the track record to prove it.

### SELECTIVITY IN SCIENCE

Discover our unique approach to target selection, computational drug design, translational medicine, and clinical development.

LEARN MORE

### SELECTIVITY IN MOLECULES

Explore our highly selective product candidates for oncology, immunology, and metabolic indications.

LEARN MORE

## SELECTIVITY IN TALENT

See what sets our experienced discovery, development, and operational nimbi apart.

LEARN MORE

## NEWS

MAY 23, 2024  
Nimbus Therapeutics Presents New Positive Monotherapy Phase 1/2 Clinical Data of HFK1 Inhibitor in Treatment of Advanced Solid Tumors at 2024 ASCO Annual Meeting

READ MORE

MAY 07, 2024  
Nimbus Therapeutics Appoints Anita Schueber, M.D., Ph.D., as Senior Vice President, Therapeutic Area Head, Oncology

READ MORE

**CONTACT** info@nimbustx.com 22 Boston Wharf Road, Floor 9 Boston, MA 02210 USA

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ABOUT SCIENCE PIPELINE NEWS CULTURE & CAREERS

## BUILDING UPON OUR SUCCESS

We are currently advancing multiple compelling molecules for the potential treatment of oncology, immunology, metabolic, and other indications.

INDICATOR	DEVELOPED	LEAD OPTIMIZATION	PRECLINICAL	CLINICAL
INTERNAL PROGRAMS	100%	100%	100%	100%
EXTERNAL PROGRAMS	100%	100%	100%	100%
ACQUIRED PROGRAMS	100%	100%	100%	100%

## FOR PATIENTS

We're focused on making breakthrough medicines for the people who need them most.

**NON ENROLLING** PHASE 1/2 CLINICAL TRIAL EVALUATING NIM101150 IN ADULTS WITH SOLID TUMORS

In this trial we are evaluating the safety, tolerability and preliminary efficacy of our first-in-class, NIM101150.

LEARN MORE

**EXPANDED ACCESS STATEMENT**

Expanded access, or compassionate use, is the use of an investigational medicine prior to regulatory approval and outside of a clinical trial. Nimbus does not currently have an expanded access program for any of our investigational products. We encourage people to speak with their physician about options that may be right for them including ongoing clinical trials and approved medicines.

**CONTACT** info@nimbustx.com 22 Boston Wharf Road, Floor 9 Boston, MA 02210 USA

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ABOUT SCIENCE PIPELINE NEWS CULTURE & CAREERS

## SHAPING THE FUTURE OF MEDICINE

Nimbus is a private company located in Boston, MA with a passionate, talented, multidisciplinary team of "nimbi." United by a shared mission to develop breakthrough medicines for patients through precision small molecule design, our people and culture are the driving force behind our success.

### PROVEN EXCELLENCE

Since our founding in 2009, we've consistently delivered by developing multiple clinical candidates, securing investor confidence, meeting global regulatory goals, and forging partnerships that fuel our innovation.

### AGILE AND ADAPTIVE

With a core team of under 100, we pride ourselves on our ability to move quickly. Through strategic partnerships and collaborations, we scale our resources to meet the demands of an ever-evolving market.

### AUTHENTICITY AND INCLUSION

Diversity, equity and inclusion aren't just initiatives—they're foundational to who we are. We believe that by fostering an environment where everyone can bring their authentic selves to work, we cultivate the honesty, transparency, trust, and collaboration that drive our continued success.

### UNMATCHED CULTURE

Our company is more than a workplace—it's a close-knit community where a fast-paced, entrepreneurial spirit meets thoughtful leadership. With cutting-edge science at our core, we aim to inspire and bring out the best in one another.

## HOW NIMBI SHINE

**ELEVATE OUR PERSPECTIVES**

We act in service of our patients, our mission, and the company. We remember the bigger picture of designing breakthrough medicines.

**LEAN INTO THE TEAM**

Developing medicines takes a village. We focus on a shared priority: the hardest problems are solved collectively through integration and collaboration.

**RESPECTFULLY CHALLENGE**

We bring forward the best ideas when we challenge each other, hold one another accountable, engage in productive debate, and support the final decision.

**ROLL UP OUR SLEEVES**

We are a team. Everyone pitches in and is willing to contribute to help achieve our shared objectives. We are strategic thinkers who can execute.

"I like that there is both efficiency and empathy here. We get things done while staying human."

-LEILA DOOKA

## DIVERSITY, EQUITY, AND INCLUSION ARE EXTRAORDINARILY IMPORTANT TO US

**DEBI MISSION STATEMENT**

We believe a sense of belonging empowers us to bring our individual talents to deliver breakthrough medicines to patients. Through collaboration, communication, curiosity, and collaboration of all backgrounds and identities, we commit to fostering an inclusive culture for our employees and communities.

**CHAMPIONS OF THE MASSBIO PLEDGE FOR A MORE EQUITABLE AND INCLUSIVE LIFE SCIENCES INDUSTRY**

We are proud to be one of the original companies to sign the Massachusetts Biotechnology Council (MassBio) Pledge for a More Equitable and Inclusive Life Sciences Industry. By voluntarily supporting this initiative, we have demonstrated our belief in helping to address the disparities in the life sciences industry as multiple, specific, and measurable DEBI initiatives.

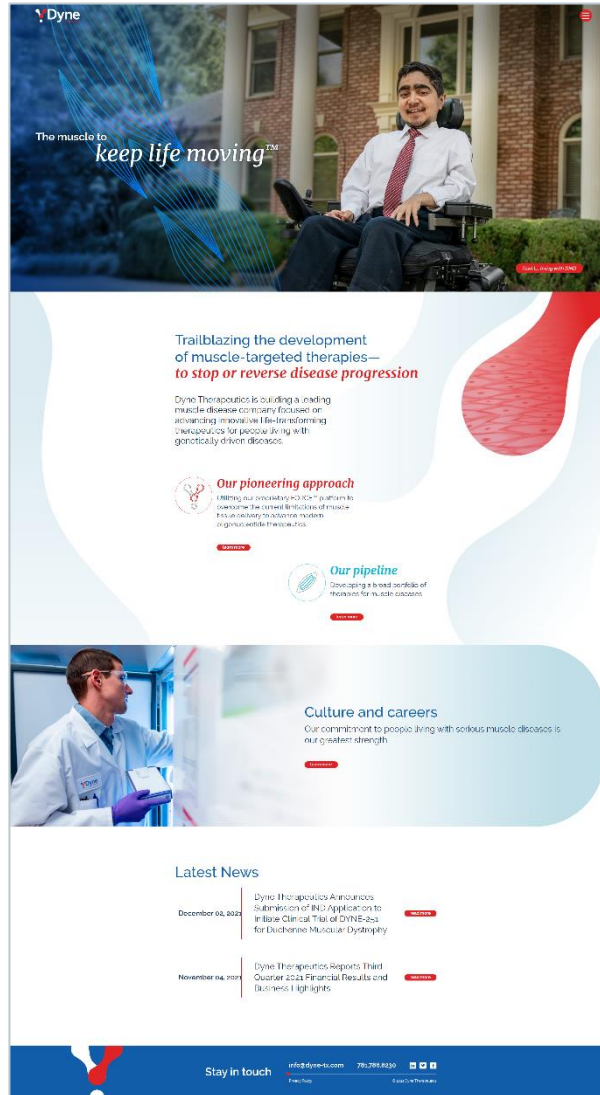
**Recent DEBI initiatives include:**

- Diversity and cultural events (Big Datal, Asian American and Pacific Islander Month)
- Education and awareness (ing LGBTQ+ advocacy and legislation seminar, unconscious bias training)
- Participation of LGBTQ+ and inclusion (ing Boston Pride, End conversion)
- Community outreach and involvement (ing Project Catalyst, Women's History Month panel)
- Equity-focused talent programs (ing parent-leave programs, recruitment, onboarding new hires)
- Internal DEBI network (ing Life Science Career, Boston Link)

# CORPORATE BRANDING

## Dyne Therapeutics

<https://www.dyne-tx.com/>



**Dyne**

The muscle to keep life moving™

Trailblazing the development of muscle-targeted therapies—**to stop or reverse disease progression**

Dyne Therapeutics is building a leading muscle disease company focused on accelerating innovative life-changing therapeutics for people living with genetically driven diseases.

**Our pioneering approach**  
Leveraging our proprietary DYT™ platform to overcome the current limitations of muscle disease therapies, we are developing innovative therapies to improve muscle function.

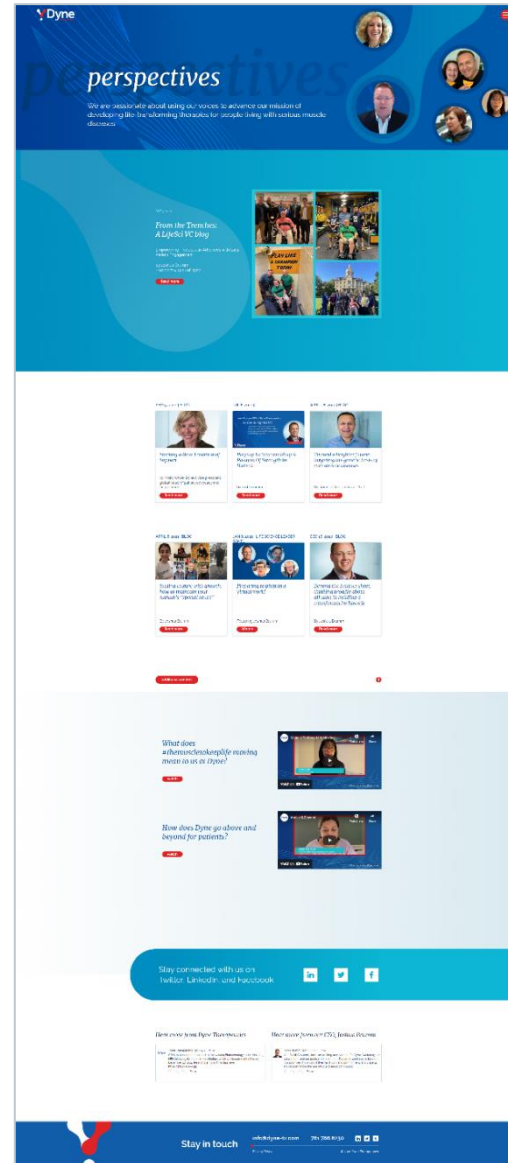
**Our pipeline**  
Developing a broad portfolio of therapies for muscle disease.

**Culture and careers**  
Our commitment to people living with serious muscle disease is our greatest strength.

**Latest News**

- December 08, 2021 Dyne Therapeutics Announces Submission of IND Application to In-Phase Clinical Trial of DYT-253 for Facioscapulohumeral Dystrophy
- November 04, 2021 Dyne Therapeutics Reports Third Quarter 2021 Financial Results and Business Highlights

Stay in touch [info@dyne-tx.com](mailto:info@dyne-tx.com) 781.288.8130



**Dyne**

### perspectives

We are passionate about using our science to advance our mission of developing life-changing therapeutics for people living with serious muscle disease.

**From the Therapies, A LIPSO VC story**

**What does a life-changing therapy look like?**

**How does Dyne go above and beyond for patients?**

Stay connected with us on [Twitter](#), [LinkedIn](#), and [Facebook](#)

Stay in touch [info@dyne-tx.com](mailto:info@dyne-tx.com) 781.288.8130



**Dyne**

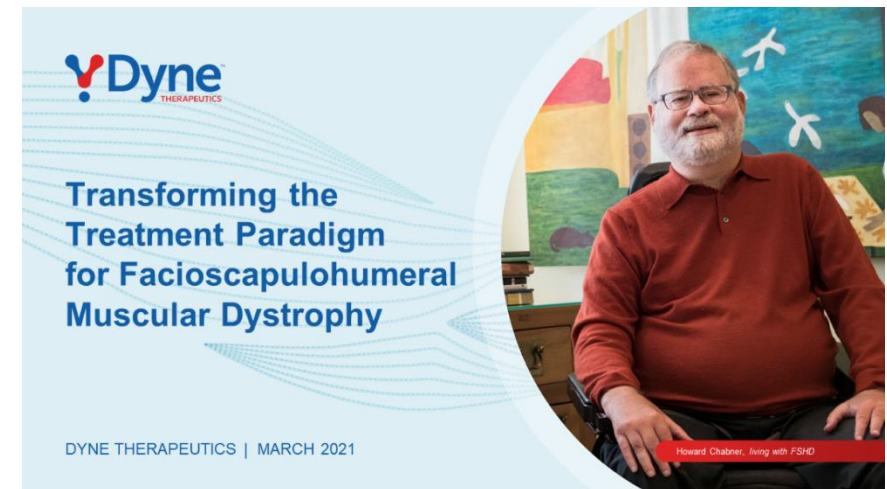
## Building the World's Leading Muscle Disease Company

COMPANY OVERVIEW | SEPTEMBER 2020

CONFIDENTIAL

Ravi, living with DM1

Corporate PPT Template



**Dyne** THERAPEUTICS

## Transforming the Treatment Paradigm for Facioscapulohumeral Muscular Dystrophy

DYNE THERAPEUTICS | MARCH 2021

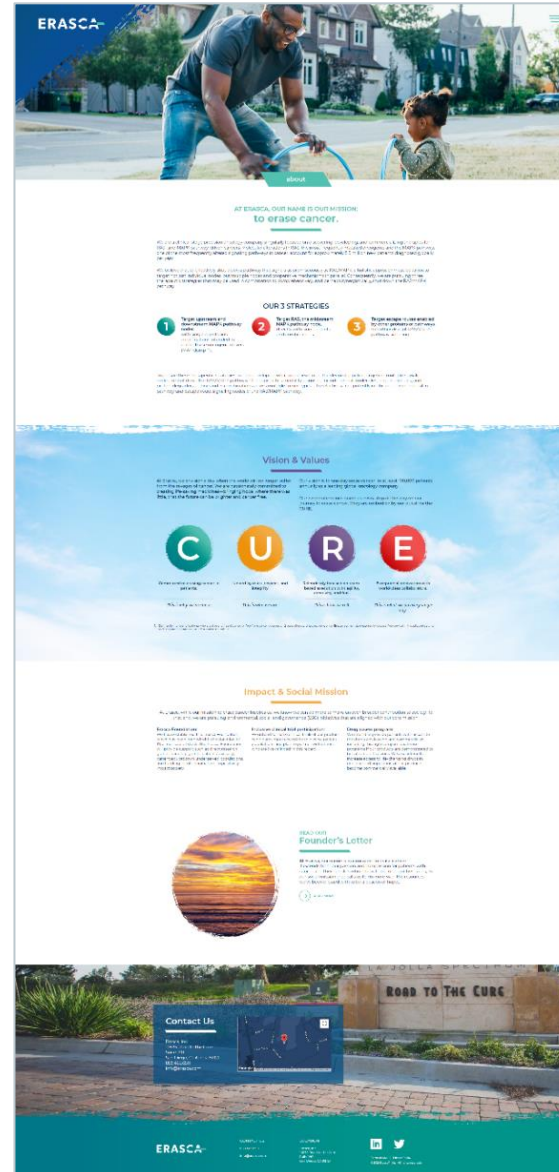
Howard Chabner, living with FSHD

Patient PPT Template

# CORPORATE BRANDING

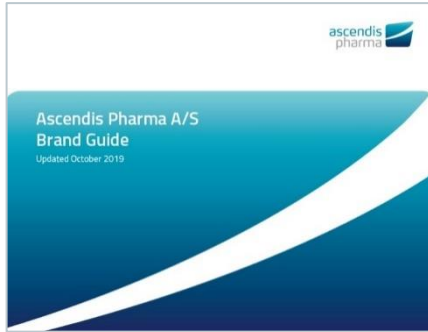
## ERASCA

<https://www.erasca.com/>

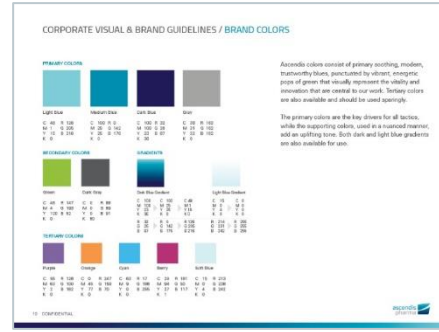
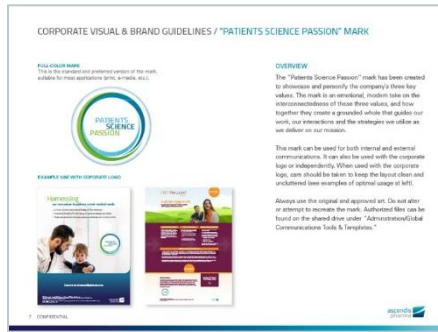


PPT Template

# CORPORATE BRAND GUIDES



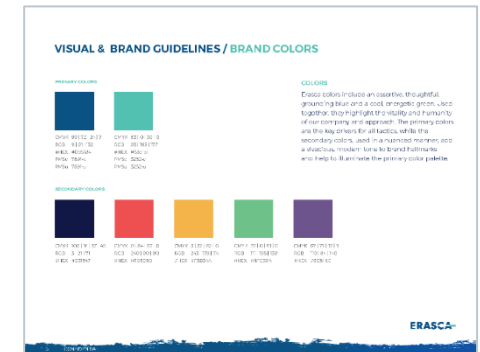
Ascendis Brand Guide



89bio Brand Guide



Erasca Brand Guide





# CORPORATE PPT

**Building the World's Leading Muscle Disease Company**

COMPANY OVERVIEW | NOVEMBER 2024

*Sarah, living with DM1*

**Developing Novel Treatments for Fibrotic Diseases**

NOVEMBER 2024

© 2024 PLIANT THERAPEUTICS

### ACHIEVE Trial Design

Global, Randomized, Placebo-Controlled Stage Evaluating Once Monthly or Less Frequent Administration of DYNE-101 in Adult Patients Living with DM1

**MAD Study Details**

- IV administration of DYNE-101 or placebo every 4 weeks or every 8 weeks
- Muscle biopsies: Baseline, 12 weeks, 24 weeks
- Patients in MAD study escalated to highest tolerable dose in OLE and LTE

Global Strategy & Adaptive Trial Design To Enable Rapid Achievement of Potentially Registrational Clinical Data

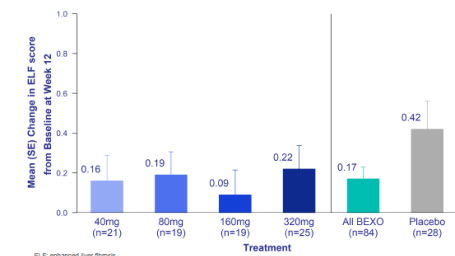
**Dyne** Doses provided refer to ASO component of DYNE-101. Recovery cohort Q4W x 2 doses then placebo for the remainder of the 24W placebo-controlled period. Q4W with booster includes Q4W x 3 doses then Q8W dosing. Study protocol allows for dosing up to 10.2 mg/kg.

### Pliant Development Pipeline

Program	Indication	Preclinical	Clinical			Anticipated Milestone	Global Rights
			Phase 1	Phase 2a	Phase 2b / 3		
<b>Bexotegrast (PLN-74809)</b>	Idiopathic Pulmonary Fibrosis					BEACON-IPF Phase 2b enrollment complete 1Q 2025; data mid-2026	PLIANT
Dual selective inhibitor of $\alpha_1\beta_1/\alpha_2\beta_1$	Primary Sclerosing Cholangitis					24-Week 320 mg data presented	
<b>PLN-101095</b>	Solid Tumors					Initial data early 2025	
<b>PLN-101325</b>	DMD Other Muscular Dystrophies					Phase 1 ready	

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**ELF Score – Change from Baseline at Week 12 Safety Population**



**Bexotegrast reduced ELF score relative to placebo at all doses**

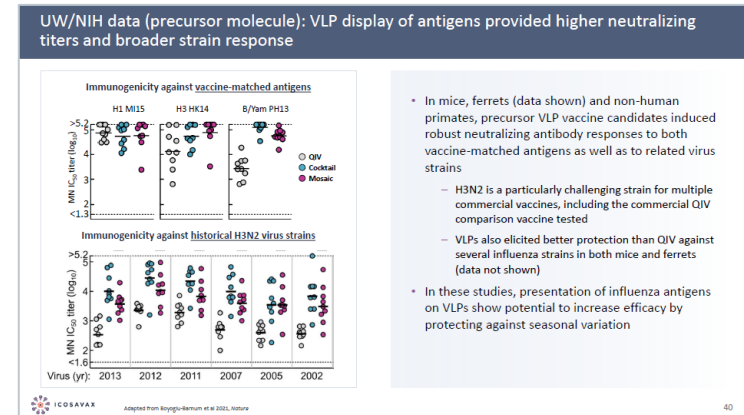
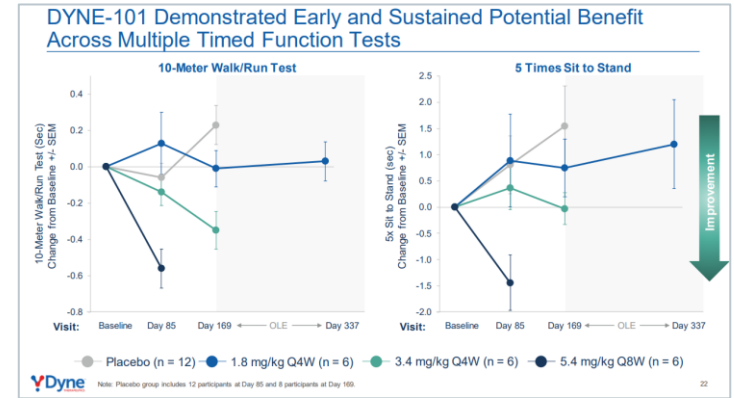
# CORPORATE PPT

**89bio**

Powerful Science  
Meaningful Medicines  
Changing Lives

Nasdaq: ETNB

November 2024



## Pegozafermin is an FGF21 Analog Optimally Engineered to Balance Efficacy and Long Dosing Interval

RECEPTOR	FGF21		Pegozafermin	
	EC <sub>50</sub> (nM)	Mean ± S.D.	EC <sub>50</sub> (nM)	Mean ± S.D.
KLB	nd	nd	nd	nd
KLB/FGFR1	4.5 ± 1.0	0.3 ± 0.07		
KLB/FGFR2	4.5 ± 0.9	1.1 ± 0.4		
KLB/FGFR3	1.8 ± 0.3	1.2 ± 0.4		
KLB/FGFR4	nd	nd		

nd – not determined; rMGF19 EC<sub>50</sub> at FGFR4 = 1.7 ± 0.4

- Proprietary glycoPEGylation technology commercially validated with approved products
- Increases half-life of native FGF21 (<2 hours) to 55-100 hours based on single ascending dose study
- Composition of matter patent expires in 2038, assuming no patent term extensions

## ENLIVEN Trial Evaluated Weekly (QW) and Every-Two-Week (Q2W) Dosing in Non-cirrhotic Patients

**PRIMARY ENDPOINTS**

- ≥1-stage fibrosis improvement with no worsening of MASH<sup>1</sup>
- MASH resolution with no worsening of fibrosis<sup>2</sup>

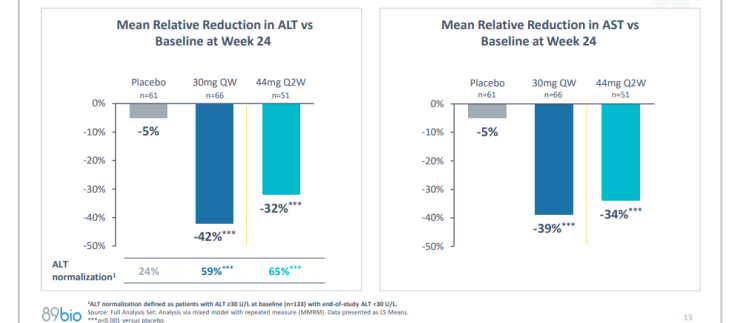
**KEY SECONDARY EFFICACY ENDPOINTS**

- ≥2-point change in NAS with no worsening of fibrosis
- Non-invasive liver markers (liver fat, liver injury, fibrosis markers)

Legend: Liver Biopsy, MRI-PDFF

Improvement in liver fibrosis by ≥1 stage and no worsening of steatohepatitis, defined as no increase in NAS for ballooning, inflammation, or steatosis (FDA draft guidance). Resolution of steatohepatitis is defined as absent fatty liver disease or isolated or simple steatosis without steatohepatitis and a NAS score of 0-1 for inflammation, 0 for ballooning and any value for steatosis (FDA draft guidance).  
<sup>1</sup>Some placebo patients were re-randomized in the extension phase to receive pegozafermin.  
 NAS, NAFLD Activity Score; MRI-PDFF, Magnetic resonance imaging-estimated proton density fat fraction; QW, Every week; Q2W, Every 2 weeks

## Pegozafermin Demonstrated Significant Improvements in Markers of Liver Injury/Inflammation (ALT and AST)



Note DMG works both in excel and prism to colorize and clean-up charts and graphs

# SCIENTIFIC POSTERS

## 89bio Population Pharmacokinetics (PK) and Pharmacodynamics (PD) of Pegzofermin, a Novel GlycoPEGylated FGF21, in a Phase 2 Study in Severe Hypertriglyceridemia

Leo Tang, Nermal Bafar, Teresa Parf, Hank Muenbach, Rishi M. Sood  
89bio, Inc., 440, 425 Montgomery Street, 15th floor, San Francisco, CA, USA \*Department of Bioengineering and Therapeutic Sciences, University of California San Francisco

### PURPOSE

Pegzofermin (PZG) is a specifically engineered, long-acting glycoPEGylated analog of fibroblast growth factor 21 (FGF21) under development for the treatment of metabolic dysfunction-associated steatotic liver disease (MASLD) and severe hypertriglyceridemia (HTG). In a randomized Phase 2 trial (NCT04501515) in MASLD patients (N=500 mg QW), PZG-treated patients showed a significant reduction in median TG levels versus placebo (57.2% for pooled PZG versus 11.9% for placebo, with placebo-corrected difference of -43.7%, 95% confidence interval [CI]: -67.2% to -20.3%, P<0.001). Pharmacokinetics (PK) and pharmacodynamics (PD) data from this study were analyzed using a population modeling approach to support dose selection for Phase 3 studies. Weekly doses of 20 mg and 30 mg are currently being investigated in the Phase 3 (NCT04501515) HTG study (NCT04501515).

### METHODS

Subjects in this analysis included PZG treatment groups at 9 mg (n=12), 18 mg (n=12), 27 mg (n=12) administered once weekly (QW) and at 36 mg (n=12) administered once-every-two-weeks (Q2W). PK and PD (TG) data were characterized based on a population nonlinear mixed-effects modeling approach using NONMEM 7.4.2. A prior PZG PK model was used as template and the model was then adjusted with new data.

POP/PZG modeling included patients with dosing history/PK data > TG data > 67 (D: 736 D: 736). PK profile was first reconstructed for each patient using estimated PK individual parameters. A POP model for TG over time as a function of individual predicted plasma concentration (C<sub>p</sub>) was then built.

Simulation-based diagnostics, such as visual predictive checks (VPC), were used for model evaluation. Treated covariates included sex, age, weight, ethnicity, race and immunogenicity for PK and additional parameters (ALT, AST, HbA1c) added for PD. The effects of covariates were assessed using a method involving stepwise testing of linear and nonlinear relationships in a forward selection (P<0.05) followed by a backward elimination (P<0.05) procedure.

### PK POP MODEL

**Pop PK Model Structure**

**Pop PK Model Parameters**

Parameter (units)	Estimate (95% CI)	80% (95% CI)
ka (h <sup>-1</sup> )	0.0363 (0.01)	67% (10)
MTT (h) (n=12)	1.68 (0.97)	169% (24)
z	1 (fixed)	-
V (L)	14.5 (20)	20% (25)
CL (L/h)	0.24 (0.1)	25% (14)
CV (%)	0.0602 (0.01)	-
Residual error (log scale)	21.1 (46)	-
Proportional error (CV%)	0.294 (0.01)	-

**Pop PK Profiles**

### POP PD

**Pop PK Summary Results**

- Pharmacokinetic data were characterized based on a population nonlinear mixed-effects modeling approach using the software NONMEM 7.4.2.
- 1 compartment PK model with one additional transit absorption compartment adequately describes the data. The model was adjusted for the Pop PK kinetics.
- IV was estimated on ka, CL, V and MTT parameter.
- Covariate identification was done using the stepwise covariate modeling (SCM) through the Pop software. Significant covariates included in the final model was WT on CL.
- 95% change in CL for each 10 kg change in body weight.

**Pop PD Summary**

- An indirect response model was used to describe the longitudinal effect on TG. No significant covariates were identified.
- Pop PD modeling data showed that 27 mg QW dose was the most efficacious as demonstrated by more pronounced reduction in TG as compared to the other doses.

**CONCLUSIONS**

- Population PK/PD modeling provides rationale to support dose selection for the recently initiated Phase 3 (NCT04501515) study in MASLD. PZG 20 mg QW was selected to maximize efficacy and 30 mg QW was selected not only for its efficacy effect, but also to allow the sponsor to further explore the efficacy and tolerability profiles between two doses.
- Among covariates examined, only body weight can affect PZG pharmacokinetics.

**REFERENCES**

Nat Med. 2023; 29(7): 1762-1770.  
\*Cell Pharmaceut. 2023 Dec;14(8):1323-1331.

## Phase 1/2 dose escalation and expansion study of FLX475 alone and in combination with pembrolizumab in advanced cancer

ASCO 2020 Abstract TPS3195

John D. Powderly II,<sup>1</sup> Bartosz Chmielowski,<sup>2</sup> Julie R. Brahmer,<sup>3</sup> Sarina Anne Pina-Paul,<sup>4</sup> Samantha Elizabeth Bowyer,<sup>5</sup> Patricia LoRusso,<sup>6</sup> Daniel V.T. Catenacci,<sup>7</sup> Christina Wu,<sup>8</sup> Minal A. Barve,<sup>9</sup> Michael Jon Chisnom,<sup>10</sup> Nicole Nasrath,<sup>11</sup> Dan Johnson,<sup>12</sup> William Ho<sup>13</sup>,  
<sup>1</sup>Carolina Biotechnology Institute, Huntersville, NC, <sup>2</sup>Division of Hematology/Oncology, David Geffen School of Medicine at UCLA, Los Angeles, CA, <sup>3</sup>Osney Mitchell Comprehensive Cancer Center at Johns Hopkins, Baltimore, MD, <sup>4</sup>Department of Investigational Cancer Therapeutics (Phase I Program), The University of Texas MD Anderson Cancer Center, Houston, TX, <sup>5</sup>Leikin Clinical Research, Perth, Australia, <sup>6</sup>UCLA University School of Medicine, West Haven, CT, <sup>7</sup>University of Chicago Medical Center and Biological Sciences, Chicago, IL, <sup>8</sup>Thony University, Atlanta, GA, <sup>9</sup>Mayo Clinic Cancer Research Center, Dallas, TX, <sup>10</sup>Novartis and Co., Kenilworth, NJ, <sup>11</sup>TRAP Therapeutics, Orem, UT, <sup>12</sup>TRAP Therapeutics, Orem, UT, <sup>13</sup>TRAP Therapeutics, Orem, UT

### ABSTRACT

Background: Regulatory T cells (T<sub>reg</sub>) can dampen anti-tumor immune responses in the tumor microenvironment (TME). The predominant chemokine receptor on human T<sub>reg</sub> is CCR4, the receptor for the chemokines CCL17 and CCL22, which are produced by tumor cells, tumor-associated macrophages and dendritic cells, as well as by effector T cells (T<sub>H</sub>1) in the setting of an inflammatory anti-tumor response. Preclinical studies with orally-available CCR4 antagonists have demonstrated potent inhibition of T<sub>reg</sub> migration into tumors, an increase in the intratumoral T<sub>H</sub>1/T<sub>reg</sub> ratio, and anti-tumor efficacy as a single agent and in combination with checkpoint inhibitors. In a first-in-human trial conducted in healthy volunteers, the oral CCR4 antagonist FLX475 was demonstrated to be well tolerated with outstanding PK properties. A robust PD assay measuring receptor occupancy on circulating T<sub>reg</sub> demonstrated the ability to safely achieve exposure levels predicted to maximally inhibit T<sub>reg</sub> recruitment into tumors via CCR4 signaling. These human PK, PD, and safety data have enabled a streamlined design of a Phase 1/2 study of FLX475 in cancer patients both as monotherapy and in combination with checkpoint inhibitor.

Methods: This clinical trial is a Phase 1/2, open-label, dose-escalation and cohort expansion study to determine the safety and preliminary anti-tumor activity of FLX475 as monotherapy and in combination with pembrolizumab. The study is being conducted in 2 parts, a dose-escalation phase (Part 1) and a cohort expansion phase (Part 2). In Part 1 (Phase 1) of the study, at least 3 to 6 eligible subjects are being enrolled in sequential cohorts treated with successively higher doses of FLX475 as monotherapy (Part 1a) or in combination with pembrolizumab (Part 1b). In Part 2 (Phase 2) of the study, expansion cohorts of both checkpoint-naïve and checkpoint-experienced patients with tumor types predicted to be enriched for T<sub>reg</sub> and/or CCR4 ligand expression (i.e. "charged tumors") – including both EBV+ and HPV+ tumors and NSCLC, HNSCC, and TNBC – will be enrolled using a Simon 2-stage design. As of February 4, 2020, Phase 1 dose escalation has been completed and a recommended Phase 2 dose chosen for both FLX475 monotherapy and combination therapy with pembrolizumab. Enrollment into Phase 2 expansion cohorts has been initiated.

### Preclinical Data\*

CCR4 Antagonists Block the Recruitment of T<sub>reg</sub> and Increase the Number of Activated CD8+ T Cells in Tumors

CCR4 Antagonists Potentiate Anti-Tumor Effects of Immune Modulators

### METHODS

**FLX475-02 Study Design**

Phase 1 Dose Escalation (Original Schema)

Phase 2 Expansion Cohorts

**Major Eligibility Criteria**

**Study Sites**

**Acknowledgments**

**References**

### Phase 1 Healthy Volunteer Data\*

Foundation for Target PK and PD in Humans: Efficacy Linked to Exposure

Phase 1 Healthy Volunteer Study Established Well-Tolerated Potentially Therapeutic Dose

75% Receptor Occupancy is Required for Maximal Inhibition of T<sub>reg</sub> Migration

FLX475 is a potent, orally-available, small molecule antagonist of CCR4 designed to specifically block the recruitment of T<sub>reg</sub> into tumors.

With a goal of shifting the T<sub>H</sub>1/T<sub>reg</sub> ratio in favor of effector T cells.

## A model incorporating levels of complement activation more accurately predicts Huntington's disease progression than neurofilament light

Pegun Sarf, Amy Morgan, Vasa Andrews, Zorilleg, Nils Bahner, Kham Alwan, Julian Low, Sethu Sankaranarayanan, Laura Byrne, Ping Liu, How Andre Kroon, Tod Yednock, Edward Wilder, Elton Cahill-McFarlane  
The Center for Neurodegenerative Science, The University of Texas at Dallas, Dallas, TX, USA \*The Center for Neurodegenerative Science, The University of Texas at Dallas, Dallas, TX, USA

### BACKGROUND

There is an urgent need to identify and test of disease progression biomarkers for HD. Neurofilament light (NfL) is a widely used biomarker for HD progression, but its utility is limited by its low specificity and sensitivity. We have developed a model incorporating levels of complement activation (C3a and C5a) and neurofilament light (NfL) to predict HD progression. This model was validated in a cohort of HD patients and compared to a model using only NfL. The model incorporating levels of complement activation more accurately predicted HD progression than NfL alone.

### OBJECTIVE

To evaluate the utility of a model incorporating levels of complement activation (C3a and C5a) and neurofilament light (NfL) to predict HD progression compared to a model using only NfL.

### METHOD

Discovery and validation of the model incorporating levels of complement activation (C3a and C5a) and neurofilament light (NfL) to predict HD progression. The model was validated in a cohort of HD patients and compared to a model using only NfL.

### RESULTS

The model incorporating levels of complement activation (C3a and C5a) and neurofilament light (NfL) more accurately predicted HD progression than NfL alone.

### MODELING APPROACH

Figure 1: Model incorporating levels of complement activation (C3a and C5a) and neurofilament light (NfL) to predict HD progression.

Figure 2: Validation of the model incorporating levels of complement activation (C3a and C5a) and neurofilament light (NfL) to predict HD progression.

Figure 3: Comparison of the model incorporating levels of complement activation (C3a and C5a) and neurofilament light (NfL) to predict HD progression to a model using only NfL.

Figure 4: Validation of the model incorporating levels of complement activation (C3a and C5a) and neurofilament light (NfL) to predict HD progression.

Figure 5: Validation of the model incorporating levels of complement activation (C3a and C5a) and neurofilament light (NfL) to predict HD progression.

Figure 6: Validation of the model incorporating levels of complement activation (C3a and C5a) and neurofilament light (NfL) to predict HD progression.

Figure 7: Validation of the model incorporating levels of complement activation (C3a and C5a) and neurofilament light (NfL) to predict HD progression.

Figure 8: Validation of the model incorporating levels of complement activation (C3a and C5a) and neurofilament light (NfL) to predict HD progression.

Figure 9: Validation of the model incorporating levels of complement activation (C3a and C5a) and neurofilament light (NfL) to predict HD progression.

Figure 10: Validation of the model incorporating levels of complement activation (C3a and C5a) and neurofilament light (NfL) to predict HD progression.

### CONCLUSIONS

The model incorporating levels of complement activation (C3a and C5a) and neurofilament light (NfL) more accurately predicted HD progression than NfL alone.

Figure 11: Validation of the model incorporating levels of complement activation (C3a and C5a) and neurofilament light (NfL) to predict HD progression.

Figure 12: Validation of the model incorporating levels of complement activation (C3a and C5a) and neurofilament light (NfL) to predict HD progression.

Figure 13: Validation of the model incorporating levels of complement activation (C3a and C5a) and neurofilament light (NfL) to predict HD progression.

Figure 14: Validation of the model incorporating levels of complement activation (C3a and C5a) and neurofilament light (NfL) to predict HD progression.

Figure 15: Validation of the model incorporating levels of complement activation (C3a and C5a) and neurofilament light (NfL) to predict HD progression.

Figure 16: Validation of the model incorporating levels of complement activation (C3a and C5a) and neurofilament light (NfL) to predict HD progression.

Figure 17: Validation of the model incorporating levels of complement activation (C3a and C5a) and neurofilament light (NfL) to predict HD progression.

Figure 18: Validation of the model incorporating levels of complement activation (C3a and C5a) and neurofilament light (NfL) to predict HD progression.

Figure 19: Validation of the model incorporating levels of complement activation (C3a and C5a) and neurofilament light (NfL) to predict HD progression.

Figure 20: Validation of the model incorporating levels of complement activation (C3a and C5a) and neurofilament light (NfL) to predict HD progression.



# SAMPLE WORK – BOOTH DESIGN

# BOOTH DESIGN – 10x10



# BOOTH DESIGN – 10x20





# SAMPLE WORK – CLINICAL TRIAL BRANDING

# CLINICAL TRIAL BRANDING

## Ascendis Pharma: heiGHt Trial

**heiGHt TRIAL**

A Phase 3 clinical trial comparing once-weekly TransCon Growth Hormone to daily growth hormone (hGH) in children with growth hormone deficiency (GHD). This study is expected to begin mid-2016.

Interested in more information about the heiGHt Trial? Register for updates.

NAME:

EMAIL:

**SUBMIT**

**heiGHt TRIAL**

**About the heiGHt Trial**

Over the past 25 years, daily hGH has been optimized for treating GHD. Daily injections can be difficult for children and families. Research shows two out of three patients miss more than one injection on average per week. Poor compliance with daily hGH therapy is associated with reduced height velocity and impaired quality of life.

The once-weekly TransCon Growth Hormone being studied in the heiGHt Trial contains somatotrin, the same active ingredient in daily hGH products. The hope is that fewer injections may be preferable to children and their families, so fewer doses may be missed. In turn, this may lead to better treatment outcomes.

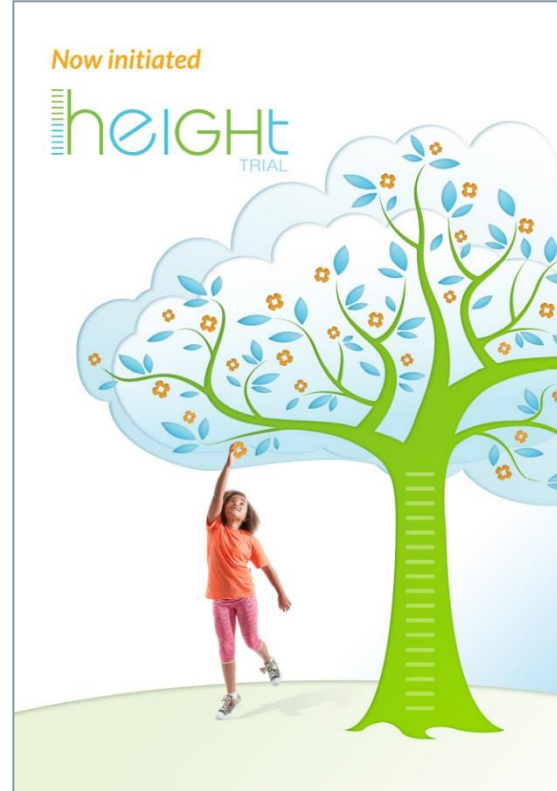
**Once-weekly TransCon Growth Hormone**

hGH (somatotropin) → Inactive Prodrug → hGH (somatotropin)

Creation of TransCon Prodrug → Predictable release of hGH in the body

TransCon Growth Hormone is an investigational sustained-release prodrug that is designed to predictably deliver the same somatotropin as approved daily hGH products, with one weekly, once-weekly dosing.

<http://heighttrial.com>



Brochure



Booth



Growth Hormone Trial logos



# CLINICAL TRIAL BRANDING

## Rubius Therapeutics

Join us in exploring a new era in cellular medicine

At Rubius, our vision is to bring potentially life-changing cellular therapies to people living with rare metabolic and inflammatory disorders, cancer and autoimmune diseases. We call these potential medicines Red Cell Therapeutics™.

LEARN ABOUT RED CELL THERAPEUTICS™

FIND A CLINICAL TRIAL

Open Clinical Studies

METABOLIC DISORDERS

Phenylketonuria (PKU)

Rubius Therapeutics is enrolling adults with PKU into a Phase 2b clinical trial to evaluate a new potential treatment option called RTX-134.

LEARN MORE ABOUT THE PKU CLINICAL TRIAL

Sign up to learn more about Red Cell Therapeutics™ and receive updates about clinical trials for the potential treatment of rare metabolic disorders, inflammatory disorders, cancer and autoimmune diseases.

First Name, Last Name, Email, Phone Number, Zip code, Disease (Metabolic Disorders, Inflammatory Disorders, Cancer, Autoimmune Diseases)

Submit

Find a Trial

Advancing new treatment options for people living with rare metabolic disorders, inflammatory disorders, cancer and autoimmune diseases.

Phenylketonuria (PKU)

Rubius Therapeutics is currently enrolling patients in a Phase 2b trial to evaluate a single dose of RTX-134, an enzyme replacement therapy contained inside a red blood cell for the potential new treatment of PKU. Our ultimate goal in developing RTX-134 is to provide patients with a safe and effective treatment option to lower phenylalanine levels via infrequent administration, allowing people to have to a normal diet.

VIEW RTX-134 CLINICAL TRIAL DETAILS

Don't see a clinical trial for you?

Sign up to learn more about Red Cell Therapeutics™ and receive updates about clinical trials for the potential treatment of rare metabolic disorders, inflammatory disorders, cancer and autoimmune diseases.

First Name, Last Name, Email, Phone Number, Zip code, Disease (Metabolic Disorders, Inflammatory Disorders, Cancer, Autoimmune Diseases)

Submit

Be a part of a new era in cellular medicine for the potential treatment of phenylketonuria

PKU is an inherited metabolic disorder that is characterized by the body's inability to metabolize the essential dietary amino acid, phenylalanine, due to a lack of or deficiency in the phenylalanine hydroxylase (PAH) enzyme.

Rubius Therapeutics is developing a potential new treatment option for phenylketonuria (PKU), called RTX-134. RTX-134 is an enzyme replacement therapy using the enzyme phenylalanine ammonia lyase (PAL) inside a red blood cell and is designed to breakdown phenylalanine as it circulates through the bloodstream.

At Rubius Therapeutics, our ultimate goal in developing RTX-134 is to provide patients with a safe and effective treatment option that lowers phenylalanine via infrequent IV administration and allows people to enjoy to a normal diet.

LEARN ABOUT PKU CLINICAL TRIAL

Sign up to learn more about Red Cell Therapeutics and PKU clinical trials.

First Name, Last Name, Email, Phone Number, Zip code

Submit

Clinical Trials

Participating in a clinical trial is a significant commitment. We are grateful for the important contributions of the volunteers who take part in this important research.

About the RTX-134 Phase 2b Clinical Trial

The Phase 2b clinical trial is designed to establish whether RTX-134 is safe, how much RTX-134 needs to be given for it to be effective and how often it should be given to be effective.

In this trial, participants will receive a single dose of RTX-134, given by intravenous infusion up to 10 weeks with PKU. The trial will be evaluating:

- Any side effects of the treatment
- Non-enrolled human red blood cells can live up to 120 days in a person's body
- In this trial, the concentration of the cells will be measured, and it will help determine how often the treatment will need to be administered
- Any medications in the body and any increases in TCA, one of the byproducts of the body, during the trial
- Whether any side effects or changes in weight occur

All Study Participants Receive at No Cost:

- The study drug, RTX-134. The medical costs and associated expenses related to the clinical trial
- Travel and lodging throughout the clinical trial or an overnight stay
- Compensation for participants, including travel support for those who qualify

Who Can Participate?

Upon reviewing the clinical trial eligibility criteria, speak with your doctor about any questions you may have and clinical trials that may benefit you.

Adults who meet the following criteria may be able to participate in the trial:

- Men 18 years old or older, women of non-childbearing age between 18 and 45 years old with PKU who have the lowest measured PKU levels
- Patients who have had previous PKU levels between three weeks from their first dose of RTX-134
- Patients who receive their first dose of RTX-134 within three weeks of receiving a dose of PKU; you are not eligible for trial participation

Adults who do not meet the following criteria are not eligible to participate in this Phase 2b clinical trial, but may be eligible to participate in future clinical trials once we establish the preliminary safety of RTX-134:

- Patients who have had previous PKU levels more than three weeks from their first dose of RTX-134
- Patients who receive their first dose of RTX-134 within three weeks of receiving a dose of PKU; you are not eligible for trial participation

What to Expect Once Enrolled

Screening and Eligibility	Infusion Care	Follow-Up Visits
Participants in the trial will be screened for eligibility. At doctor's visits, bloodwork, and physical exams, and will be measured at the trial site.	In Phase 2b of the trial, a single dose of RTX-134 is given by a single IV administration of 100 mL of solution, or just over 3-4 hours of infusion.	Daily visits are required for the first three days, followed by weekly visits for four weeks. Monitoring will primarily consist of lab work and physical exams, and will be approximately 15-20 minutes.
After receiving the dose, participants will be closely monitored for the first 24 hours. For any side effects or reactions.		After the fourth week, visits are reduced to every other week for up to 100 days after dosing, and RTX-134 is no longer detected in the blood.

Throughout the clinical trial, we ask participants to:

- Keep a diary
- Make the diet that qualifies you for the clinical trial, including medical foods

PKU TRIAL FAQ

Sign up to learn more about Red Cell Therapeutics and PKU clinical trials.

First Name, Last Name, Email, Phone Number, Zip code

Submit

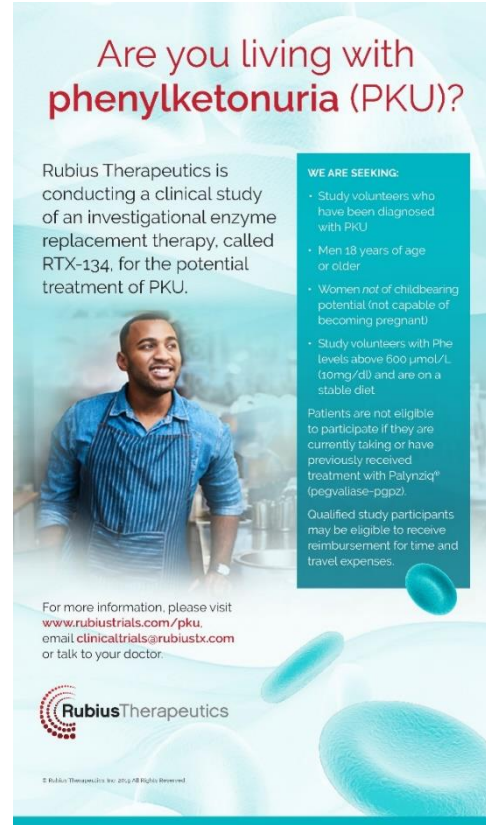
Clinical trials website

# CLINICAL TRIAL BRANDING

## Rubius Therapeutics



Clinical trial toolkit



Social media flyer



10 x 10 exhibit



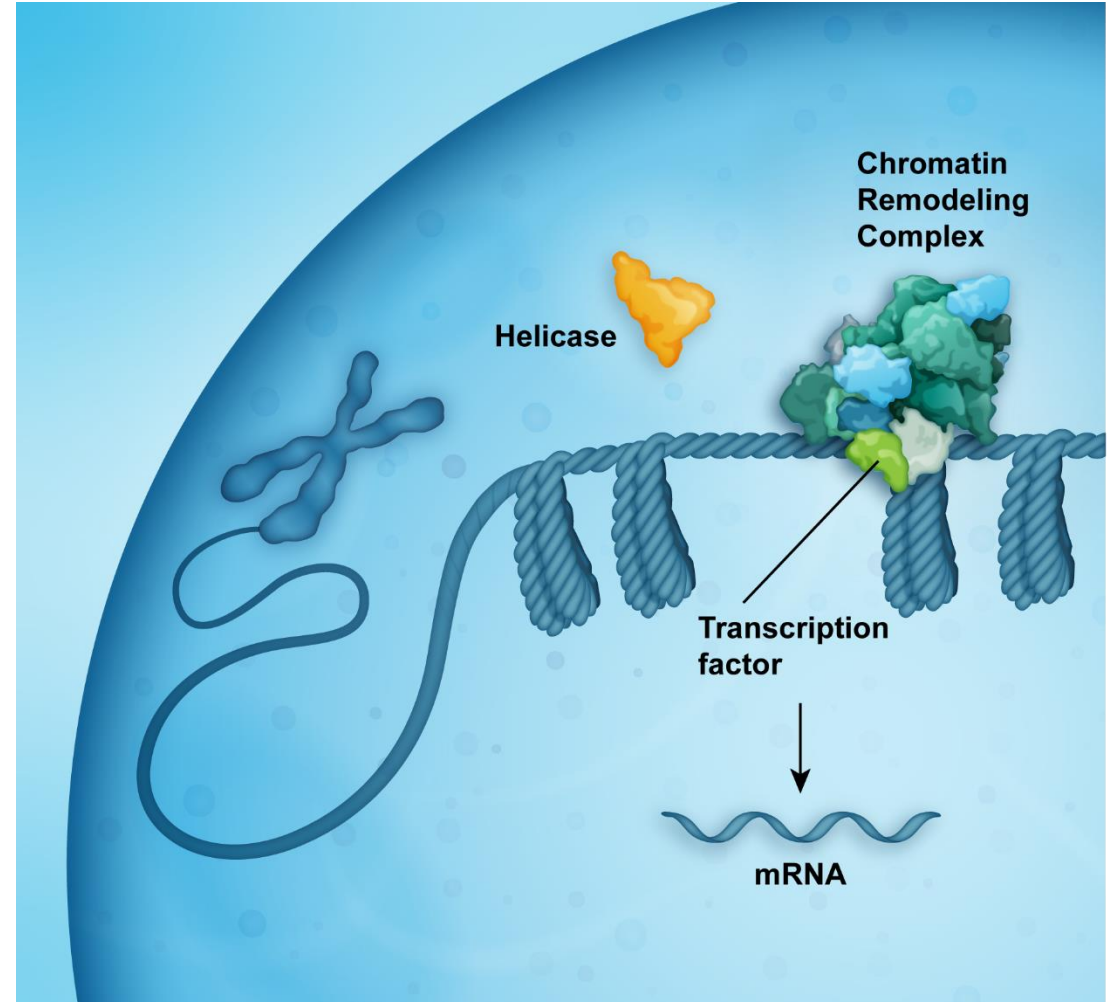
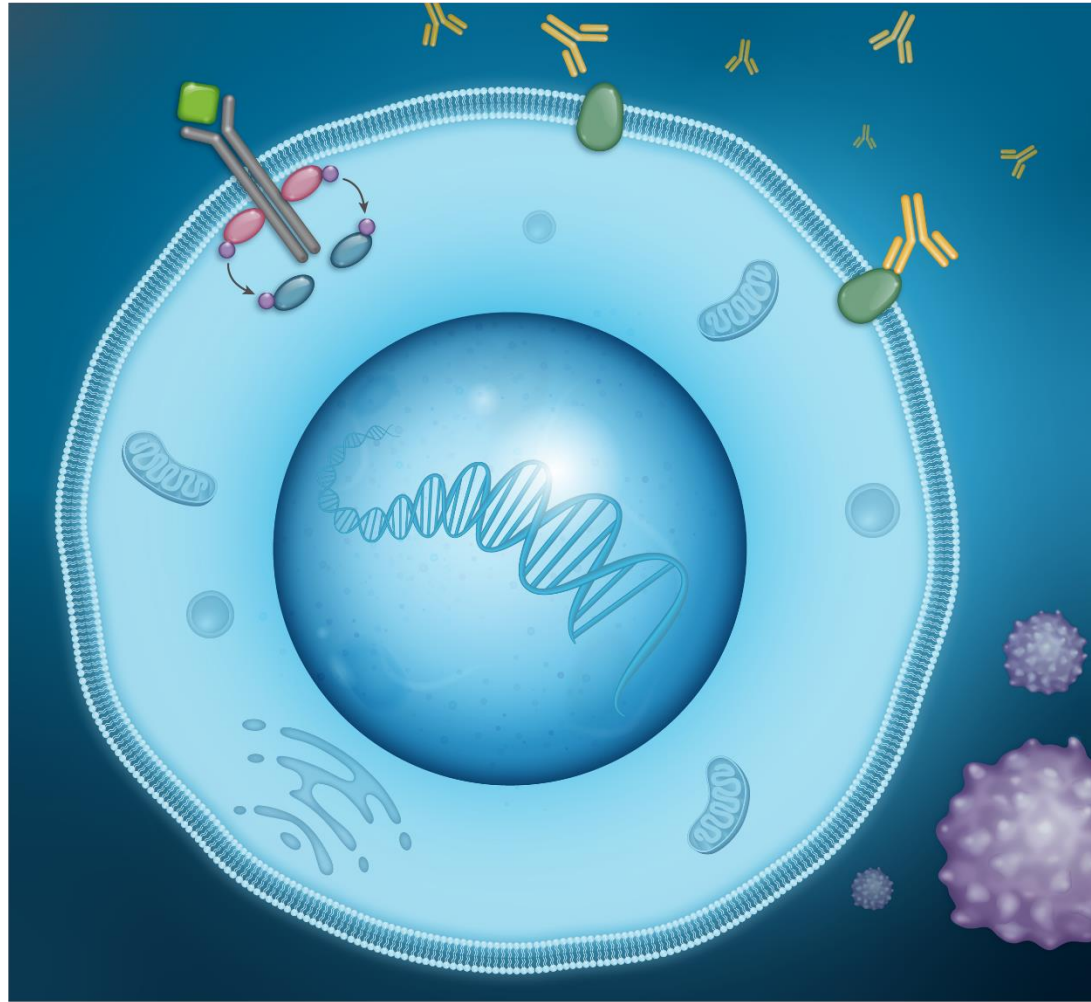
Employee T-Shirt



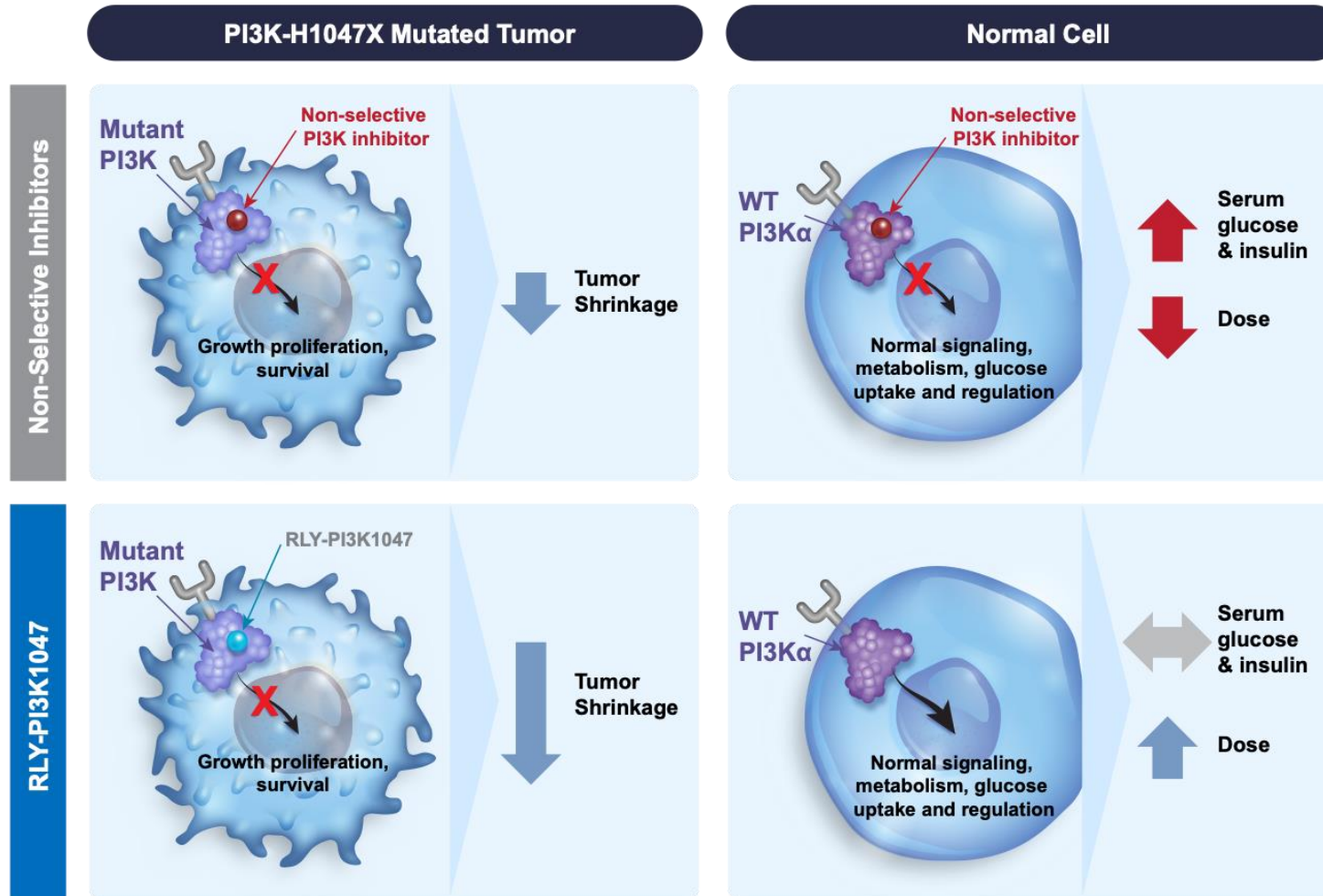


# SAMPLE WORK – MEDICAL ILLUSTRATION

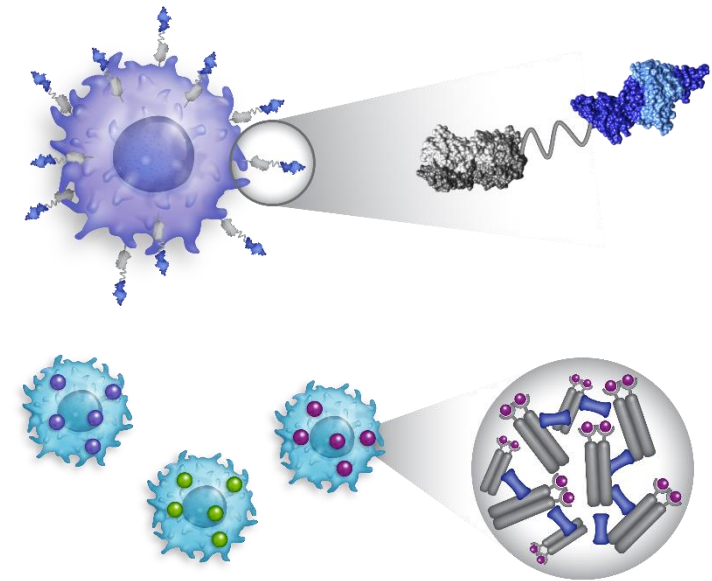
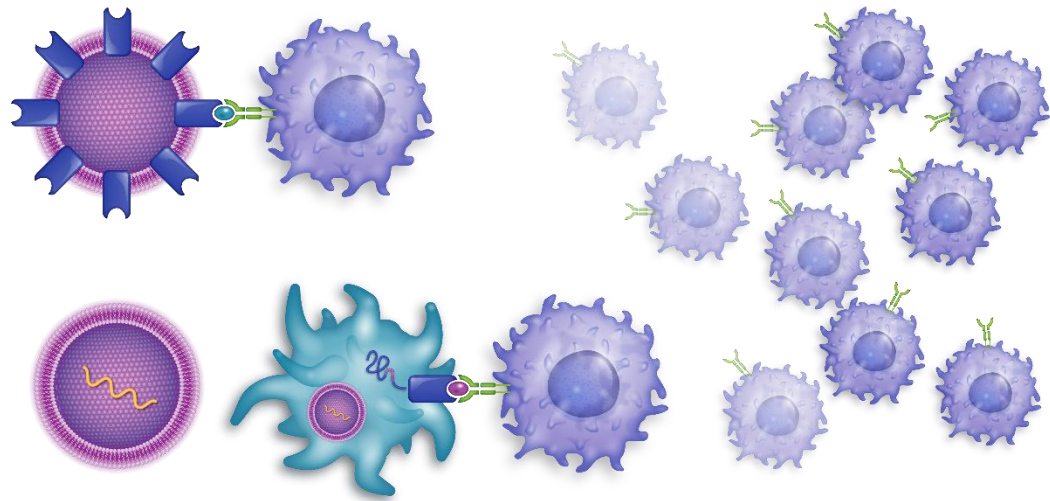
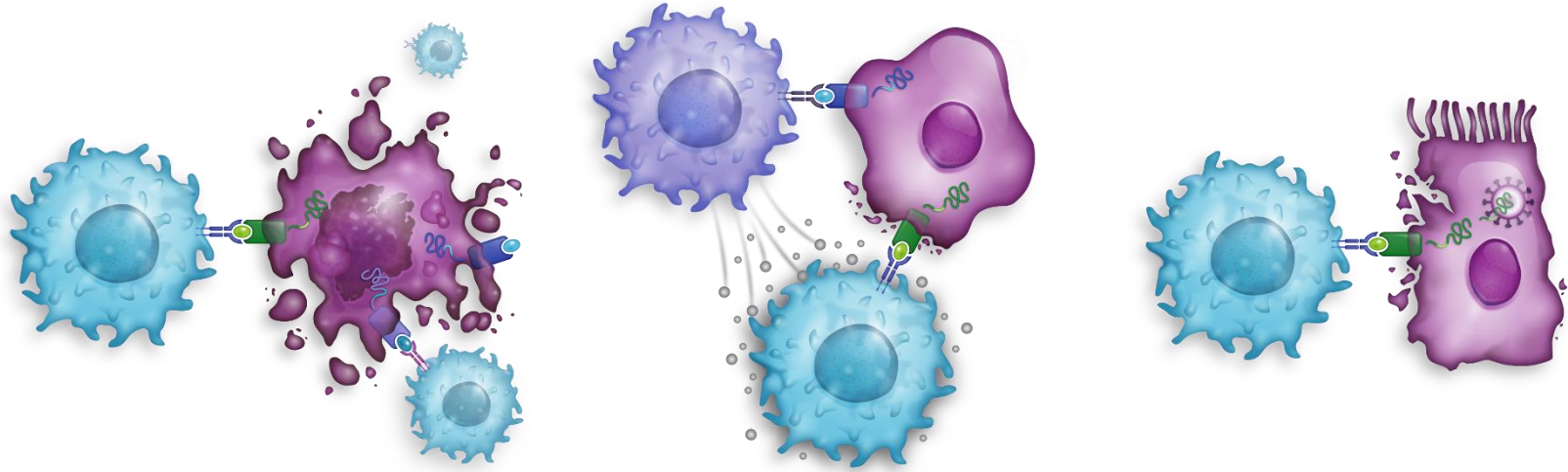
# FOGHORN THERAPEUTICS



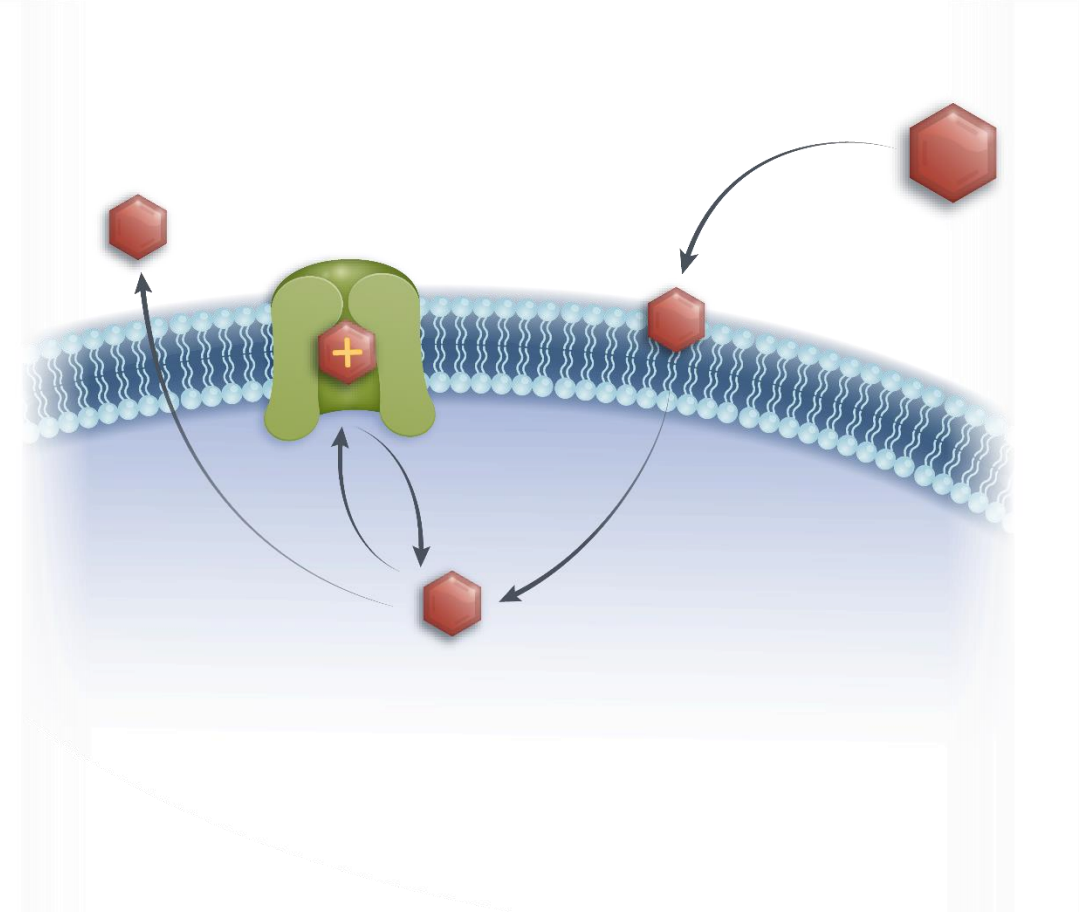
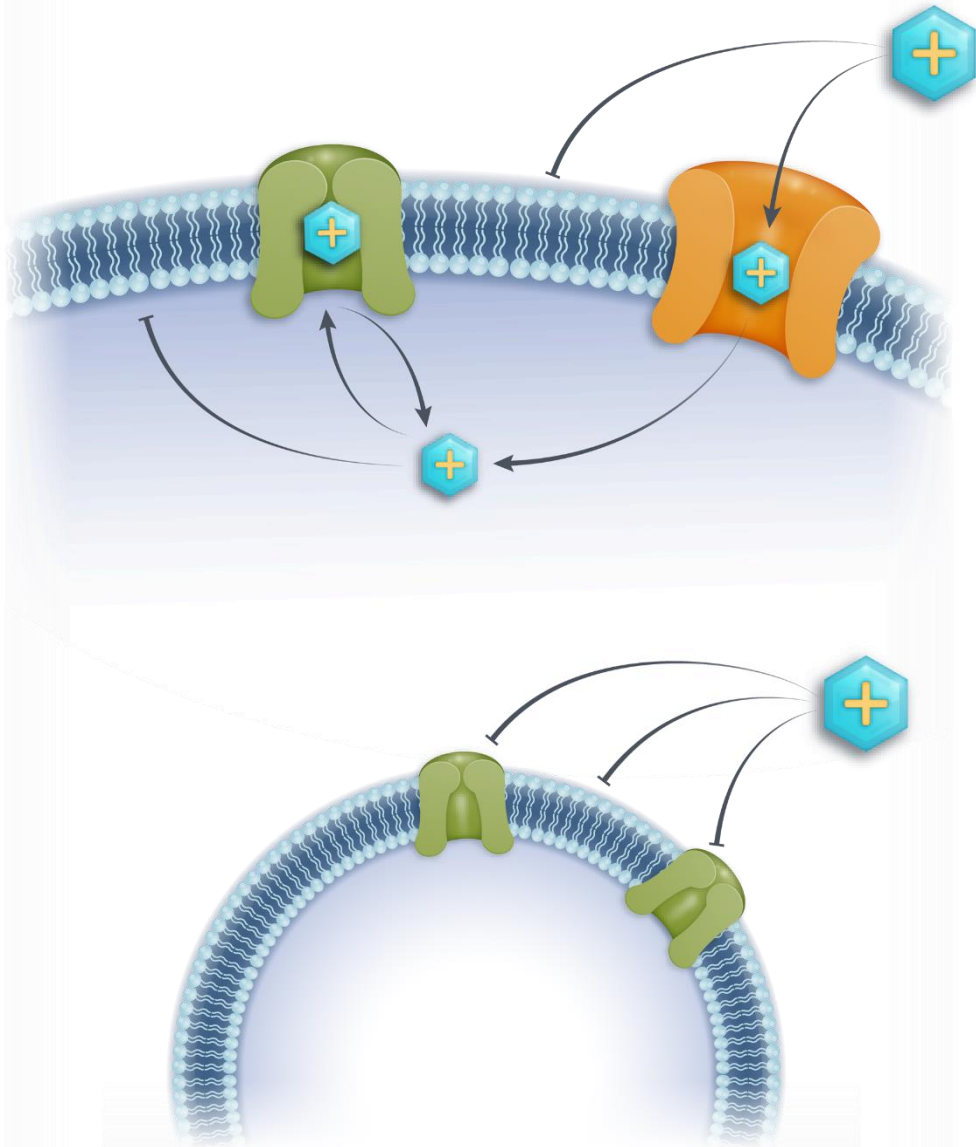
# RELAY THERAPEUTICS



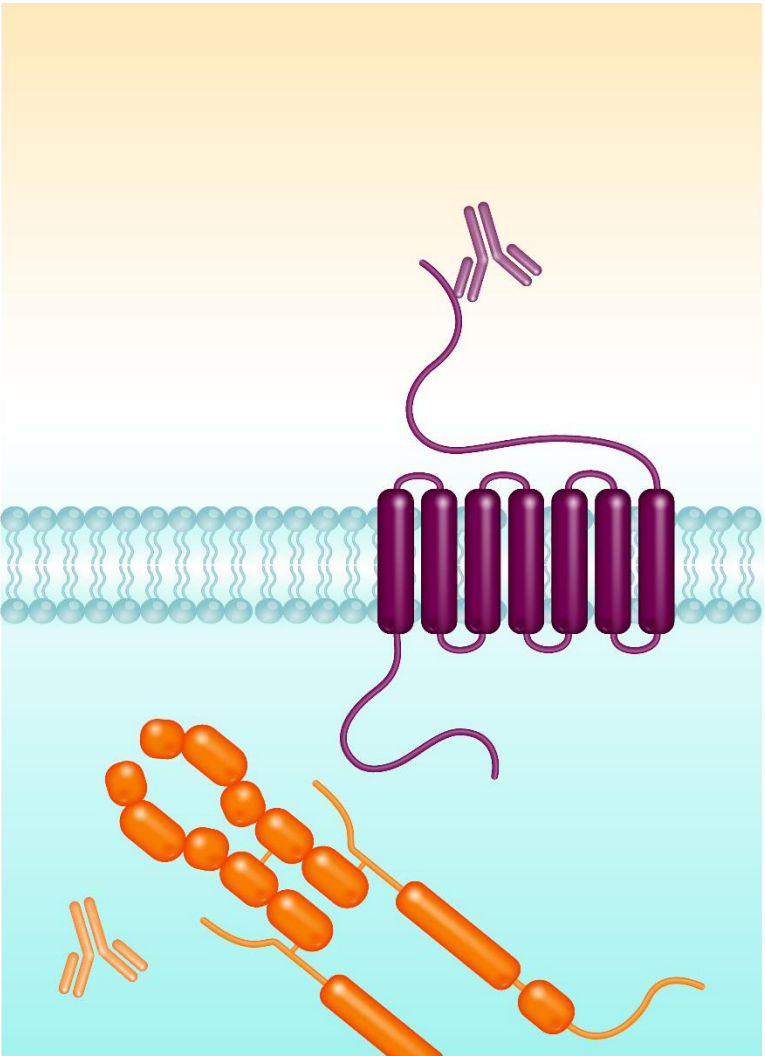
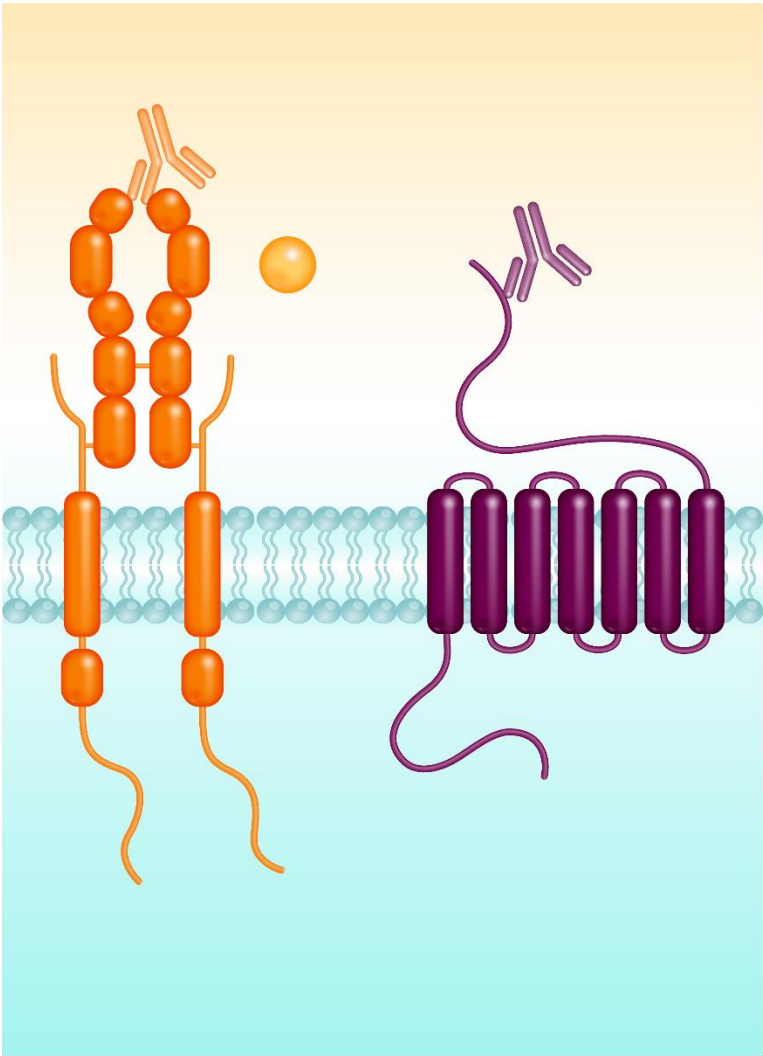
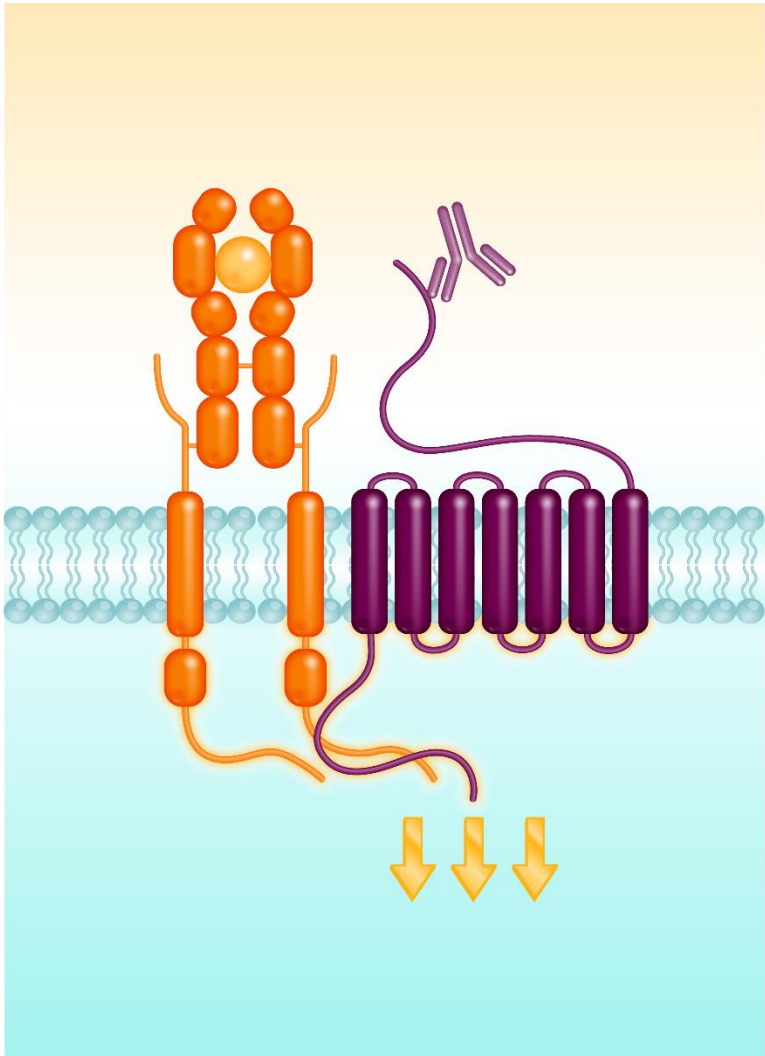
# REPERTOIRE IMMUNE MEDICINES



# NOCION THERAPEUTICS

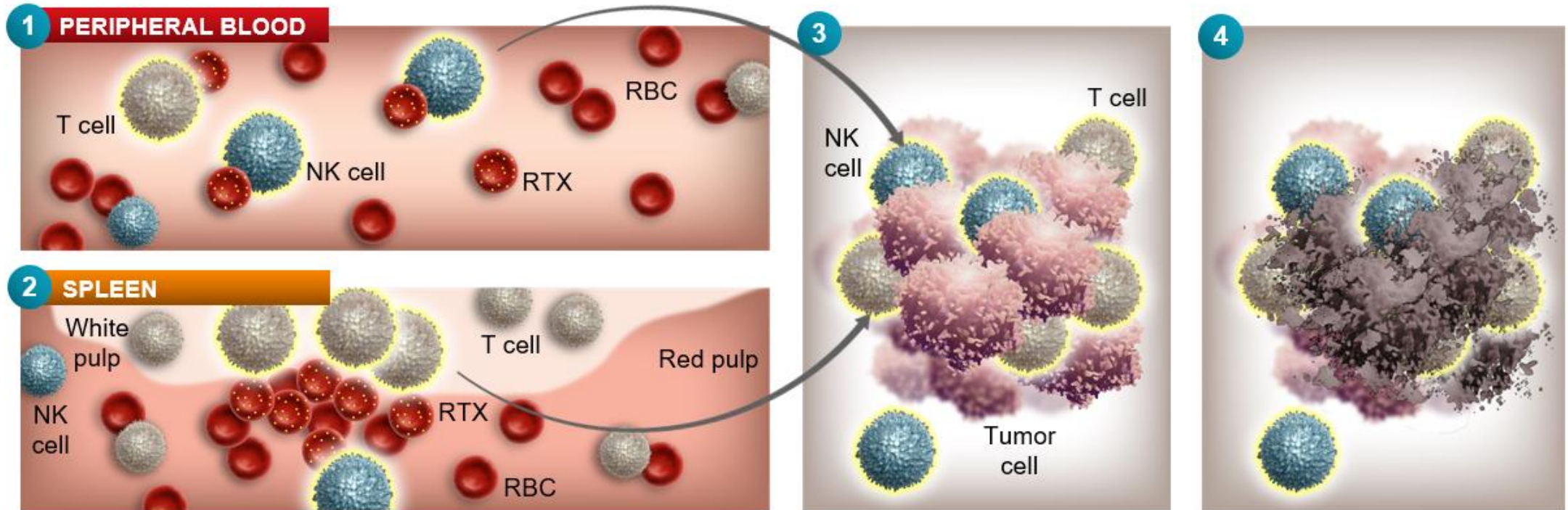


# VALENZA BIO

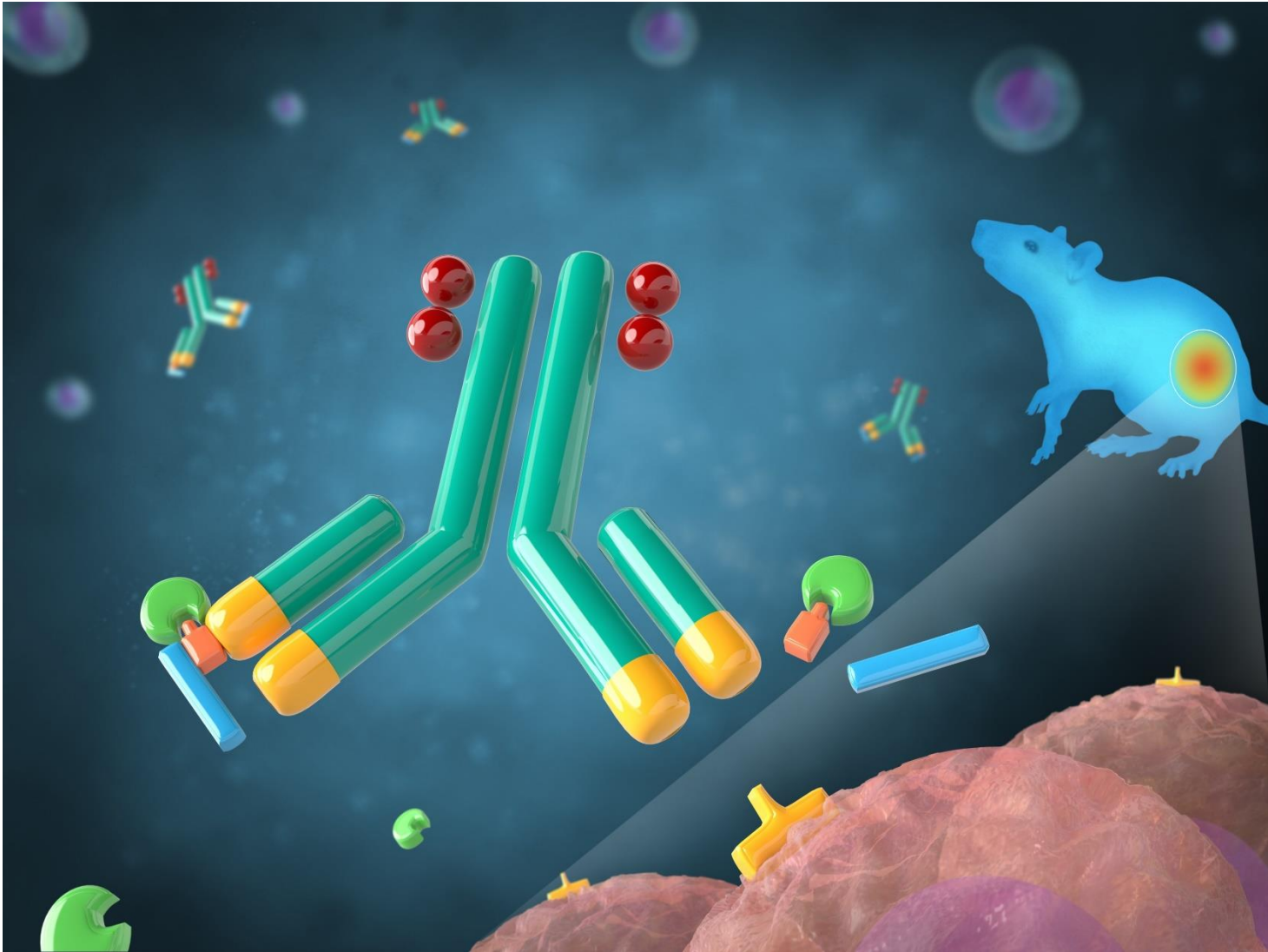




# RUBIUS THERAPEUTICS



# CYTOMX





# SAMPLE WORK – VIDEO/PHOTOGRAPHY

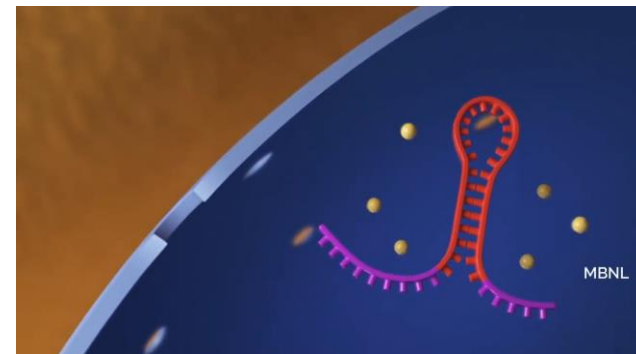
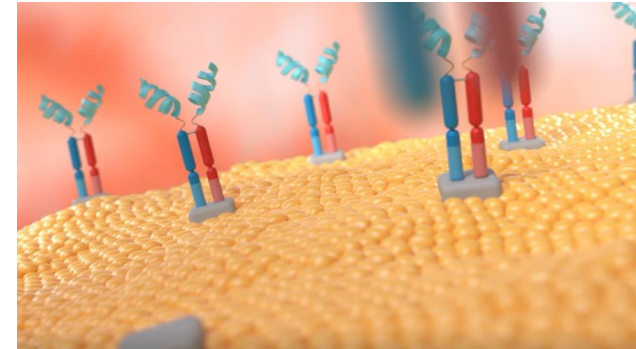
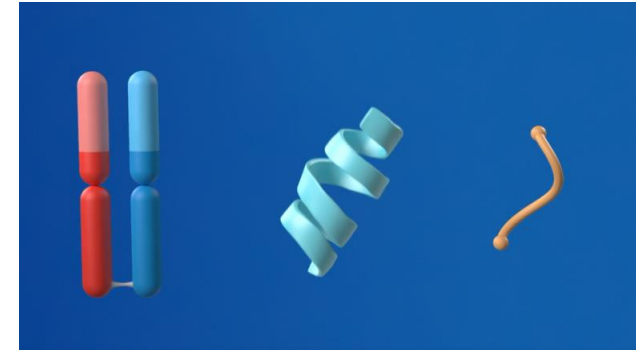
# VIDEO ANIMATION

## Dyne Therapeutics

[Dyne MOA Animation](#)



MOA Video



# PHOTOGRAPHY



# PHOTOGRAPHY



# PATIENT PHOTOGRAPHY

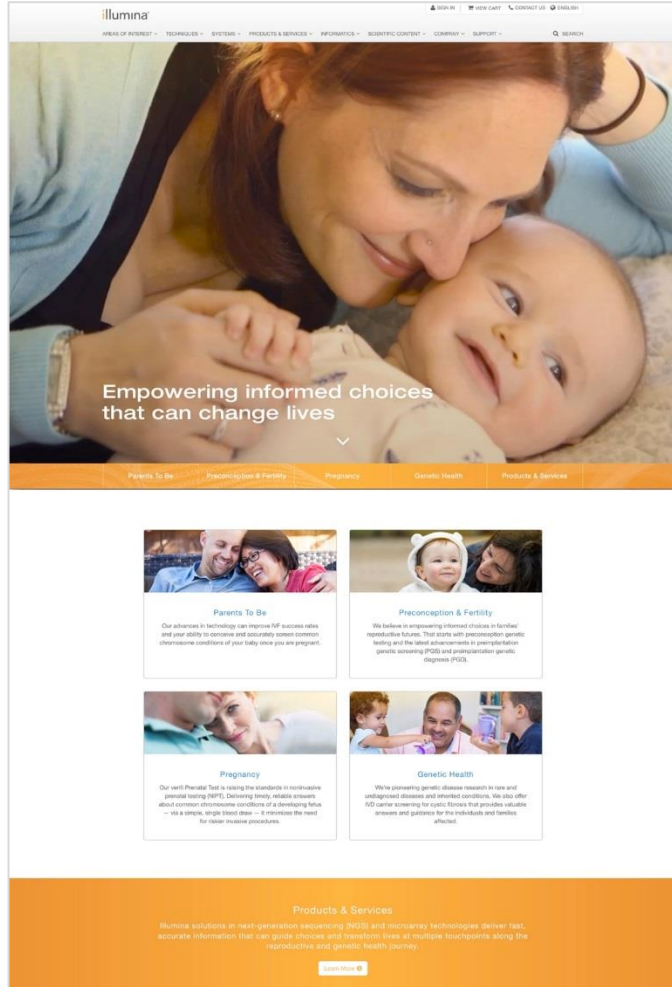




# SAMPLE WORK – ADDITIONAL CREATIVE



# CAMPAIGN DEVELOPMENT



**illumina**

## verifi<sup>®</sup> Prenatal Test

A reliable, easy, fast noninvasive prenatal test

**Empowering informed choices that can change lives**

**Parents To Be**  
Our advances in technology can improve IVF success rates and your ability to conceive and accurately screen common chromosomal conditions of your baby since you are pregnant.

**Preconception & Fertility**  
We believe in empowering informed choices in fertility's reproductive future. That starts with preconception genetic testing and the latest advances in preimplantation genetic screening (PGS) and preimplantation genetic diagnosis (PGD).

**Pregnancy**  
Our verifi Prenatal Test is raising the standards in noninvasive prenatal testing (NPT). Delivering timely, reliable answers about common chromosomal conditions of a developing fetus — via a simple, single blood draw — it minimizes the need for labor-intensive procedures.

**Genetic Health**  
We're pioneering genetic disease research in rare and undiagnosed diseases and inherited conditions. We also offer 800 cancer coverage for genetic findings that provide valuable answers and guidance for the individuals and families affected.

**Products & Services**  
Illumina solutions in next-generation sequencing (NGS) and microarray technologies deliver fast, accurate information that can guide choices and treatments from all multiple touchpoints along the reproductive and genetic health journey.

**illumina**

### An easy way to test

Noninvasive prenatal testing (NPT) is a cutting-edge screening option that professional societies, including the American College of Obstetricians and Gynecologists (ACOG), have endorsed for use in all pregnant women.<sup>1,2</sup> This test option has a higher level of sensitivity and specificity than traditional screening because NPT utilizes cell-free DNA in the maternal bloodstream to screen for fetal aneuploidy.<sup>1,4</sup>

**Cell-free DNA screening:**

- Offers the highest reported detection rate for Down syndrome<sup>1</sup>
- Offers the lowest reported false positive rate for Down syndrome<sup>1</sup>
- Can be performed as early as 10 weeks' gestation until term<sup>1,4</sup>

While highly sensitive and specific, false positives and false negatives can occur, and NPT is not a substitute for diagnostic testing.<sup>1,4</sup>

**verifi<sup>®</sup> Prenatal Test**

While there are different methods for performing NPT, next-generation sequencing (NGS), is the most-published method.<sup>1,4</sup> It has demonstrated excellent detection rates and very low false positive rates.<sup>1,4,5</sup>

The verifi Prenatal Test from Illumina uses whole-genome next-generation sequencing (WGS) and detects the most common fetal aneuploidies, with higher accuracy than traditional screening methods.<sup>1,4</sup>

**Fast, reliable answers about the most common chromosomal aneuploidies**

The verifi Prenatal Test safely and noninvasively screens for the most common chromosomal aneuploidies as early as 10 weeks gestation using a single maternal blood draw.

**Test options**

**Basic offering:**

- Trisomy 21 (Down Syndrome)
- Trisomy 18 (Edwards syndrome)
- Trisomy 13 (Patau syndrome)

**Optional add-on offerings:**

- Sex chromosome aneuploidies:
  - Monosomy X (MC, Turner syndrome)
  - XXX (Triple X)
  - XYY (Klinefelter syndrome)
  - XXY (Jacobs syndrome)
- Expanded autosomal trisomies:
  - Trisomy 9 and Trisomy 16
- Microdeletion syndromes:
  - 22q11.2 deletion syndrome (DiGeorge syndrome)
  - Prader-Willi syndrome/Angelman syndrome
  - 4p- (Wolf-Hirschhorn syndrome)
  - 5p- (Cri du Chat syndrome)
  - 1p36 deletion syndrome

**Our sequencing technology has the lowest published failure rate in the industry—0.1%.<sup>6,8</sup>**

**Reliable test results**

Test performance metrics are important for:

- Deciding which noninvasive screening option to offer your patients
- Determining which laboratory to use
- Pre-test counseling about benefits and limitations of noninvasive screening options (detection rates, false positive and false negative rates)
- Post-test counseling for patients with positive results about the likelihood of a true positive, positive predictive value

**Trisomy 21 Detection Rate: Cell-Free DNA Screening vs. First Trimester Quadrant Screening (FTQS)**

Cell-free DNA screening consistently offers higher detection rates than FTQS.

**Trisomy 21 False Positive Rate: Cell-Free DNA Screening vs. First Trimester Quadrant Screening**

Cell-free DNA screening consistently offers lower false positive rates than FTQS.

**Trisomy 21 Positive Predictive Value: Cell-Free DNA Screening vs. First Trimester Quadrant Screening**

High rates of retained pregnancies with Down syndrome are observed when using FTQS. The high number of retained pregnancies with Down syndrome is likely due to the high false positive rate of FTQS.

**Trisomy 21 Positive Predictive Value: Cell-Free DNA Screening vs. First Trimester Quadrant Screening**

High rates of retained pregnancies with Down syndrome are observed when using FTQS. The high number of retained pregnancies with Down syndrome is likely due to the high false positive rate of FTQS.

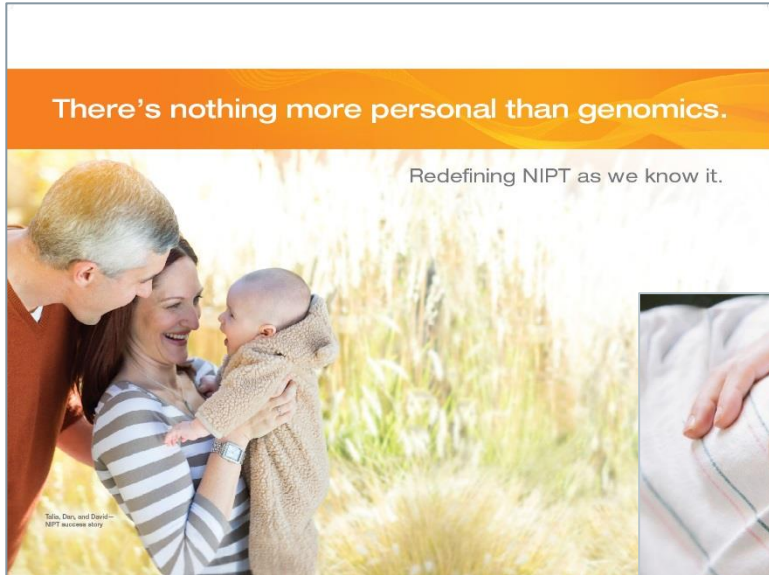
**Trisomy 21 Positive Predictive Value: Cell-Free DNA Screening vs. First Trimester Quadrant Screening**

High rates of retained pregnancies with Down syndrome are observed when using FTQS. The high number of retained pregnancies with Down syndrome is likely due to the high false positive rate of FTQS.

HCP Brochure

<https://www.illumina.com/rgb>

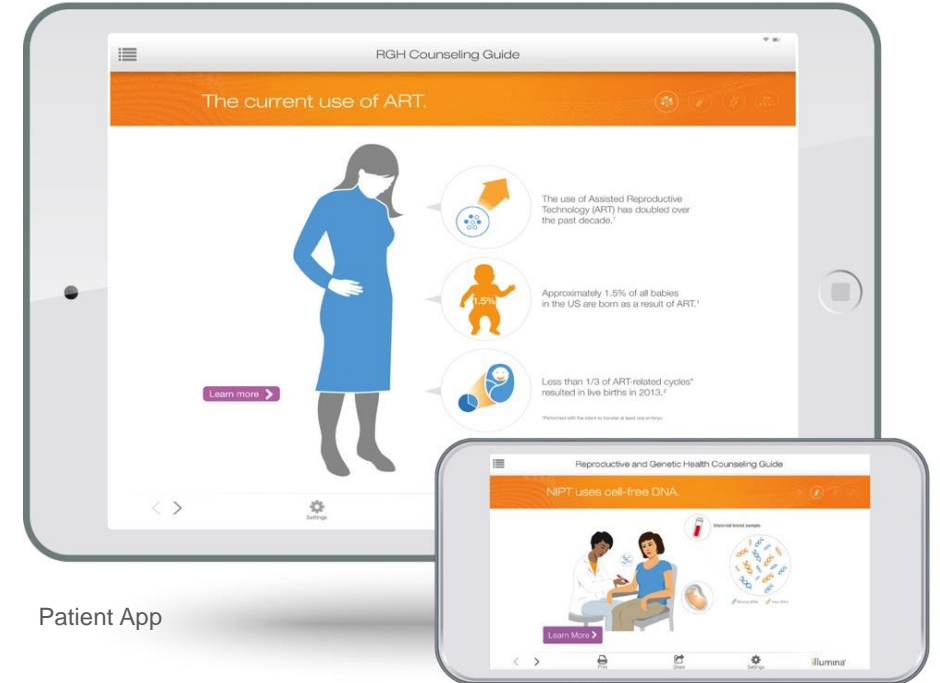
# CAMPAIGN DEVELOPMENT



Convention Booth Panel



Patient Print Ad



Patient App

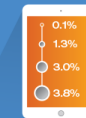
# INFOGRAPHICS



## The veriFi<sup>®</sup> Prenatal Test Send Out (TSO) Partner Program

Get the competitive edge

Illumina is taking its leadership position in noninvasive prenatal testing (NIPT) to the next level with the creation of our veriFi Prenatal Test Send Out Partner Program. This enterprise underscores our unwavering commitment to you—our valued clinical lab partners. It combines our whole-genome sequencing technology with clinical and marketing expertise. The goal is to collaboratively provide you with everything you'll need to deliver the highest quality NIPT results to your customers—and competitively grow your business in the process.



### Confidence you can count on

Among NIPT options, the veriFi Prenatal Test has the lowest test failure rate of only 0.1%, excluding administrative failed samples.<sup>1</sup> That's more than 10x lower than its closest competitor.<sup>2-4</sup> This means the veriFi Prenatal Test provides results 99.9% of the time—minimizing delays and potentially minimizing the need for invasive testing, which in turn should reduce patient anxiety.

### Comprehensive onboarding

As our NIPT Partner, you will automatically receive a thorough onboarding package, including a checklist of important Illumina contacts, complete ordering, reporting, and shipping information, and customizable marketing tools and training to keep you a step ahead of your competitors.



### Customizable marketing materials

You'll also be provided with a valuable toolbox of downloadable resources, including competitive and customizable marketing materials to support and help grow your lab's customer base and business.

### Clinical expertise and access

Our TSO Partner Program gives you access to clinically relevant publications and scientifically accurate information and data on NIPT—potentially helping to increase your credibility and respect as a leader in this dynamic field. You can also have access to ongoing interactions with our clinical genetic experts and other specialists—to ensure the competitive edge you need to thrive in this rapidly changing market.

### Communications to keep you informed

Receive monthly articles, quarterly e-newsletters, and other newsworthy communications to keep you in the know about the latest advances in NIPT—and help you accelerate and expand your experience and optimize your implementation of NIPT in clinical practice.



A large dandelion seed head is positioned on the left side of the frame, with its stem extending downwards. Numerous seeds are shown in mid-air, blowing away from the head towards the right. The background is a solid, vibrant blue. The text 'PARTNER BIOS' is centered in the right half of the image.

# PARTNER BIOS

# BETSY DENNIG



Principal/  
Managing Director

Betsy has over 25 years of experience working in healthcare marketing communications. She has extensive experience in corporate and product branding and tactical execution and has a background in medical education, publication planning and KOL/advocacy development. Betsy develops strategically driven communication plans and builds lasting relationships with her clients and colleagues. Her strong leadership, decision-making and organizational skills along with her dedication, positive nature and can-do attitude, has enabled her to build a successful marketing company over the last 15 years. She's an expert at listening to her client's needs and turning them into one-of-a-kind solutions that generate outstanding results. She received her bachelor's degree in marketing and art from Bucknell University.

# HABEEBA CLARK



Principal/  
Creative Director

Habeeba is an exceptionally experienced and innovative marketer, with unparalleled abilities to see the big picture, build cohesive brands, lead teams, and produce something unique and impactful with every project she touches. Highly skilled in branding and conceptual work, Habeeba's been involved with pharmaceutical, device and diagnostic products spanning virtually every disease category. She's worked extensively with product launches and campaigns, corporate communications, patient and physician educational initiatives and in the digital realm. Habeeba specializes in big ideas and honing-in on unusual creative approaches.

THANK YOU