

Opportunities and Priorities for the Office of New Drugs: Optimizing Outcomes

Kelly Close

founder, The diaTribe Foundation
president, Close Concerns

Emily Fitts

Senior Manager, Advocacy &
Policy, The diaTribe Foundation

Cherise Shockley

Community Manager,
The diaTribe Foundation

OND, FDA – November 7th, 2019

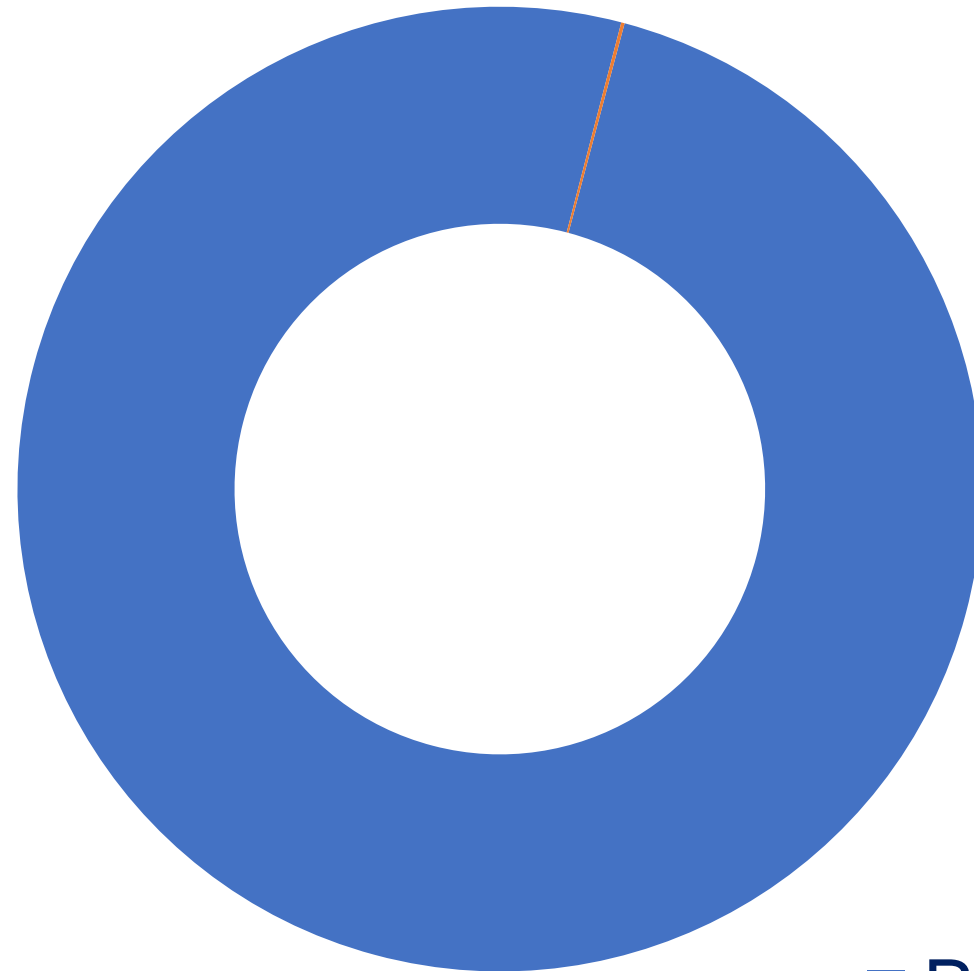


Thank you immeasurably!

Diabetes Management = Self-Management

People with diabetes spend **24,000 - 110,000 minutes** a year making decisions about their diabetes.

People with diabetes spend **15-120 minutes** a year with health care professionals



■ PWD ■ HCP

diaTribe[®]



Expand primary and secondary endpoints that affect patient outcomes



Self-management support



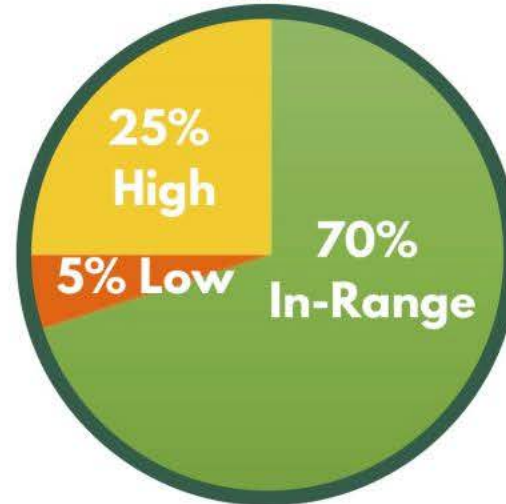
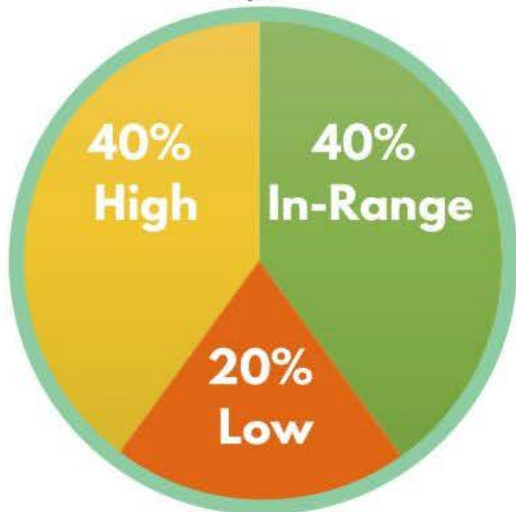
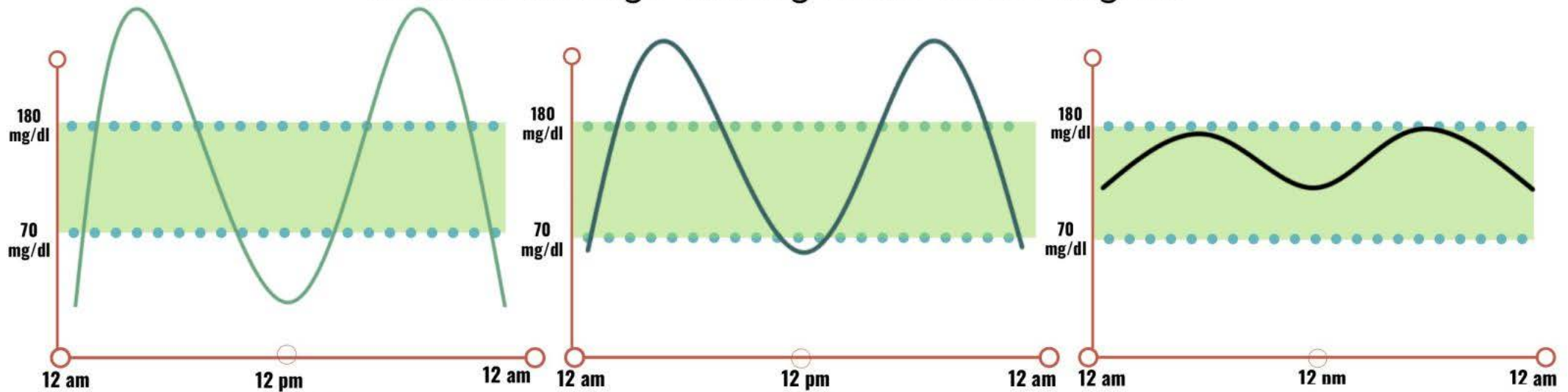
Improved medical and
psychosocial outcomes



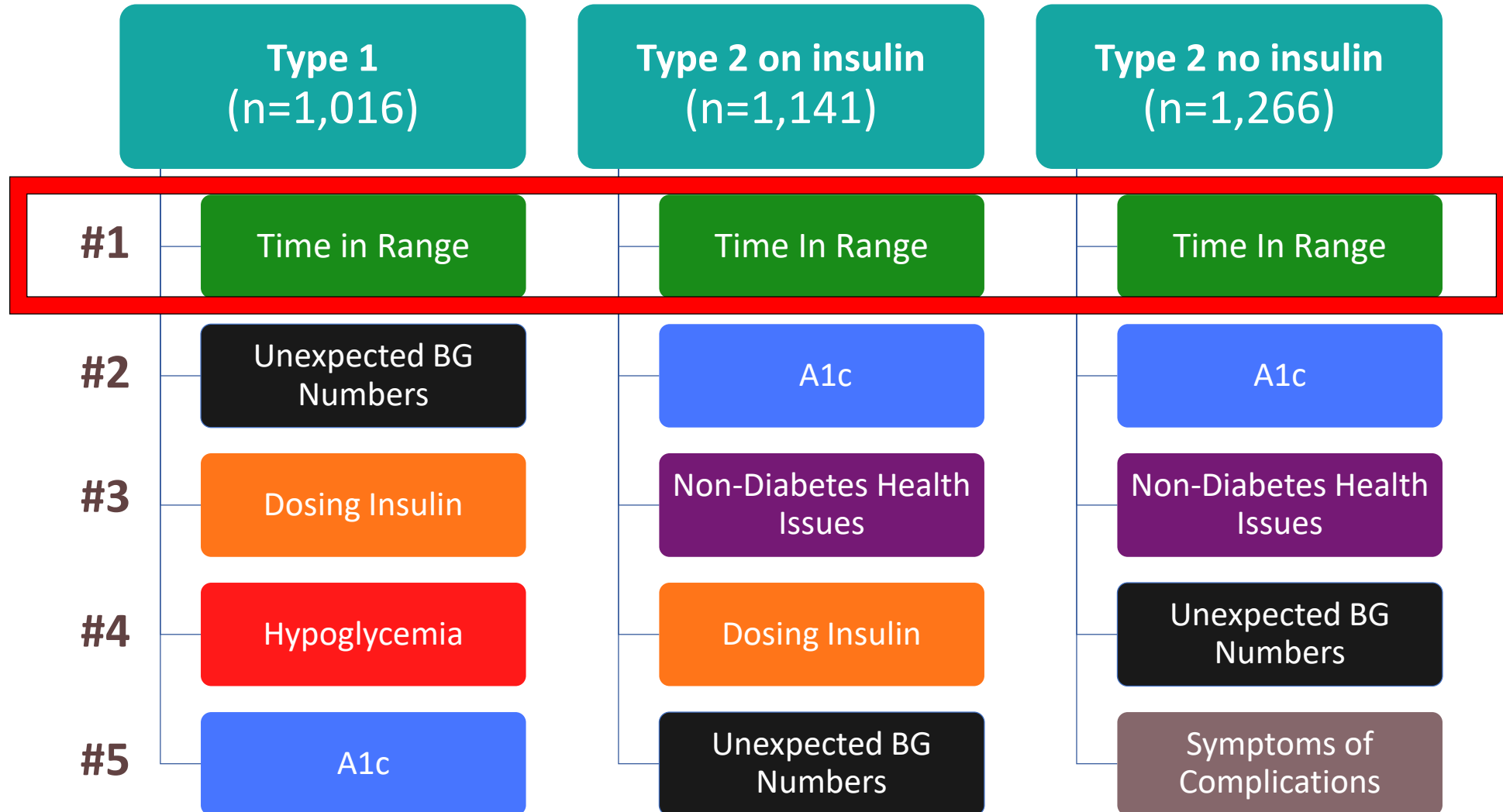
Lower costs to the entire
healthcare system

THE MANY FACES OF A 7% A1C



















(and an average blood glucose of 154 mg/dl)






“A Big Impact” On Daily Life, Rank Order: Many Differences, but Time in Range is #1 For All



Patients are far from feeling “very successful” (n=3,455)

| | Type 1 | Type 2 insulin | Type 2 non-insulin |
|--------------------------------|---|---|---|
| Blood glucose goals/excursions |  |  |  |
| Complications |  |  |  |
| Emotional well-being |  |  |  |
| Burden of diabetes care |  |  |  |
| Family/relationships |  |  |  |
| Social/stigma |  |  |  |

-  <33% feel ‘very successful’
-  34%-66% feel ‘very successful’
-  >66% feel ‘very successful’

A cultural shift – seeing time in range, AGP, improving from any base

7 days Oct 23, 2019 - Oct 29, 2019

Time in Range



Glucose Management Indicator (GMI)

Not enough data available

Average Glucose (CGM)

148 mg/dL

Patterns

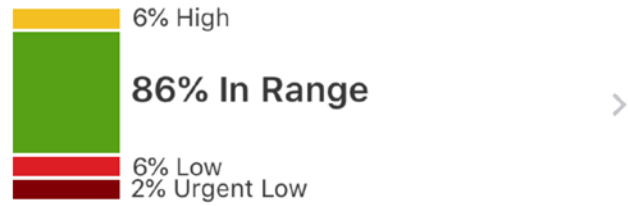
Nighttime Highs

Best Day

Sunday, October 27

7 days Oct 5, 2019 - Oct 11, 2019

Time in Range



Glucose Management Indicator (GMI)

Not enough data available

Average Glucose (CGM)

117 mg/dL

Patterns

No patterns detected

Best Day

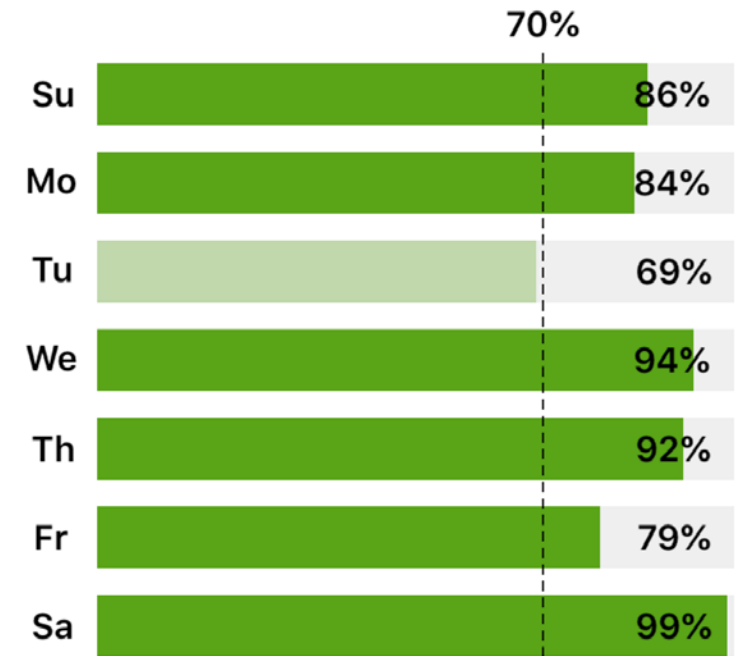
Wednesday, October 9

7 Days

You reached your Goal: Time in Range 6 out of 7 days.

[Edit Goal](#)

Oct 6, 2019 - Oct 12, 2019



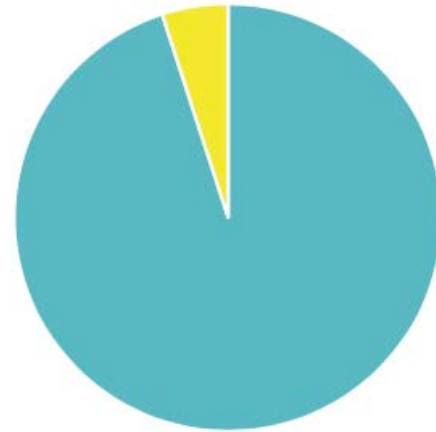
Validation of Time in Range as an Outcome Measure for Diabetes Clinical Trials

Roy W. Beck,¹ Richard M. Bergenstal,² Tonya D. Riddlesworth,¹ Craig Kollman,¹ Zhaomian Li,¹ Adam S. Brown,³ and Kelly L. Close⁴

Diabetes Care 2019;42:400–405 | <https://doi.org/10.2337/dc18-1444>

Each incremental 5% increase in TIR is associated with clinically significant benefits for type 1 and type 2

5% change in TIR = 1 hour a day



Every 10% increase in TIR = ~0.5-0.8% A1C reduction

Policy Recommendations for FDA Office of New Drugs



Expand primary and secondary endpoints that affect patient outcomes



Establish hypoglycemia as a clinically meaningful endpoint and incorporate hypoglycemia the label for therapeutic differentiation purposes



Acknowledge and establish time-in-range as an important complement to A1C



Investigate other endpoints that are meaningful to patients (e.g., weight loss, diabetes distress, fear of hypo)

Policy Recommendations for FDA Office of New Drugs



Expand harmonization across FDA divisions, particularly related to glucose measurement



Assess CGM data and metrics in clinical trials for diabetes therapies



Encourage greater harmonization among clinical, professional, patient, and regulatory adoption of advanced treatments to improve care and patient outcomes

Policy Recommendations for FDA Office of New Drugs



Improve speed and transparency of guidance creation and dissemination process



Create therapeutic labels that are even more clinically-relevant and patient-friendly



Further consider greater focus on prevention; specifically, establishing a prediabetes pathway

At diaTribe, we are committed to improving the lives of people with diabetes and amplifying patient voices.

Education



Advocacy

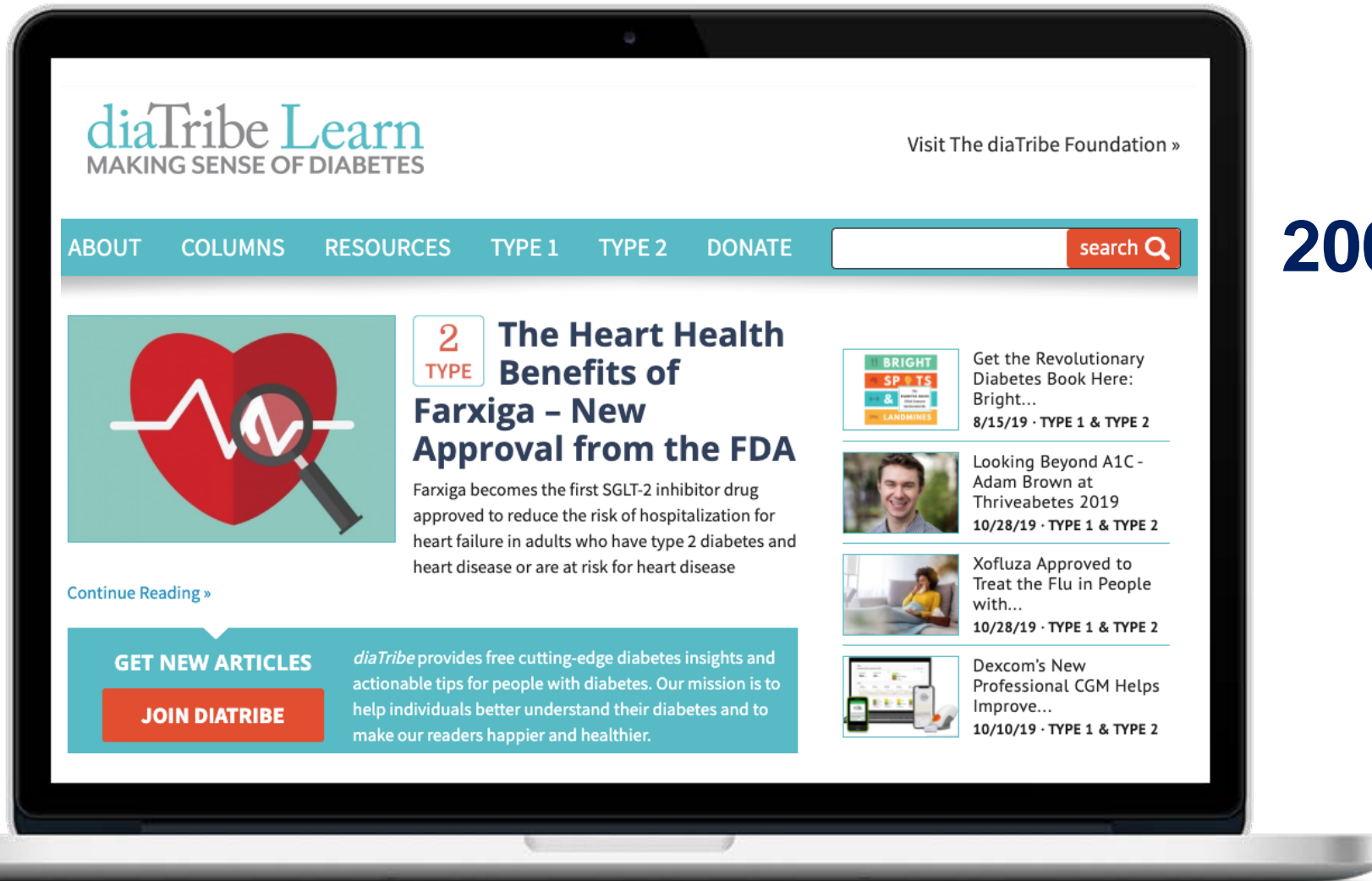


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contact@diaTribe.org

Kelly Close

 @KellyClose

 @klclose

kelly.close@diaTribe.org

Cherise Shockley

  @sweetercherise

cherise.shockley@diatribe.org

Emily Fitts

emily.fitts@diatribe.org



Thank you!