1

00:00:00,000 --> 00:00:03,486

[MUSIC PLAYING]

2

00:00:03,486 --> 00:01:42,052

3

00:01:42,052 --> 00:01:43,510

FRANCIS S. COLLINS:

So much of what

4

00:01:43,510 --> 00:01:45,640

we've done in medicine

over the years

5

00:01:45,640 --> 00:01:49,460

has not really taken into

account individual differences.

6

00:01:49,460 --> 00:01:52,220

And this is an opportunity

to be part of something,

7

00:01:52,220 --> 00:01:53,480

something historic.

8

00:01:53,480 --> 00:01:55,810

ROBERT WINN: Most studies

and most clinical trials

9

00:01:55,810 --> 00:01:58,880

have always been with

the average white male.

10

00:01:58,880 --> 00:02:01,810

So as we start thinking about

this in the context of building

11

00:02:01,810 --> 00:02:03,640

trust, I think we

get back that trust

12

00:02:03,640 --> 00:02:06,190

by involving the community,

not saying you come to us

13

00:02:06,190 --> 00:02:08,270

or we'll just do things to you.

14

00:02:08,270 --> 00:02:10,539

We're going to do things

with you and, in fact,

15

00:02:10,539 --> 00:02:13,910

allow that information

to be accessible to you,

16

00:02:13,910 --> 00:02:14,720

the individual.

17

00:02:14,720 --> 00:02:16,095

LYNDA JACKSON-ASSAD:

You're going

18

00:02:16,095 --> 00:02:18,620

to have some individuals that

are going to say, yes, good,

19

00:02:18,620 --> 00:02:20,990

we're getting in on the

ground level of a study.

20

00:02:20,990 --> 00:02:24,280

And then you're going to have

those that some trepidations

21

00:02:24,280 --> 00:02:24,880

about it.

22

00:02:24,880 --> 00:02:27,010

My thing is to bring

them aboard and let

23

00:02:27,010 --> 00:02:29,432

them know that this is for

the greater good for them.

24

00:02:29,432 --> 00:02:31,140

RACHELE PETERSON: Good

morning, everyone.

25

00:02:31,140 --> 00:02:33,580

Thank you for

joining us virtually.

26

00:02:33,580 --> 00:02:34,760

I'm Rachele Peterson.

27

00:02:34,760 --> 00:02:37,970

I'm the chief of staff for the

All of Us Research Program.

28

00:02:37,970 --> 00:02:39,700

Today, we're kicking

off our meeting

29

00:02:39,700 --> 00:02:43,540

of the All of Us Research

Program Advisory Panel.

30

00:02:43,540 --> 00:02:46,330

If we can go ahead

and show the slides.

31

00:02:46,330 --> 00:02:48,640

This is our external

governance group

32

00:02:48,640 --> 00:02:51,940

who provides input and feedback

on the vision and direction

33

00:02:51,940 --> 00:02:55,750

of the program, our five-year

strategic goals and how they

34

00:02:55,750 --> 00:02:59,560

relate to the broader

precision health ecosystem,

35

00:02:59,560 --> 00:03:02,830

as well as our current

projects and efforts.

36

00:03:02,830 --> 00:03:06,640

Periodically, the program hosts

this public and open session

37

00:03:06,640 --> 00:03:09,910

as part of the regular

advisory panel meeting

38

00:03:09,910 --> 00:03:13,570

to share program updates

and progress towards goals.

39

00:03:13,570 --> 00:03:15,850

That's what brings us

together this morning.

40

00:03:15,850 --> 00:03:17,320

These public

sessions are intended

41

00:03:17,320 --> 00:03:20,590

to increase awareness and trust

and fulfill our commitment

42

00:03:20,590 --> 00:03:24,750

to transparency, which is

part of our core values.

43

00:03:24,750 --> 00:03:26,895

So you can see here the

members on our screen.

44

00:03:26,895 --> 00:03:28,270

They're chosen

for their insights

45

00:03:28,270 --> 00:03:31,180

into the diverse

communities as well as

46

00:03:31,180 --> 00:03:32,650

for their scientific

subject matter

47

00:03:32,650 --> 00:03:35,500

expertise relevant to

the goals of the program.

48

00:03:35,500 --> 00:03:38,890

Our advisory panel is a working

group of the NIH Council

49

00:03:38,890 --> 00:03:39,980

of Councils.

50

00:03:39,980 --> 00:03:43,910

And there is, at any given

time, an individual member

51

00:03:43,910 --> 00:03:48,470

who also is a liaison on that

council of councils and a link

52

00:03:48,470 --> 00:03:50,910

then to the All of

Us advisory panel.

53

00:03:50,910 --> 00:03:53,360

So in the past,

that has been Scout,

54

00:03:53,360 --> 00:03:55,250

who last year rotated

off the council

55

00:03:55,250 --> 00:03:56,790

upon completing their term.

56

00:03:56,790 --> 00:03:59,720

And then we recently welcomed

Dr. Rhonda Robinson Beale

57

00:03:59,720 --> 00:04:02,330

to the advisory panel,

who is our current liaison

58

00:04:02,330 --> 00:04:04,340

to that council of councils.

59

00:04:04,340 --> 00:04:06,420

We also have, as

you can see here,

60

00:04:06,420 --> 00:04:08,700

the inclusion of

participant ambassadors,

61

00:04:08,700 --> 00:04:10,320

including Ms. Evelyn Ortiz.

62

00:04:10,320 --> 00:04:13,580

And joining our panel as well

as a participant ambassador

63

00:04:13,580 --> 00:04:16,110

perspective is

Christina Bell Andrews.

64

00:04:16,110 --> 00:04:18,860

If we can go to the

next slide, please.

65

00:04:18,860 --> 00:04:21,500

So I just wanted to pause

and say a little bit more

66

00:04:21,500 --> 00:04:23,480

about Christina.

67

00:04:23,480 --> 00:04:25,970

We're so happy that

she's joining us.

68

00:04:25,970 --> 00:04:29,780

She is the executive director

of the Wassaja Carlos Montezuma

69

00:04:29,780 --> 00:04:32,240

Center for Native American

Health at the University

70

00:04:32,240 --> 00:04:34,250

of Arizona College of Medicine.

71

00:04:34,250 --> 00:04:37,220

As I said, she is a

participant ambassador.

72

00:04:37,220 --> 00:04:40,670

And she is a member of

the Tohono O'odham Nation,

73

00:04:40,670 --> 00:04:45,830

as well as the Hia-Ced

O'odham member as well.

74

00:04:45,830 --> 00:04:47,760

And so thank you,

Christina, for joining us.

75

00:04:47,760 --> 00:04:49,880

And if we can go

to the next slide,

76

00:04:49,880 --> 00:04:51,770

I'm now pleased to

turn our session over

77

00:04:51,770 --> 00:04:55,310

to Dr. Josh Denny, who is the

CEO of the All of Us Research

78

00:04:55,310 --> 00:04:55,920

Program.

79

00:04:55,920 --> 00:04:57,480

He'll be providing

a program update.

80

00:04:57,480 --> 00:04:58,897

And then at the

end of that, we'll

81

00:04:58,897 --> 00:05:00,710

be joined by three

members of the public

82

00:05:00,710 --> 00:05:02,340

in a question-and-answer

session.

83

00:05:02,340 --> 00:05:04,920

So thank you all.

84

00:05:04,920 --> 00:05:07,870

JOSH DENNY: Rachele, thank you

so much for kicking us off.

85

00:05:07,870 --> 00:05:10,000

And thank you, everyone

who's joining us.

86

00:05:10,000 --> 00:05:11,730

It's great to have

you with us today

87

00:05:11,730 --> 00:05:14,170

as we give our open

session update.

88

00:05:14,170 --> 00:05:16,120

The All of Us Research

Program mission,

89

00:05:16,120 --> 00:05:19,150

which probably many of you

are well acquainted with,

90

00:05:19,150 --> 00:05:22,512

established in the beginning,

is to accelerate health research

91

00:05:22,512 --> 00:05:23,970

and medical

breakthroughs, enabling

92

00:05:23,970 --> 00:05:25,800

individualized

prevention, treatment,

93

00:05:25,800 --> 00:05:27,270

and care for All of Us.

94

00:05:27,270 --> 00:05:28,920

And I start with

this slide often

95

00:05:28,920 --> 00:05:32,730

because I want to remind us

that the bedrock of the program

96

00:05:32,730 --> 00:05:36,960

is starting with partnerships

with the goal of a million

97

00:05:36,960 --> 00:05:41,010

or more participants that

will be with us for decades

98

00:05:41,010 --> 00:05:44,290

and who reflect the diversity

of the United States.

99

00:05:44,290 --> 00:05:47,700

And we want to take the

data that people contribute

100

00:05:47,700 --> 00:05:51,540

and deliver it into as many

hands as possible to do research

101

00:05:51,540 --> 00:05:53,410

in ways that are

safe and secure,

102

00:05:53,410 --> 00:05:58,510

promote trust, preserve

privacy, and importantly,

103

00:05:58,510 --> 00:06:03,070

accelerate science that matters

to elevate health for everyone.

104

00:06:03,070 --> 00:06:06,620

And then this is part of a

ecosystem of communities,

105

00:06:06,620 --> 00:06:09,700

researchers, and funders with

the vision that All of Us

106

00:06:09,700 --> 00:06:13,660

will be an indispensable part of

health research in the future.

107

00:06:13,660 --> 00:06:16,600

And we also established

a set of core values

108

00:06:16,600 --> 00:06:20,470

at the beginning that talked

about transparency, that access

109

00:06:20,470 --> 00:06:23,570

and enrollment is open to

anyone in the United States,

110

00:06:23,570 --> 00:06:27,460

that we want to be a positive

catalyst for change in research

111

00:06:27,460 --> 00:06:29,420

going forward and others.

112

00:06:29,420 --> 00:06:32,240

And these are throughout

the awards that we make

113

00:06:32,240 --> 00:06:33,680

and our websites.

114

00:06:33,680 --> 00:06:34,320

Next slide.

115

00:06:34,320 --> 00:06:38,193

116

00:06:38,193 --> 00:06:39,860

I want to give you a

little bit of sense

117

00:06:39,860 --> 00:06:42,350

of the status of the

program and the timeline

118

00:06:42,350 --> 00:06:44,480

that we've accomplished.

119

00:06:44,480 --> 00:06:46,350

We started in 2015.

120

00:06:46,350 --> 00:06:49,730

And that was the

announcement of what

121

00:06:49,730 --> 00:06:53,250

was then called the Precision

Medicine Initiative.

122

00:06:53,250 --> 00:06:56,840

As part of that, there

was a defined definition

123

00:06:56,840 --> 00:06:59,060

for what was originally

called the Precision Medicine

124

00:06:59,060 --> 00:07:00,720

Initiative Cohort Program.

125

00:07:00,720 --> 00:07:06,800

And we launched in 2016

with a series of awards.

126

00:07:06,800 --> 00:07:10,100

We piloted with community

engagement studios

127

00:07:10,100 --> 00:07:14,000

across the country asking

countries questions like,

128

00:07:14,000 --> 00:07:15,750

how would you want to consent?

129

00:07:15,750 --> 00:07:17,910

What's the value in

precision medicine?

130

00:07:17,910 --> 00:07:19,170

Was that concept mean?

131

00:07:19,170 --> 00:07:21,030

How could we return

value to you?

132

00:07:21,030 --> 00:07:24,560

We did a number of piloting

efforts across the country

133

00:07:24,560 --> 00:07:27,000

and in 2017 enrolled

our first participant.

134

00:07:27,000 --> 00:07:30,260

By 2018, we had our

national launch.

135

00:07:30,260 --> 00:07:33,530

At that point, we had done

alpha and beta testing

136

00:07:33,530 --> 00:07:35,780

at a number of sites

across the country

137

00:07:35,780 --> 00:07:39,480

and were ready to really

open national enrollment.

138

00:07:39,480 --> 00:07:43,330

In 2019, we released our

first public data browser,

139

00:07:43,330 --> 00:07:47,940

which gave people a taste of the

kind of data that participants

140

00:07:47,940 --> 00:07:52,110

were contributing and electronic

health record data, survey data.

141

00:07:52,110 --> 00:07:54,760

And that is a tool that

anyone can look at.

142

00:07:54,760 --> 00:07:56,220

And it gives you

aggregate counts

143

00:07:56,220 --> 00:07:59,370

that preserve privacy

and minimal senses

144

00:07:59,370 --> 00:08:03,090

of the distribution

of those diseases

145

00:08:03,090 --> 00:08:06,240

and lets you sense that we

are a part of community.

146

00:08:06,240 --> 00:08:09,930

In 2020, we released

our first dataset

147

00:08:09,930 --> 00:08:12,330

that researchers could have

access to that really--

148

00:08:12,330 --> 00:08:14,250

to start doing science.

149

00:08:14,250 --> 00:08:17,040

That also correlated

with, as we all

150

00:08:17,040 --> 00:08:20,260

remember, COVID hitting

this country and the world.

151

00:08:20,260 --> 00:08:23,490

And we recognized that we

had the unique ability to do

152

00:08:23,490 --> 00:08:26,850

something at this time because

we were enrolling about 3,000

153

00:08:26,850 --> 00:08:31,200

people a week during the early

stages of COVID until we paused

154

00:08:31,200 --> 00:08:32,320

for safety.

155

00:08:32,320 --> 00:08:34,799

And so we were able to go

back and do a serology study

156

00:08:34,799 --> 00:08:38,070

show in a number

of-- several states

157

00:08:38,070 --> 00:08:42,880

that we identified cases earlier

than were known in those states.

158

00:08:42,880 --> 00:08:48,630

And it pushed the evidence

of community spread

159

00:08:48,630 --> 00:08:51,960

earlier than we thought and

established that information

160

00:08:51,960 --> 00:08:54,280

through our study.

161

00:08:54,280 --> 00:08:59,270

Researchers started using this

larger in 2020 time frame.

162

00:08:59,270 --> 00:09:03,760

In 2021, as we were able

to get supplies back

163

00:09:03,760 --> 00:09:08,260

from COVID testing, we started

our own genotyping efforts

164

00:09:08,260 --> 00:09:10,750

and whole genome

sequencing that allowed

165

00:09:10,750 --> 00:09:13,720

us to start returning results

on genetic information

166

00:09:13,720 --> 00:09:15,010

to participants.

167

00:09:15,010 --> 00:09:20,890

In the end of 2022, we started

returning genetic health

168

00:09:20,890 --> 00:09:22,180

results.

169

00:09:22,180 --> 00:09:27,090

And at this point, we also hit

the 500,000 enrollment mark.

170

00:09:27,090 --> 00:09:29,890

We have had other

ancillary studies start.

171

00:09:29,890 --> 00:09:33,780

The biggest of those is in 2023,

the Nutrition for Precision

172

00:09:33,780 --> 00:09:39,320

Health Effort, which will really

be a deep study into nutrition

173

00:09:39,320 --> 00:09:43,900

intersections with

environment and genomics,

174

00:09:43,900 --> 00:09:47,040

diet, and the effects

on our health.

175

00:09:47,040 --> 00:09:49,560

We also started to release

other kinds of information

176

00:09:49,560 --> 00:09:53,800

and hit the quarter-million

mark of genomic data available.

177

00:09:53,800 --> 00:10:00,570

And in 2024, where we are now,

we have returned DNA results

178

00:10:00,570 --> 00:10:03,202

to 360,000 individuals.

179

00:10:03,202 --> 00:10:05,410

That includes a couple of

different types of results,

180

00:10:05,410 --> 00:10:06,618

which we'll talk about later.

181

00:10:06,618 --> 00:10:08,920

We have over 830,000

participants.

182

00:10:08,920 --> 00:10:13,230

We actually are right around

13,000 researchers now that are

183

00:10:13,230 --> 00:10:14,350

using the resource.

184

00:10:14,350 --> 00:10:17,940

And I'll tell you, when we set

our-- when I joined the NIH

185

00:10:17,940 --> 00:10:20,770

in 2020 and about the

end of the first year,

186

00:10:20,770 --> 00:10:24,767

we set a strategic plan for

five years, for the end of 2026,

187

00:10:24,767 --> 00:10:26,350

that we would have

10,000 researchers.

188

00:10:26,350 --> 00:10:31,450

So we hit our goal there about

almost three years early.

189

00:10:31,450 --> 00:10:35,050

And you can see we're well

on our way to beat that

190

00:10:35,050 --> 00:10:36,290

quite significantly.

191

00:10:36,290 --> 00:10:36,960

Next slide.

192

00:10:36,960 --> 00:10:40,710

193

00:10:40,710 --> 00:10:44,520

So this gives you a sense of our

current status with the program

194

00:10:44,520 --> 00:10:47,640

about approaching 840,000

participants that have joined

195

00:10:47,640 --> 00:10:49,710

the program.

196

00:10:49,710 --> 00:10:52,560

The vast majority of those

agree to share electronic health

197

00:10:52,560 --> 00:10:53,380

records.

198

00:10:53,380 --> 00:10:56,880

There's a gap between those

who agree to share them

199

00:10:56,880 --> 00:10:58,510

and our ability to capture them.

200

00:10:58,510 --> 00:11:01,260

And that's the difference

between that 840,000

201

00:11:01,260 --> 00:11:03,210

and the 450,000.

202

00:11:03,210 --> 00:11:05,010

It's fine if you

don't want to share.

203

00:11:05,010 --> 00:11:06,990

We allow people to

join the program

204

00:11:06,990 --> 00:11:09,030

and participate

in different ways.

205

00:11:09,030 --> 00:11:10,150

And we welcome them.

206

00:11:10,150 --> 00:11:14,510

You can see that we have

590,000 for which have shared

207

00:11:14,510 --> 00:11:16,640

biosamples, the minimum

of which is DNA.

208

00:11:16,640 --> 00:11:21,480

We also collect blood serum,

plasma, cell free DNA, RNA,

209

00:11:21,480 --> 00:11:24,440

and urine from

most participants.

210

00:11:24,440 --> 00:11:27,540

If you live in a place

where it's either not

211

00:11:27,540 --> 00:11:31,500

convenient to donate a

sample or it's not convenient

212

00:11:31,500 --> 00:11:35,790

for you to actually go into a

facility due to disabilities

213

00:11:35,790 --> 00:11:37,788

or other things, we have

ways of reaching you.

214

00:11:37,788 --> 00:11:40,080

Some places we actually can

send someone to your house.

215

00:11:40,080 --> 00:11:42,770

And we can also send saliva

kits anywhere in the country.

216

00:11:42,770 --> 00:11:45,520

As you can see on the

right, we have all US states

217

00:11:45,520 --> 00:11:48,610

represented with what we

call core participants that

218

00:11:48,610 --> 00:11:49,840

have donated DNA.

219

00:11:49,840 --> 00:11:54,430

And then we also have most US

territories represented as well.

220

00:11:54,430 --> 00:11:57,730

We think about diversity in a

number of different metrics.

221

00:11:57,730 --> 00:12:00,250

A lot of times, people talk

about race and ethnic diversity.

222

00:12:00,250 --> 00:12:01,730

And we have that.

223

00:12:01,730 --> 00:12:06,640

Nearly 47% identify

as a minoritized

224

00:12:06,640 --> 00:12:08,860

racial or ethnic population.

225

00:12:08,860 --> 00:12:11,290

But in addition, that

broader classification

226

00:12:11,290 --> 00:12:13,090

of underrepresented

biomedical research

227

00:12:13,090 --> 00:12:14,980

includes many other categories.

228

00:12:14,980 --> 00:12:17,090

We have evolved this

definition over time.

229

00:12:17,090 --> 00:12:19,720

For instance, disability

wasn't on our initial surveys.

230

00:12:19,720 --> 00:12:21,700

And we added a survey for that.

231

00:12:21,700 --> 00:12:25,180

We recently also added health

care access and utilization

232

00:12:25,180 --> 00:12:28,280

for those who have

difficulty getting a doctor.

233

00:12:28,280 --> 00:12:30,530

And so that overlaps,

for instance,

234

00:12:30,530 --> 00:12:31,970

with rural populations a lot.

235

00:12:31,970 --> 00:12:34,300

It's not completely

defined by that.

236

00:12:34,300 --> 00:12:36,400

And so these are different

axes of information

237

00:12:36,400 --> 00:12:38,240

that we collect in this.

238

00:12:38,240 --> 00:12:41,060

And the vast majority

of these populations,

239

00:12:41,060 --> 00:12:45,790

both by race or ethnicity

or by other measure

240

00:12:45,790 --> 00:12:49,870

of underrepresentation,

we exceed

241

00:12:49,870 --> 00:12:52,300

what would be census estimates.

242

00:12:52,300 --> 00:12:53,510

Some cases we don't.

243

00:12:53,510 --> 00:12:56,380

We're still working on

increasing our rural population.

244

00:12:56,380 --> 00:12:59,200

We are looking to

increase our enrollment

245

00:12:59,200 --> 00:13:01,090

of Asian-American,

Native Hawaiian

246

00:13:01,090 --> 00:13:03,200

and Pacific Islanders more.

247

00:13:03,200 --> 00:13:05,200

And we have focused

engagement partners

248

00:13:05,200 --> 00:13:08,940

that help us with those

kinds of efforts as we go on.

249

00:13:08,940 --> 00:13:11,620

Next slide.

250

00:13:11,620 --> 00:13:14,380

To give you a sense

of the available data

251

00:13:14,380 --> 00:13:16,970

that we collect from

participants and researchers,

252

00:13:16,970 --> 00:13:19,270

what we've made

available to researchers,

253

00:13:19,270 --> 00:13:20,930

this slide walks through this.

254

00:13:20,930 --> 00:13:23,090

Regardless of how you

enroll in the program,

255

00:13:23,090 --> 00:13:24,532

we have a common

consent process,

256

00:13:24,532 --> 00:13:26,990

which includes authorization

for electronic health records.

257

00:13:26,990 --> 00:13:28,660

We have core sets of

surveys that you fill out

258

00:13:28,660 --> 00:13:30,202

at the beginning

and then others that

259

00:13:30,202 --> 00:13:32,890

go on through your

journey with us

260

00:13:32,890 --> 00:13:35,350

to collect some physical

measurements, which can also

261

00:13:35,350 --> 00:13:37,450

be entered remotely,

the bio samples I've

262

00:13:37,450 --> 00:13:41,770

talked about and then

ability to share Fitbit data

263

00:13:41,770 --> 00:13:45,700

or other types of digital

health technology data.

264

00:13:45,700 --> 00:13:47,300

And then we also

give out Fitbit--

265

00:13:47,300 --> 00:13:50,470

we've been giving out Fitbit

devices to people as well

266

00:13:50,470 --> 00:13:52,420

to close some of

those gaps in those

267

00:13:52,420 --> 00:13:55,120

who would be underrepresented

in biomedical research.

268

00:13:55,120 --> 00:13:59,720

To researchers, our current

data release is described there.

269

00:13:59,720 --> 00:14:03,670

And I'll talk about the

upcoming data release later.

270

00:14:03,670 --> 00:14:06,370

I mentioned that we have a

quarter million approximately

271

00:14:06,370 --> 00:14:10,310

whole genome sequences in

that, 15,000 Fitbit records.

272

00:14:10,310 --> 00:14:12,770

The vast majority

of those people

273

00:14:12,770 --> 00:14:15,290

also have things like

electronic health records.

274

00:14:15,290 --> 00:14:19,100

Pretty much everyone has some

kind of survey data available

275

00:14:19,100 --> 00:14:19,710

there.

276

00:14:19,710 --> 00:14:23,690

And so these data have

been a powerful tool

277

00:14:23,690 --> 00:14:27,180

for researchers that are

coming in and making use of it.

278

00:14:27,180 --> 00:14:30,840

And we also, importantly, give

data back to participants.

279

00:14:30,840 --> 00:14:32,840

They can view their

survey results.

280

00:14:32,840 --> 00:14:36,705

If they link in,

individual EHR providers

281

00:14:36,705 --> 00:14:38,080

can view some of

that information

282

00:14:38,080 --> 00:14:40,038

in their physical

measurements that we collect.

283

00:14:40,038 --> 00:14:43,130

We publish out scientific

findings through research

284

00:14:43,130 --> 00:14:47,630

highlights that are

delivered and more often,

285

00:14:47,630 --> 00:14:50,670

My Medical Minutes, types of

newsletters to participants.

286

00:14:50,670 --> 00:14:53,010

And then most importantly,

we heard from participants

287

00:14:53,010 --> 00:14:56,227

DNA results have been a real

interest for participants

288

00:14:56,227 --> 00:14:57,060

joining the program.

289

00:14:57,060 --> 00:14:59,350

Next slide.

290

00:14:59,350 --> 00:15:03,250

And so top level, the first

thing we started offering people

291

00:15:03,250 --> 00:15:04,870

is genetic ancestry and traits.

292

00:15:04,870 --> 00:15:07,570

And so they have access to

that kind of information.

293

00:15:07,570 --> 00:15:12,470

And over 220,000 people have

viewed information like that.

294

00:15:12,470 --> 00:15:15,230

But one of the more innovative

pieces was delivering

295

00:15:15,230 --> 00:15:19,520

health-related genetic results

in this "you can enroll

296

00:15:19,520 --> 00:15:21,410

anywhere" kind of program.

297

00:15:21,410 --> 00:15:23,760

We are supported by

genetic counselors.

298

00:15:23,760 --> 00:15:25,820

All the hereditary

disease risk reports

299

00:15:25,820 --> 00:15:28,250

are returned through

genetic counselors.

300

00:15:28,250 --> 00:15:34,010

And over 124,000 have

viewed reports for 59 genes.

301

00:15:34,010 --> 00:15:37,400

About 3% of people will have

a positive result in one

302

00:15:37,400 --> 00:15:38,910

of these 59 genes.

303

00:15:38,910 --> 00:15:42,330

Each of these cases

are actionable.

304

00:15:42,330 --> 00:15:46,160

So if you learn of a risk based

on your genetics of breast

305

00:15:46,160 --> 00:15:48,380

or ovarian cancer,

for instance, that

306

00:15:48,380 --> 00:15:50,360

can lead to increased

screening or discussions

307

00:15:50,360 --> 00:15:52,520

with physicians of

whether you'd want

308

00:15:52,520 --> 00:15:56,700

to do a prophylactic mastectomy

or just do increased screening.

309

00:15:56,700 --> 00:15:59,970

There are other interventions

here for each of these.

310

00:15:59,970 --> 00:16:03,470

And it's things that you could

do that avert a potentially very

311

00:16:03,470 --> 00:16:07,490

serious disease that potentially

leaves a life-changing result

312

00:16:07,490 --> 00:16:08,920

by knowing this information.

313

00:16:08,920 --> 00:16:12,180

We know from many studies

that most people who

314

00:16:12,180 --> 00:16:15,360

have these variants will

be learning something new

315

00:16:15,360 --> 00:16:16,990

through these results.

316

00:16:16,990 --> 00:16:21,150

And so we also have

stories already where

317

00:16:21,150 --> 00:16:24,330

we've had participant

learn a result,

318

00:16:24,330 --> 00:16:26,340

and that's lead

to family testing,

319

00:16:26,340 --> 00:16:30,420

identifying others that are

at risk and discussion of what

320

00:16:30,420 --> 00:16:32,280

interventions need to be taken.

321

00:16:32,280 --> 00:16:34,860

The next kind of health

result that we return

322

00:16:34,860 --> 00:16:37,950

is Medicine and Your DNA,

our pharmacogenetics report.

323

00:16:37,950 --> 00:16:41,690

It currently

supports seven genes

324

00:16:41,690 --> 00:16:44,070

that support about 50

different common medications.

325

00:16:44,070 --> 00:16:46,940

You can see those

there in contrast

326

00:16:46,940 --> 00:16:49,372

to the health-related results,

where we have about 3%

327

00:16:49,372 --> 00:16:50,330

of people are positive.

328

00:16:50,330 --> 00:16:52,400

With Medicine and Your

DNA, about 90% of people

329

00:16:52,400 --> 00:16:53,700

will have a positive result.

330

00:16:53,700 --> 00:16:57,170

And when we look at those

retrospectively in our research

331

00:16:57,170 --> 00:17:01,160

resource, we see

that those who have

332

00:17:01,160 --> 00:17:05,660

pharmacogenetic results,

about 20% of them

333

00:17:05,660 --> 00:17:07,530

are also exposed to a drug.

334

00:17:07,530 --> 00:17:10,369

So we think that

basically about 20%

335

00:17:10,369 --> 00:17:12,470

of the population that

gets these results will

336

00:17:12,470 --> 00:17:14,609

have actionable

results based on them.

337

00:17:14,609 --> 00:17:17,395

Of course, we're just

generating these data now.

338

00:17:17,395 --> 00:17:18,770

And we'll have to

do more studies

339

00:17:18,770 --> 00:17:20,520

to follow up and look

at the actual impact

340

00:17:20,520 --> 00:17:21,839

of these kinds of results.

341

00:17:21,839 --> 00:17:22,539

Next slide.

342

00:17:22,539 --> 00:17:25,180

343

00:17:25,180 --> 00:17:29,020

In terms of research data, we

have multiple tiers of data.

344

00:17:29,020 --> 00:17:31,010

The first is what we

call our public tier.

345

00:17:31,010 --> 00:17:33,800

And I mentioned a

data browser earlier,

346

00:17:33,800 --> 00:17:38,230

which allows researchers and

participants-- we use this a lot

347

00:17:38,230 --> 00:17:40,570

at our mobile engagement

units for participants

348

00:17:40,570 --> 00:17:45,550

so they can see what

diseases do people have

349

00:17:45,550 --> 00:17:49,120

or how do they compare

perhaps to other parts

350

00:17:49,120 --> 00:17:50,270

of the population.

351

00:17:50,270 --> 00:17:52,205

And then we make

available information

352

00:17:52,205 --> 00:17:54,580

like all of our surveys, so

they can be borrowed and used

353

00:17:54,580 --> 00:17:56,000

by other resources.

354

00:17:56,000 --> 00:17:57,590

They're all freely available.

355

00:17:57,590 --> 00:17:59,540

We have something called a

research project directory which

356

00:17:59,540 --> 00:18:01,123

we want to highlight

at the end, which

357

00:18:01,123 --> 00:18:02,578

is just a list of

all the studies

358

00:18:02,578 --> 00:18:03,620

that people are starting.

359

00:18:03,620 --> 00:18:05,745

We make it very easy for

people to write and update

360

00:18:05,745 --> 00:18:06,860

their descriptions.

361

00:18:06,860 --> 00:18:10,090

And then those descriptions

are publicly available.

362

00:18:10,090 --> 00:18:13,900

And a participant or anyone else

can look at those descriptions,

363

00:18:13,900 --> 00:18:16,970

search them, and if they

have any concerns too,

364

00:18:16,970 --> 00:18:20,750

they can also flag it for our

resource access board to review.

365

00:18:20,750 --> 00:18:24,320

Then to do research on

individual row level data,

366

00:18:24,320 --> 00:18:25,590

you have to register.

367

00:18:25,590 --> 00:18:29,220

Your institution has to

sign an agreement with us.

368

00:18:29,220 --> 00:18:31,350

And then you have access

to the registered tier.

369

00:18:31,350 --> 00:18:33,308

And the controlled tier

are two different tiers

370

00:18:33,308 --> 00:18:37,160

of increasing different

granularity of data.

371

00:18:37,160 --> 00:18:40,700

They all are individual

data, but the controlled tier

372

00:18:40,700 --> 00:18:43,100

has the genomics data into it.

373

00:18:43,100 --> 00:18:45,120

It also has everything

in the registered tier.

374

00:18:45,120 --> 00:18:47,328

It also has-- controlled

tier has real dates in it

375

00:18:47,328 --> 00:18:49,370

as well, so it supports

different kinds of study.

376

00:18:49,370 --> 00:18:53,390

And we guide people

to use the tier

377

00:18:53,390 --> 00:18:55,890

that they need to for the kind

of research they want to do.

378

00:18:55,890 --> 00:18:59,040

Next slide.

379

00:18:59,040 --> 00:19:00,520

This is our current status.

380

00:19:00,520 --> 00:19:03,990

So you can see we have over

13,000 researchers now from over

381

00:19:03,990 --> 00:19:06,057

900 organizations.

382

00:19:06,057 --> 00:19:08,140

We'll talk about the

publications in a little bit.

383

00:19:08,140 --> 00:19:10,500

They are growing to

where we're averaging

384

00:19:10,500 --> 00:19:12,540

over a publication a day now.

385

00:19:12,540 --> 00:19:17,040

And we launched two

international institutions

386

00:19:17,040 --> 00:19:19,020

at the end of last year.

387

00:19:19,020 --> 00:19:21,750

We have institutions

on six continents

388

00:19:21,750 --> 00:19:24,750

now, including low- and

middle-income countries.

389

00:19:24,750 --> 00:19:30,730

And with our US researchers

in US organizations,

390

00:19:30,730 --> 00:19:33,780

we have really focused

on reaching out

391

00:19:33,780 --> 00:19:37,807

to underrepresented populations

in the biomedical workforce.

392

00:19:37,807 --> 00:19:39,640

That includes a number

of different metrics,

393

00:19:39,640 --> 00:19:40,807

includes race and ethnicity.

394

00:19:40,807 --> 00:19:42,840

It also includes

stage of training,

395

00:19:42,840 --> 00:19:45,840

what kinds of institution

you're at and reaching,

396

00:19:45,840 --> 00:19:50,340

HBCUs, historically Black

schools of medicine, as well

397

00:19:50,340 --> 00:19:52,860

as Hispanic-serving

institutions,

398

00:19:52,860 --> 00:19:55,800

and working on engagement

partners that reach out to them.

399

00:19:55,800 --> 00:19:58,640

In addition, recently

and over the summer,

400

00:19:58,640 --> 00:20:01,100

we started opening to

commercial access as well.

401

00:20:01,100 --> 00:20:01,890

Next slide.

402

00:20:01,890 --> 00:20:04,920

403

00:20:04,920 --> 00:20:06,230

I'd mentioned the publications.

404

00:20:06,230 --> 00:20:09,030

And you can see some

growth of some of those now

405

00:20:09,030 --> 00:20:12,210

and just some screenshots

of some of the publications

406

00:20:12,210 --> 00:20:13,470

on the left.

407

00:20:13,470 --> 00:20:15,720

One I'll just mention

here is the one

408

00:20:15,720 --> 00:20:22,140

on the bottom, which is an

example of our resource enabling

409

00:20:22,140 --> 00:20:26,880

a clinical trial, making it

relevant to a diverse population

410

00:20:26,880 --> 00:20:29,830

where it wouldn't have

really been able to be done.

411

00:20:29,830 --> 00:20:35,220

So in this case, the researchers

of the NHGRI-supported eMERGE

412

00:20:35,220 --> 00:20:38,640

network took 10

polygenic risk scores

413

00:20:38,640 --> 00:20:42,450

that were developed largely

on European genetic ancestry

414

00:20:42,450 --> 00:20:45,420

populations and were

able to use All of Us

415

00:20:45,420 --> 00:20:49,230

to create a more

representative polygenic risk

416

00:20:49,230 --> 00:20:52,900

score that they could show works

across diverse populations.

417

00:20:52,900 --> 00:20:57,450

And so that is enrolling and

testing the clinical validity

418

00:20:57,450 --> 00:21:03,000

of genetic risk scores to

predict and work and intervene

419

00:21:03,000 --> 00:21:04,670

for health conditions.

420

00:21:04,670 --> 00:21:06,460

And because of

All of Us, they're

421

00:21:06,460 --> 00:21:09,370

able to do this test

in diverse populations

422

00:21:09,370 --> 00:21:12,730

and have it not just be

applicable to the European

423

00:21:12,730 --> 00:21:14,710

genetic ancestry populations.

424

00:21:14,710 --> 00:21:17,330

Next slide.

425

00:21:17,330 --> 00:21:20,090

This is a paper that

was published looking

426

00:21:20,090 --> 00:21:23,180

at our genomic data release.

427

00:21:23,180 --> 00:21:26,520

In that data release, with

these quarter million genomes,

428

00:21:26,520 --> 00:21:29,370

roughly, we've seen over a

billion genetic variants.

429

00:21:29,370 --> 00:21:33,330

Over 275 million variants

were previously unreported.

430

00:21:33,330 --> 00:21:36,680

This paper also did

some validation studies

431

00:21:36,680 --> 00:21:37,530

in different ways.

432

00:21:37,530 --> 00:21:40,790

And so on the left, you're

seeing a genome-wide association

433

00:21:40,790 --> 00:21:45,440

study against LDL levels

and replicating many known

434

00:21:45,440 --> 00:21:48,300

associations in

similar effect sizes,

435

00:21:48,300 --> 00:21:50,270

as you see in other studies.

436

00:21:50,270 --> 00:21:53,900

In the middle, you're

looking at a study

437

00:21:53,900 --> 00:21:55,700

of what's called the

Duffy blood group

438

00:21:55,700 --> 00:22:00,080

locus, which is associated

and positively selected

439

00:22:00,080 --> 00:22:01,530

for with malaria.

440

00:22:01,530 --> 00:22:04,370

And so you can see that

there's different phenotypic

441

00:22:04,370 --> 00:22:08,360

associations in different

genetic ancestry populations.

442

00:22:08,360 --> 00:22:10,340

And it just highlights

the diversity

443

00:22:10,340 --> 00:22:13,820

of what we have in our resource.

444

00:22:13,820 --> 00:22:16,830

And then on the box on

the right is testing it

445

00:22:16,830 --> 00:22:18,820

against a number of

known associations.

446

00:22:18,820 --> 00:22:21,900

And probably one of the most

important things to see about

447

00:22:21,900 --> 00:22:25,680

this is this is showing some

of these genetic variants,

448

00:22:25,680 --> 00:22:29,310

3,000 of them, with known

association against 117

449

00:22:29,310 --> 00:22:30,190

diseases.

450

00:22:30,190 --> 00:22:32,850

And the percentages of

replication on the bottom

451

00:22:32,850 --> 00:22:36,430

are high and as expected across.

452

00:22:36,430 --> 00:22:40,560

But the middle row there,

of the 18 of 25 or 13 of 13

453

00:22:40,560 --> 00:22:44,820

tell you, for instance, how many

known associations that are just

454

00:22:44,820 --> 00:22:47,190

out there with

different predominantly

455

00:22:47,190 --> 00:22:51,580

genetic given different

reference population similarity.

456

00:22:51,580 --> 00:22:54,420

And you can see that there's

just a whole lot more known

457

00:22:54,420 --> 00:22:56,910

about people who have a

predominant similarity

458

00:22:56,910 --> 00:23:01,500

to a European genetic ancestry

with over 1,000 replications we

459

00:23:01,500 --> 00:23:04,960

can see, but just not much

else in the other populations,

460

00:23:04,960 --> 00:23:07,260

even though we have a large

number of participants

461

00:23:07,260 --> 00:23:11,080

in especially the first

two of those columns.

462

00:23:11,080 --> 00:23:13,440

And so it just shows where

we can help close some

463

00:23:13,440 --> 00:23:16,530

of that evidence gap

and transferability

464

00:23:16,530 --> 00:23:20,390

of diverse population in an

understanding of genetics.

465

00:23:20,390 --> 00:23:22,520

Next slide.

466

00:23:22,520 --> 00:23:24,890

This is one of those studies.

467

00:23:24,890 --> 00:23:30,380

This looks at APOL1,

which is a gene that

468

00:23:30,380 --> 00:23:33,440

is associated with

chronic kidney disease

469

00:23:33,440 --> 00:23:37,400

and end-stage kidney disease in

people of West African ancestry.

470

00:23:37,400 --> 00:23:42,980

It arised through associations

with African sleeping sickness

471

00:23:42,980 --> 00:23:44,220

as a protective effect.

472

00:23:44,220 --> 00:23:47,135

But if you get two

copy of these you

473

00:23:47,135 --> 00:23:49,070

are about three-

to four-fold risk

474

00:23:49,070 --> 00:23:52,250

of increased risk of

developing kidney disease.

475

00:23:52,250 --> 00:23:56,720

And so 70% of the

excess kidney disease

476

00:23:56,720 --> 00:23:59,360

risk in African-Americans

is thought

477

00:23:59,360 --> 00:24:03,210

related to having two copies

of APOL1 risk variants.

478

00:24:03,210 --> 00:24:06,350

And so what you can

see here is if you

479

00:24:06,350 --> 00:24:08,630

take those risk

variants, but then

480

00:24:08,630 --> 00:24:11,870

looking at another very rare

risk variant that happens

481

00:24:11,870 --> 00:24:17,600

to be in the APOL1 channel,

that other risk variant actually

482

00:24:17,600 --> 00:24:20,640

protects against the risk

that you would have had.

483

00:24:20,640 --> 00:24:23,460

So this rare variant

here-- and you can see

484

00:24:23,460 --> 00:24:26,490

in the blue there's much

less risk of kidney disease

485

00:24:26,490 --> 00:24:27,880

and end-stage kidney disease.

486

00:24:27,880 --> 00:24:29,490

And then in the

red, when you don't

487

00:24:29,490 --> 00:24:33,330

have that rare extra

variant, it points a path

488

00:24:33,330 --> 00:24:36,760

to how this condition

could be treated.

489

00:24:36,760 --> 00:24:40,200

This inherited condition could

be ameliorated by potentially

490

00:24:40,200 --> 00:24:44,130

blocking that channel and

similar things that might

491

00:24:44,130 --> 00:24:46,960

work against the APOL1 protein.

492

00:24:46,960 --> 00:24:48,676

And so what's

happening now are there

493

00:24:48,676 --> 00:24:52,980

are drugs that are in trial

looking at doing this as well.

494

00:24:52,980 --> 00:24:55,430

Next slide.

495

00:24:55,430 --> 00:24:57,783

We are readying a

new data release.

496

00:24:57,783 --> 00:24:59,450

That new data release

will substantially

497

00:24:59,450 --> 00:25:02,690

increase the number of

participants in our research

498

00:25:02,690 --> 00:25:03,600

resource.

499

00:25:03,600 --> 00:25:06,510

That will go from

400,000 to 633,000,

500

00:25:06,510 --> 00:25:08,630

so about a 50% increase.

501

00:25:08,630 --> 00:25:11,930

It will include a lot

more genomic data.

502

00:25:11,930 --> 00:25:17,570

We'll be nearly tripling those

that have long-read sequences,

503

00:25:17,570 --> 00:25:20,180

a lot more survey data, and

we're actually including

504

00:25:20,180 --> 00:25:22,340

more survey data as well.

505

00:25:22,340 --> 00:25:24,890

So it will be more

detailed survey answers

506

00:25:24,890 --> 00:25:28,250

for things like race and

ethnic subpopulations

507

00:25:28,250 --> 00:25:30,020

that people identify.

508

00:25:30,020 --> 00:25:32,780

The Fitbit data is quadrupling.

509

00:25:32,780 --> 00:25:35,450

And that is a result

of the inclusion

510

00:25:35,450 --> 00:25:38,130

of some of the pilots we've been

doing and giving devices out,

511

00:25:38,130 --> 00:25:40,850

as well as people sharing

devices that they already had.

512

00:25:40,850 --> 00:25:45,800

And one of the really important

pieces of this next data release

513

00:25:45,800 --> 00:25:48,140

is it will be the first

time that we will include

514

00:25:48,140 --> 00:25:50,990

self-identified American Indian

and Alaska Native participant

515

00:25:50,990 --> 00:25:51,515

data.

516

00:25:51,515 --> 00:25:52,015

Next slide.

517

00:25:52,015 --> 00:25:54,630

518

00:25:54,630 --> 00:25:57,480

So to talk a little

bit about that,

519

00:25:57,480 --> 00:26:01,560

we have gone through

several formal consultations

520

00:26:01,560 --> 00:26:05,940

with tribal communities and

worked with the Tribal Advisory

521

00:26:05,940 --> 00:26:11,200

Committee with the NIH and the

Tribal Health Research Office,

522

00:26:11,200 --> 00:26:15,270

as well as other groups to

really thoughtfully engage

523

00:26:15,270 --> 00:26:19,360

tribal communities, tribal

nations in this process.

524

00:26:19,360 --> 00:26:21,410

Our participants

are self-identified.

525

00:26:21,410 --> 00:26:25,320

We do not know formal tribal

membership in this process.

526

00:26:25,320 --> 00:26:28,780

And we have been careful

in that discussion.

527

00:26:28,780 --> 00:26:33,540

We also don't recruit on tribal

lands, things like that as well.

528

00:26:33,540 --> 00:26:35,400

And a number of

promises we made through

529

00:26:35,400 --> 00:26:37,067

these tribal

consultations-- and you can

530

00:26:37,067 --> 00:26:39,060

read about this on our website.

531

00:26:39,060 --> 00:26:40,740

What we will do

with this process

532

00:26:40,740 --> 00:26:45,030

is we have notified participants

who self-identify as AIN.

533

00:26:45,030 --> 00:26:47,190

Through the process,

we will continue

534

00:26:47,190 --> 00:26:50,610

to do this as we move towards

release, letting folks know

535

00:26:50,610 --> 00:26:55,550

as well as our tribal

communities in this process.

536

00:26:55,550 --> 00:26:58,180

And it also involves

new processes

537

00:26:58,180 --> 00:27:00,460

we've put in place

with our program

538

00:27:00,460 --> 00:27:04,150

in terms of protections

of their data,

539

00:27:04,150 --> 00:27:08,140

inclusion of more Indigenous

researchers through our review

540

00:27:08,140 --> 00:27:10,630

process, and things

like that as well.

541

00:27:10,630 --> 00:27:12,860

Next slide.

542

00:27:12,860 --> 00:27:15,020

As part of this, we've

had Indigenous researchers

543

00:27:15,020 --> 00:27:19,020

doing demonstration projects

with early access to AIN data.

544

00:27:19,020 --> 00:27:22,980

This goes on a phenotypic

process in a genotypic project.

545

00:27:22,980 --> 00:27:25,160

And so they're

looking at comparisons

546

00:27:25,160 --> 00:27:28,840

to other reference populations

like the NHLBI Strong Heart

547

00:27:28,840 --> 00:27:29,450

study.

548

00:27:29,450 --> 00:27:32,450

And they're helping

advise us and make sure

549

00:27:32,450 --> 00:27:35,210

that we have the appropriate

protections in place and things

550

00:27:35,210 --> 00:27:36,030

like that.

551

00:27:36,030 --> 00:27:38,870

And we hope that they'll

publish their findings

552

00:27:38,870 --> 00:27:41,460

and tell stories to help

guide us in our process.

553

00:27:41,460 --> 00:27:44,010

Next slide.

554

00:27:44,010 --> 00:27:47,050

I want to mention one leadership

transition that's undergoing.

555

00:27:47,050 --> 00:27:51,630

So Dr. Martin Mendoza was our

initial chief health equity

556

00:27:51,630 --> 00:27:54,250

officer of the program.

557

00:27:54,250 --> 00:28:00,540

And he has since left to take

that similar role at CMS.

558

00:28:00,540 --> 00:28:05,260

We will start a national search

for this position very soon.

559

00:28:05,260 --> 00:28:07,710

In the meantime,

Dr. Janeth Sanchez

560

00:28:07,710 --> 00:28:10,740

has been the Acting Director

of Health Equity for us.

561

00:28:10,740 --> 00:28:13,380

And she is doing a

fabulous job with her team

562

00:28:13,380 --> 00:28:15,360

that was built by Martin.

563

00:28:15,360 --> 00:28:17,320

We wish him the

best of luck at CMS.

564

00:28:17,320 --> 00:28:18,420

And CMS is a partner.

565

00:28:18,420 --> 00:28:21,420

And we're thrilled to have

him there and look forward

566

00:28:21,420 --> 00:28:23,370

to filling this

position as well.

567

00:28:23,370 --> 00:28:24,110

Next slide.

568

00:28:24,110 --> 00:28:27,300

So if you have interest,

look for that announcement.

569

00:28:27,300 --> 00:28:30,000

And I encourage you to apply.

570

00:28:30,000 --> 00:28:34,440

As we think about how we

are a platform for research,

571

00:28:34,440 --> 00:28:37,020

most of the research-- you

know from researchers using

572

00:28:37,020 --> 00:28:38,430

the platform--

573

00:28:38,430 --> 00:28:39,450

we don't do.

574

00:28:39,450 --> 00:28:40,560

They are doing it.

575

00:28:40,560 --> 00:28:45,160

And similarly, much of the

data generated for our program

576

00:28:45,160 --> 00:28:48,430

is not going to be

generated by our program.

577

00:28:48,430 --> 00:28:50,860

We are building a foundation

with genomics, collection

578

00:28:50,860 --> 00:28:54,170

of biospecimen surveys, and

then partnering with others,

579

00:28:54,170 --> 00:28:56,230

including the COVID

serology study I mentioned

580

00:28:56,230 --> 00:28:59,320

earlier with partners with NCI.

581

00:28:59,320 --> 00:29:03,940

Exploring the Mind is a task

that participants complete

582

00:29:03,940 --> 00:29:07,090

and answer questions about

behavior and cognitive

583

00:29:07,090 --> 00:29:09,440

traits in game-like fashion.

584

00:29:09,440 --> 00:29:11,440

And Nutrition for Precision

Health-- and there's

585

00:29:11,440 --> 00:29:14,710

a video from Good Morning

America on the side.

586

00:29:14,710 --> 00:29:17,770

I encourage you to watch

at your own leisure.

587

00:29:17,770 --> 00:29:20,170

It's a great summary of

the program Nutrition

588

00:29:20,170 --> 00:29:23,020

for Precision Health, which

involves 18 institutes, centers,

589

00:29:23,020 --> 00:29:24,470

and offices across the NIH.

590

00:29:24,470 --> 00:29:27,460

So we really have broad

buy-in from the NIH

591

00:29:27,460 --> 00:29:29,000

with ancillary studies.

592

00:29:29,000 --> 00:29:31,850

Next slide.

593

00:29:31,850 --> 00:29:34,470

I want to talk a little

bit about what's coming.

594

00:29:34,470 --> 00:29:36,840

Ancillary studies are a

huge part of the future.

595

00:29:36,840 --> 00:29:37,920

And that's what you

see on the right.

596

00:29:37,920 --> 00:29:39,378

I've talked about

nutrition health.

597

00:29:39,378 --> 00:29:41,210

And we have two more starting--

598

00:29:41,210 --> 00:29:43,160

one that started,

actually, and one

599

00:29:43,160 --> 00:29:47,180

that's going to start in

2025 that are really moving,

600

00:29:47,180 --> 00:29:49,160

and a number of

others, actually, that

601

00:29:49,160 --> 00:29:51,360

are in process in

various stages.

602

00:29:51,360 --> 00:29:53,210

So one with the

National Eye Institute

603

00:29:53,210 --> 00:29:55,670

will be putting OCT

devices that will

604

00:29:55,670 --> 00:29:59,540

do retinal imaging

with our participants

605

00:29:59,540 --> 00:30:01,950

in four locations as a pilot.

606

00:30:01,950 --> 00:30:04,160

And then the bottom

one is looking

607

00:30:04,160 --> 00:30:08,030

at individuals who developed

type 2 diabetes after they

608

00:30:08,030 --> 00:30:09,060

enrolled in the program.

609

00:30:09,060 --> 00:30:13,070

So we can take biospecimens

and do assessments

610

00:30:13,070 --> 00:30:16,940

of exposures in

exposomic fashion

611

00:30:16,940 --> 00:30:19,640

with the National Institutes of

Environmental Health Sciences

612

00:30:19,640 --> 00:30:22,460

to look for environmental

and genomic influences

613

00:30:22,460 --> 00:30:25,410

on those who develop

diabetes over time.

614

00:30:25,410 --> 00:30:28,100

And so that was a

test of this program.

615

00:30:28,100 --> 00:30:30,350

And one exciting thing

as we've looked at this

616

00:30:30,350 --> 00:30:34,130

is we estimate that there's

probably a 70% to 80%

617

00:30:34,130 --> 00:30:37,880

cost savings in both

of these programs

618

00:30:37,880 --> 00:30:40,430

through cost of

recruitment and getting

619

00:30:40,430 --> 00:30:44,060

the national representation, not

to mention all the other kinds

620

00:30:44,060 --> 00:30:46,520

of data that we have,

which may or may not

621

00:30:46,520 --> 00:30:49,307

have been available if they

were to start up in a new study.

622

00:30:49,307 --> 00:30:51,140

And then on the left,

I want to just mention

623

00:30:51,140 --> 00:30:53,160

one thing that's

happening different,

624

00:30:53,160 --> 00:30:55,700

because we want to

accelerate ancillary studies.

625

00:30:55,700 --> 00:30:57,720

And we want to better

support our participants.

626

00:30:57,720 --> 00:31:02,360

We will be transitioning our

participant-facing technologies

627

00:31:02,360 --> 00:31:04,430

soon this year.

628

00:31:04,430 --> 00:31:07,580

And so that will happen

over the end of 2024

629

00:31:07,580 --> 00:31:10,790

and early '25, where we'll be

moving to a new technology that

630

00:31:10,790 --> 00:31:14,810

will help us better support

participants, reaching them

631

00:31:14,810 --> 00:31:17,990

in different kinds of

ways, and also help us

632

00:31:17,990 --> 00:31:21,150

do ancillary studies

in a more scalable way.

633

00:31:21,150 --> 00:31:25,700

And so that will initially be a

big change for a lot of people

634

00:31:25,700 --> 00:31:28,580

as we move them, but we're going

to support them in the process.

635

00:31:28,580 --> 00:31:31,520

And we are excited

that this will really

636

00:31:31,520 --> 00:31:35,090

enable new kinds of information

return over the future

637

00:31:35,090 --> 00:31:37,760

and also better support

of ancillary studies.

638

00:31:37,760 --> 00:31:40,800

Next slide.

639

00:31:40,800 --> 00:31:46,300

We launched pediatrics in a

very limited way this summer.

640

00:31:46,300 --> 00:31:51,280

We had our first participant

enroll in the end of 2023.

641

00:31:51,280 --> 00:31:53,910

And I'll tell you, that picture

in the middle of-- that foot--

642

00:31:53,910 --> 00:31:57,570

is probably my favorite

picture of 2023 for our program

643

00:31:57,570 --> 00:32:00,570

because it is our first

pediatric participant's

644

00:32:00,570 --> 00:32:02,760

foot enrolling in the program.

645

00:32:02,760 --> 00:32:06,660

And excited to have these

five sites enrolling

646

00:32:06,660 --> 00:32:10,350

in a limited test

fashion for the program.

647

00:32:10,350 --> 00:32:13,290

Next slide.

648

00:32:13,290 --> 00:32:15,240

And so finally, I

want to conclude

649

00:32:15,240 --> 00:32:18,930

talking a little bit about

a report that was generated

650

00:32:18,930 --> 00:32:21,780

from the advisory panel,

which is a working

651

00:32:21,780 --> 00:32:23,620

group of the

Council of Councils.

652

00:32:23,620 --> 00:32:27,540

It was presented

recently and accepted

653

00:32:27,540 --> 00:32:33,000

by the director of DPCPSI of the

Council of Councils, Dr. Tara

654

00:32:33,000 --> 00:32:33,770

Schwetz.

655

00:32:33,770 --> 00:32:37,470

This report is a

summary of where we are

656

00:32:37,470 --> 00:32:40,230

and where we should go,

answering several questions

657

00:32:40,230 --> 00:32:44,340

around the program, guiding

where we could go in the future.

658

00:32:44,340 --> 00:32:46,435

This is available online.

659

00:32:46,435 --> 00:32:47,560

I encourage you to read it.

660

00:32:47,560 --> 00:32:51,660

I want to give it a big call out

to Russ Altman, Marilyn Richie,

661

00:32:51,660 --> 00:32:55,770

and Rhonda Robinson Beale for

their leadership of developing

662

00:32:55,770 --> 00:32:58,710

this, as well as all

of the advisory panel

663

00:32:58,710 --> 00:33:01,710

efforts in making this happen.

664

00:33:01,710 --> 00:33:06,300

As we look at this, we can go

ahead and go to the next slide

665

00:33:06,300 --> 00:33:08,310

because it walks

through, really,

666

00:33:08,310 --> 00:33:12,730

their top 10 points of a much

longer, more detailed reports.

667

00:33:12,730 --> 00:33:18,850

So the first three points really

characterize the foundation

668

00:33:18,850 --> 00:33:20,350

and where we're headed.

669

00:33:20,350 --> 00:33:23,110

It emphasizes the primary

strength of our program

670

00:33:23,110 --> 00:33:24,740

being the diversity

of the cohort,

671

00:33:24,740 --> 00:33:26,200

particularly among those

who are underrepresented

672

00:33:26,200 --> 00:33:28,180

in biomedical research

and the importance

673

00:33:28,180 --> 00:33:31,170

of continuing to engage this.

674

00:33:31,170 --> 00:33:33,670

The second that we

should continue to enroll

675

00:33:33,670 --> 00:33:35,830

towards a million participants.

676

00:33:35,830 --> 00:33:40,360

And don't forget to engage in

the process and the importance

677

00:33:40,360 --> 00:33:43,600

of that and taking pride in

participation, returning value

678

00:33:43,600 --> 00:33:44,630

to participants.

679

00:33:44,630 --> 00:33:48,400

One of the things that was

looked at here is that we can

680

00:33:48,400 --> 00:33:53,060

study about three times

as many diseases at scale

681

00:33:53,060 --> 00:33:56,680

if we're at a million

versus 500,000.

682

00:33:56,680 --> 00:34:02,150

And also enables us to study a

lot more rare diseases at scale.

683

00:34:02,150 --> 00:34:07,060

So there's a lot of advantages

that come through the scale

684

00:34:07,060 --> 00:34:09,800

that we can see and

especially the diversity.

685

00:34:09,800 --> 00:34:12,489

And when you start thinking

about different populations,

686

00:34:12,489 --> 00:34:15,040

we really have to

scale to get there.

687

00:34:15,040 --> 00:34:17,690

The pediatrics is highlighted

is a really important addition.

688

00:34:17,690 --> 00:34:20,447

There just are not large

pediatric cohorts in the world.

689

00:34:20,447 --> 00:34:21,739

There's a lot of adult cohorts.

690

00:34:21,739 --> 00:34:23,906

We don't have the same kind

of information for peds.

691

00:34:23,906 --> 00:34:25,870

And this will be unique.

692

00:34:25,870 --> 00:34:29,770

They agreed with the

focus on enrolling

693

00:34:29,770 --> 00:34:33,052

parents and guardians as well

as the kids in the process.

694

00:34:33,052 --> 00:34:34,760

And so that's what

we're currently doing.

695

00:34:34,760 --> 00:34:36,800

And we will remain doing

that for zero to 12.

696

00:34:36,800 --> 00:34:38,590

And then teenagers--

we'll allow them

697

00:34:38,590 --> 00:34:42,304

to have the option of not

enrolling with a parent

698

00:34:42,304 --> 00:34:44,179

or guardian, but certainly

that is preferred.

699

00:34:44,179 --> 00:34:45,949

Next slide.

700

00:34:45,949 --> 00:34:51,120

They encouraged us to consider

robust platforms in the process

701

00:34:51,120 --> 00:34:54,810

that we have to reevaluate at

times what our platforms are

702

00:34:54,810 --> 00:34:58,320

and see what we can buy off the

shelf versus build our own when

703

00:34:58,320 --> 00:34:59,050

it makes sense.

704

00:34:59,050 --> 00:35:01,560

And a longitudinal program

that will last decades

705

00:35:01,560 --> 00:35:03,990

will have to think

about evolving partners

706

00:35:03,990 --> 00:35:05,740

and make changes over time.

707

00:35:05,740 --> 00:35:08,010

And that includes our

technology partners.

708

00:35:08,010 --> 00:35:10,260

It can also include enrollment

partners and engagement

709

00:35:10,260 --> 00:35:10,772

partners.

710

00:35:10,772 --> 00:35:12,480

We should match the

diversity of our core

711

00:35:12,480 --> 00:35:14,130

with diversity of researchers.

712

00:35:14,130 --> 00:35:17,340

They encourage the continued

growth and diversity

713

00:35:17,340 --> 00:35:20,520

of researchers across different

axes-- academia, industry

714

00:35:20,520 --> 00:35:23,490

payers, government, NGOs,

multiple other types

715

00:35:23,490 --> 00:35:24,160

of discipline.

716

00:35:24,160 --> 00:35:27,750

More diverse researchers equals

more questions and more diverse

717

00:35:27,750 --> 00:35:31,890

questions being asked and

more science being discovered.

718

00:35:31,890 --> 00:35:34,540

Build trust with high

quality communications.

719

00:35:34,540 --> 00:35:36,270

We must be transparent.

720

00:35:36,270 --> 00:35:40,560

That we should also look at our

ancillary supplemental studies

721

00:35:40,560 --> 00:35:44,070

in collaborative ways that

keep that transparency

722

00:35:44,070 --> 00:35:46,180

and add value to participants.

723

00:35:46,180 --> 00:35:49,120

That we should think

about All of Us

724

00:35:49,120 --> 00:35:52,590

as a resource for translational

research and support,

725

00:35:52,590 --> 00:35:54,340

the science of

translation, that we really

726

00:35:54,340 --> 00:35:56,772

want to make an impact

where things happen.

727

00:35:56,772 --> 00:35:58,480

Our return of results,

of genetic results

728

00:35:58,480 --> 00:35:59,950

is a key part of that.

729

00:35:59,950 --> 00:36:03,430

And we want to inform equitable

health care in the process.

730

00:36:03,430 --> 00:36:06,270

Next slide.

731

00:36:06,270 --> 00:36:10,080

We want to use those ancillary

studies or collaborative

732

00:36:10,080 --> 00:36:12,430

projects to add

data at low cost.

733

00:36:12,430 --> 00:36:16,320

They think there's a lot of

advantages and uniqueness

734

00:36:16,320 --> 00:36:16,920

to our cohort.

735

00:36:16,920 --> 00:36:18,750

And people want

to partner with us

736

00:36:18,750 --> 00:36:23,070

and add data not just across

the NIH institutes and centers

737

00:36:23,070 --> 00:36:26,440

and offices, but

also other places.

738

00:36:26,440 --> 00:36:30,720

And they encouraged

that NIH ICs really

739

00:36:30,720 --> 00:36:34,180

see this as a platform to help

them do their science faster.

740

00:36:34,180 --> 00:36:36,450

And so we have been

in close collaboration

741

00:36:36,450 --> 00:36:38,297

with the other

institutes and centers.

742

00:36:38,297 --> 00:36:39,880

I've had a number

of partner projects.

743

00:36:39,880 --> 00:36:42,940

I mentioned the ancillary

studies we have in progress.

744

00:36:42,940 --> 00:36:45,120

And we have 22

ancillary studies--

745

00:36:45,120 --> 00:36:47,430

sorry, 22 institute

centers and offices that

746

00:36:47,430 --> 00:36:51,390

are actually working with us

on ancillary studies currently.

747

00:36:51,390 --> 00:36:53,335

In the budget uncertainty

that we're facing,

748

00:36:53,335 --> 00:36:55,335

which we've talked about

before, that historic--

749

00:36:55,335 --> 00:36:59,000

a stable core budget is

key, that we really, though,

750

00:36:59,000 --> 00:37:02,730

have to make our decisions as we

face economic uncertainty with

751

00:37:02,730 --> 00:37:07,510

a really longitudinal horizon,

thinking 30-plus year project

752

00:37:07,510 --> 00:37:08,620

horizon.

753

00:37:08,620 --> 00:37:11,650

And so doing that, think

about what we need to have

754

00:37:11,650 --> 00:37:13,780

and what we would like to have.

755

00:37:13,780 --> 00:37:19,840

And finally, to think about

us as arm for national health

756

00:37:19,840 --> 00:37:21,190

emergencies.

757

00:37:21,190 --> 00:37:23,530

COVID-19 highlighted

the importance

758

00:37:23,530 --> 00:37:26,230

of having resources like that.

759

00:37:26,230 --> 00:37:29,450

And we shouldn't wait for

another health emergency

760

00:37:29,450 --> 00:37:33,280

but look at what kinds of

capabilities we could test now.

761

00:37:33,280 --> 00:37:36,972

And thinking about opioids,

dementia, obesity, depression,

762

00:37:36,972 --> 00:37:38,930

cancer are some of the

examples they mentioned.

763

00:37:38,930 --> 00:37:40,820

Next slide.

764

00:37:40,820 --> 00:37:43,770

So in light of all

their recommendations,

765

00:37:43,770 --> 00:37:47,840

I would be amiss without noting

some of the challenges we

766

00:37:47,840 --> 00:37:48,540

are facing.

767

00:37:48,540 --> 00:37:52,500

We have two sources of funding,

the 21st Century Cures Act,

768

00:37:52,500 --> 00:37:57,960

represented in orange, and base

funding, represented in blue.

769

00:37:57,960 --> 00:38:03,020

And you can see, in 2023, after

a steady growth of total budget,

770

00:38:03,020 --> 00:38:07,370

there was such a big increase

in the Cures Act funding

771

00:38:07,370 --> 00:38:10,400

for that year that as Cures

Act funding has decreased

772

00:38:10,400 --> 00:38:13,640

without having an increase

in base funding in '24,

773

00:38:13,640 --> 00:38:16,050

that resulted in

a 34% reduction.

774

00:38:16,050 --> 00:38:18,710

And then we're waiting to see

what the '25 budget will result

775

00:38:18,710 --> 00:38:19,400

in.

776

00:38:19,400 --> 00:38:23,370

There's a potential for

anywhere from restoring funding,

777

00:38:23,370 --> 00:38:26,420

which is what the

president's budget requested,

778

00:38:26,420 --> 00:38:28,460

and what's currently

in the Senate mark,

779

00:38:28,460 --> 00:38:35,720

to a 71% decrease in funding,

which means that we are planning

780

00:38:35,720 --> 00:38:39,200

for multiple budget scenarios,

of which we'll have dramatically

781

00:38:39,200 --> 00:38:41,760

different effects on the

program's ability to do things

782

00:38:41,760 --> 00:38:45,900

like start and enroll

a pediatric cohort

783

00:38:45,900 --> 00:38:50,200

or keep enrolling in general

at all based on this.

784

00:38:50,200 --> 00:38:53,550

We will prioritize protection

of data, protection

785

00:38:53,550 --> 00:38:56,970

of our current participants,

return of genetic results

786

00:38:56,970 --> 00:38:59,380

in the participants that

we have already recruited,

787

00:38:59,380 --> 00:39:01,580

and availability of

our data to researchers

788

00:39:01,580 --> 00:39:03,330

to make discoveries

that make a difference

789

00:39:03,330 --> 00:39:04,870

in our participants' lives.

790

00:39:04,870 --> 00:39:06,480

Those would be our priorities.

791

00:39:06,480 --> 00:39:09,030

And then our ability to

really engage with the future

792

00:39:09,030 --> 00:39:11,940

and do things in

pediatrics at all

793

00:39:11,940 --> 00:39:14,880

will depend on what happens

with our budget scenario.

794

00:39:14,880 --> 00:39:16,398

Next slide.

795

00:39:16,398 --> 00:39:18,190

So with that, thank

you for your attention.

796

00:39:18,190 --> 00:39:21,080

I'm happy to take

a few questions.

797

00:39:21,080 --> 00:39:22,830

RACHELE PETERSON: Thank

you so much, Josh.

798

00:39:22,830 --> 00:39:24,500

We really appreciate that.

799

00:39:24,500 --> 00:39:27,020

I'm going to call on

Edgar Gil Rico, who

800

00:39:27,020 --> 00:39:29,480

is the senior director

for innovation and program

801

00:39:29,480 --> 00:39:32,580

development at the National

Alliance for Hispanic Health.

802

00:39:32,580 --> 00:39:33,200

Edgar?

803

00:39:33,200 --> 00:39:35,450

EDGAR GIL RICO: Thank you,

Rachele, and thank you, Dr.

804

00:39:35,450 --> 00:39:36,830

Denny, for the opportunity.

805

00:39:36,830 --> 00:39:40,590

As a national community

engagement partner since 2017

806

00:39:40,590 --> 00:39:42,870

bringing this program

to Hispanic communities,

807

00:39:42,870 --> 00:39:45,570

we have received questions

for the committee saying,

808

00:39:45,570 --> 00:39:47,200

what's going on with my data?

809

00:39:47,200 --> 00:39:48,450

How is it being used?

810

00:39:48,450 --> 00:39:50,600

So do you have any

tangible examples

811

00:39:50,600 --> 00:39:53,240

on how the data from the current

participants in the program

812

00:39:53,240 --> 00:39:56,330

has been used to address those

specific community needs?

813

00:39:56,330 --> 00:39:59,285

And how are we communicating

this back to them?

814

00:39:59,285 --> 00:40:01,410

JOSH DENNY: Edgar, thanks

so much for the question.

815

00:40:01,410 --> 00:40:03,975

And I just have to say

thank you for all your work

816

00:40:03,975 --> 00:40:05,100

with the National Alliance.

817

00:40:05,100 --> 00:40:10,405

You are a great part, as are our

community partners in general,

818

00:40:10,405 --> 00:40:13,250

and so important for what we do.

819

00:40:13,250 --> 00:40:16,470

In terms of that question, a

couple of things I'll highlight.

820

00:40:16,470 --> 00:40:20,180

One thing is, as we've looked at

those 600-plus papers that have

821

00:40:20,180 --> 00:40:23,520

been published so far, the

number-one theme we see

822

00:40:23,520 --> 00:40:25,270

excitingly is health equity.

823

00:40:25,270 --> 00:40:26,858

People may be

looking at diabetes.

824

00:40:26,858 --> 00:40:28,150

They may look at heart disease.

825

00:40:28,150 --> 00:40:30,040

But health equity

comes up number one.

826

00:40:30,040 --> 00:40:32,010

So the first thing

I'm excited to say

827

00:40:32,010 --> 00:40:34,380

is people are inclusive

and looking at and tackling

828

00:40:34,380 --> 00:40:36,810

these issues head on to

make studies that are

829

00:40:36,810 --> 00:40:38,920

relevant to real populations.

830

00:40:38,920 --> 00:40:41,950

One thing I'll say, too, is

because of the questions we ask,

831

00:40:41,950 --> 00:40:45,900

we're able to answer some kinds

of questions, research questions

832

00:40:45,900 --> 00:40:48,690

in different ways,

than what people

833

00:40:48,690 --> 00:40:51,340

may do with just electronic

health record datasets.

834

00:40:51,340 --> 00:40:53,530

So there's a lot

of data out there,

835

00:40:53,530 --> 00:40:55,440

what's called the

Latino health paradox,

836

00:40:55,440 --> 00:40:59,520

of cardiovascular

disease rates compared

837

00:40:59,520 --> 00:41:02,400

to other populations

seeming to be better

838

00:41:02,400 --> 00:41:05,082

and based on other

adjusted demographics.

839

00:41:05,082 --> 00:41:06,540

And unfortunately,

we found that it

840

00:41:06,540 --> 00:41:11,350

looks like there may be

increased risk in populations,

841

00:41:11,350 --> 00:41:16,920

especially men who self-identify

as Hispanic or Latino.

842

00:41:16,920 --> 00:41:18,570

And so that's one example.

843

00:41:18,570 --> 00:41:21,240

Another example is

the APOL1 example

844

00:41:21,240 --> 00:41:23,850

I mentioned before, which

is really pointing to a way

845

00:41:23,850 --> 00:41:26,580

to treat one of the most

common causes of kidney disease

846

00:41:26,580 --> 00:41:28,710

in African-Americans.

847

00:41:28,710 --> 00:41:32,520

And people are looking at the

effect of let's get even deeper

848

00:41:32,520 --> 00:41:36,340

with health effects of

diverse populations.

849

00:41:36,340 --> 00:41:40,360

And in the Hispanic

Latino population,

850

00:41:40,360 --> 00:41:43,230

I remember another paper

looking at the effects

851

00:41:43,230 --> 00:41:45,120

of where you're born.

852

00:41:45,120 --> 00:41:46,300

Were you born in the US?

853

00:41:46,300 --> 00:41:47,740

Were you born overseas?

854

00:41:47,740 --> 00:41:50,940

And then we can start to

look even further over time

855

00:41:50,940 --> 00:41:55,210

as we get more numbers and more

data, how that might matter too,

856

00:41:55,210 --> 00:41:56,298

and where you come from.

857

00:41:56,298 --> 00:41:57,840

So all those things

are so important.

858

00:41:57,840 --> 00:42:00,250

Because we can get the

socio-demographic factors,

859

00:42:00,250 --> 00:42:02,260

we can get social

determinants of health,

860

00:42:02,260 --> 00:42:05,730

we can get at genetics, we

can put this all together

861

00:42:05,730 --> 00:42:08,490

and answer questions in a

deeper way, richer, way,

862

00:42:08,490 --> 00:42:11,590

more precise way than we've

been able to do before.

863

00:42:11,590 --> 00:42:14,028

So thanks for the

question, Edgar.

864

00:42:14,028 --> 00:42:15,820

RACHELE PETERSON: Thank

you so much, Edgar.

865

00:42:15,820 --> 00:42:19,163

And in some of the slides

you saw from the CEO update,

866

00:42:19,163 --> 00:42:20,830

our research highlights

section as well.

867

00:42:20,830 --> 00:42:23,400

So you can go to the All

of Us website and see some

868

00:42:23,400 --> 00:42:26,610

of the participant and

public-friendly explanations

869

00:42:26,610 --> 00:42:31,170

of the key highlights from the

660-plus growing scientific

870

00:42:31,170 --> 00:42:32,660

publications that are out there.

871

00:42:32,660 --> 00:42:34,410

Next, I'm going to go

to Randee Bloom, who

872

00:42:34,410 --> 00:42:36,150

is a participant partner.

873

00:42:36,150 --> 00:42:37,650

She serves on our

steering committee

874

00:42:37,650 --> 00:42:39,067

as well as on our

survey committee

875

00:42:39,067 --> 00:42:41,280

for participant-provided

information in addition

876

00:42:41,280 --> 00:42:43,270

to having a nursing background.

877

00:42:43,270 --> 00:42:44,830

Take it away, Randy.

878

00:42:44,830 --> 00:42:45,830

RANDEE BLOOM: Thank you.

879

00:42:45,830 --> 00:42:47,720

Thank you for this opportunity.

880

00:42:47,720 --> 00:42:50,480

So health care and

medical research

881

00:42:50,480 --> 00:42:53,820

seems to usually be focused

on a specific disease,

882

00:42:53,820 --> 00:42:55,720

such as cancer, for example.

883

00:42:55,720 --> 00:42:59,700

But can you please explain

how in the All of Us program,

884

00:42:59,700 --> 00:43:03,560

it's rather disease

agnostic, and that's

885

00:43:03,560 --> 00:43:07,070

why every contribution

from every participant

886

00:43:07,070 --> 00:43:10,100

is valuable, as

researchers can create

887

00:43:10,100 --> 00:43:13,850

specific cohorts to answer

research questions now

888

00:43:13,850 --> 00:43:15,660

and well into the future?

889

00:43:15,660 --> 00:43:16,910

Thanks.

890

00:43:16,910 --> 00:43:18,470

JOSH DENNY: Thanks, Randy.

891

00:43:18,470 --> 00:43:21,200

It's a different kind of cohort.

892

00:43:21,200 --> 00:43:24,980

We don't just, like you say,

recruit for cancer or heart

893

00:43:24,980 --> 00:43:29,432

disease because we're affected

by so many different conditions.

894

00:43:29,432 --> 00:43:30,890

And there have been

lots of studies

895

00:43:30,890 --> 00:43:32,610

out there just looking

at some of those.

896

00:43:32,610 --> 00:43:34,670

And we can answer

those questions, too.

897

00:43:34,670 --> 00:43:37,910

I like to say we are

really allowed to--

898

00:43:37,910 --> 00:43:40,040

we have the ability

to tackle all diseases

899

00:43:40,040 --> 00:43:41,700

across all populations.

900

00:43:41,700 --> 00:43:45,090

And it will be the

inclusion of lots of people

901

00:43:45,090 --> 00:43:46,480

that will help us do that.

902

00:43:46,480 --> 00:43:48,330

We have great power to

look at heart disease

903

00:43:48,330 --> 00:43:49,870

and lots of different cancers.

904

00:43:49,870 --> 00:43:52,720

But we also get a chance

to look at rare disease.

905

00:43:52,720 --> 00:43:55,420

And the other thing

is you don't know--

906

00:43:55,420 --> 00:43:58,050

as people enroll in different

stages of life, those

907

00:43:58,050 --> 00:44:00,450

who enroll when they're

young, when they're healthy,

908

00:44:00,450 --> 00:44:04,020

maybe we don't know

what disease we might--

909

00:44:04,020 --> 00:44:05,580

we're all going to face disease.

910

00:44:05,580 --> 00:44:10,590

And so that prospective allowing

of collecting of participants

911

00:44:10,590 --> 00:44:12,780

and the ability to

look at anything

912

00:44:12,780 --> 00:44:16,930

helps us be able to tackle

whatever affects you over time.

913

00:44:16,930 --> 00:44:20,310

And we're finding

that we can tackle

914

00:44:20,310 --> 00:44:22,360

hundreds of common diseases.

915

00:44:22,360 --> 00:44:23,340

But we can also--

916

00:44:23,340 --> 00:44:26,790

it looks like we have

hundreds of rare diseases

917

00:44:26,790 --> 00:44:29,520

already in the program that

we'll be able to tackle.

918

00:44:29,520 --> 00:44:33,890

And there's just not

a resource like this.

919

00:44:33,890 --> 00:44:35,300

RACHELE PETERSON: Thanks, Randy.

920

00:44:35,300 --> 00:44:35,640

All right.

921

00:44:35,640 --> 00:44:37,820

Now we'll go to Hugo Campos, who

is the participant partner who

922

00:44:37,820 --> 00:44:39,195

serves on our

steering committee.

923

00:44:39,195 --> 00:44:42,200

And he also adds to our ethical,

legal, and social issues brain

924

00:44:42,200 --> 00:44:44,420

trust as well as being

a patient advisor

925

00:44:44,420 --> 00:44:46,265

to engagement efforts

across the program,

926

00:44:46,265 --> 00:44:48,390

as well as at Vanderbilt

University Medical Center.

927

00:44:48,390 --> 00:44:50,740

Take it away, Hugo.

928

00:44:50,740 --> 00:44:51,830

HUGO CAMPOS: Thank you.

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00:44:51,830 --> 00:44:54,520

Thank you for the opportunity.

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00:44:54,520 --> 00:44:56,680

Dr. Denny, you

mentioned the Nutrition

931

00:44:56,680 --> 00:44:58,460

for Precision Health study.

932

00:44:58,460 --> 00:45:00,730

I'm a participant in that study.

933

00:45:00,730 --> 00:45:05,200

My question is about the impact

of new research conducted

934

00:45:05,200 --> 00:45:07,780

on the All of Us

platform is called

935

00:45:07,780 --> 00:45:10,690

the ancillary studies

that are offered

936

00:45:10,690 --> 00:45:12,910

to All of Us participants.

937

00:45:12,910 --> 00:45:17,260

How do you hope that these

studies will contribute

938

00:45:17,260 --> 00:45:21,430

to the sustainability and

scientific impact of the All

939

00:45:21,430 --> 00:45:23,650

of Us program in the future?

940

00:45:23,650 --> 00:45:25,390

JOSH DENNY: I think,

especially as we

941

00:45:25,390 --> 00:45:29,350

deal with my last slide talking

about budgetary challenges,

942

00:45:29,350 --> 00:45:31,740

it's a really important

aspect you bring up, Hugo.

943

00:45:31,740 --> 00:45:34,450

And thank you so much

for your question

944

00:45:34,450 --> 00:45:39,630

and participating both

in the program and MPH.

945

00:45:39,630 --> 00:45:43,440

We have this incredibly rich

foundation of a resource

946

00:45:43,440 --> 00:45:49,770

and touching all parts of

America and all populations.

947

00:45:49,770 --> 00:45:52,920

And one of the

things that enables

948

00:45:52,920 --> 00:45:59,520

is as people come up institutes,

centers, other funders, pharma,

949

00:45:59,520 --> 00:46:03,330

as people think about

doing research, we have--

950

00:46:03,330 --> 00:46:06,070

like yourself, I'm a

participant as well.

951

00:46:06,070 --> 00:46:08,220

We have the ability

to contribute

952

00:46:08,220 --> 00:46:13,530

to that kind of research

and be ready with all

953

00:46:13,530 --> 00:46:14,650

these kinds of data.

954

00:46:14,650 --> 00:46:18,360

And so there's incredible

cost savings for those studies

955

00:46:18,360 --> 00:46:21,210

to be done in ways with

diverse populations that

956

00:46:21,210 --> 00:46:22,750

couldn't be done otherwise.

957

00:46:22,750 --> 00:46:25,230

So I think it really

contributes to sustainability

958

00:46:25,230 --> 00:46:27,900

because it's not just

our sustainability we're

959

00:46:27,900 --> 00:46:28,750

talking about.

960

00:46:28,750 --> 00:46:33,000

It's the greater sustainability

and the greater cost efficiency.

961

00:46:33,000 --> 00:46:34,530

And more diverse

populations will

962

00:46:34,530 --> 00:46:37,360

be studied by other

institutes and centers.

963

00:46:37,360 --> 00:46:42,070

It will enable the NIH to

launch studies faster, better,

964

00:46:42,070 --> 00:46:46,450

cheaper and a ready-made place

to get that data safely to other

965

00:46:46,450 --> 00:46:49,660

participants, sorry, other

researchers in a way--

966

00:46:49,660 --> 00:46:52,310

with a [INAUDIBLE]

to return results to.

967

00:46:52,310 --> 00:46:55,330

So I think it's really one

of those examples of win-win

968

00:46:55,330 --> 00:46:57,610

that will help us

move forward as well

969

00:46:57,610 --> 00:47:00,670

as creating value for

participants and researchers

970

00:47:00,670 --> 00:47:04,140

and funders.

971

00:47:04,140 --> 00:47:05,940

RACHELE PETERSON: Thanks, Hugo.

972

00:47:05,940 --> 00:47:08,070

So we are at time,

but Jean Swindler

973

00:47:08,070 --> 00:47:09,695

did get in a very

early question.

974

00:47:09,695 --> 00:47:12,070

And so I wanted to just give

a chance, if you don't mind,

975

00:47:12,070 --> 00:47:15,060

Josh, how can we ensure

the genetic communities

976

00:47:15,060 --> 00:47:17,280

that your study is

publishing findings

977

00:47:17,280 --> 00:47:21,330

on have oversight of the

substance of the investigations

978

00:47:21,330 --> 00:47:23,422

you're undertaking?

979

00:47:23,422 --> 00:47:25,932

It's a little bit about our

resource access [INAUDIBLE].

980

00:47:25,932 --> 00:47:26,640

JOSH DENNY: Yeah.

981

00:47:26,640 --> 00:47:29,430

So as we think

about this, there's

982

00:47:29,430 --> 00:47:30,630

a couple of different ways.

983

00:47:30,630 --> 00:47:33,660

One thing is as people come

in and do research, of course,

984

00:47:33,660 --> 00:47:37,530

they go through a

training process.

985

00:47:37,530 --> 00:47:39,700

We basically do our own

human subjects training.

986

00:47:39,700 --> 00:47:43,710

But we add some elements to

that that talk about what

987

00:47:43,710 --> 00:47:46,710

could potentially be

stigmatizing research.

988

00:47:46,710 --> 00:47:49,260

And we have some

education pieces on that

989

00:47:49,260 --> 00:47:51,760

as well as a short quiz

that you have to take.

990

00:47:51,760 --> 00:47:56,080

And then, of course, that

contract is renewed annually.

991

00:47:56,080 --> 00:47:59,160

And then we have

a resource where

992

00:47:59,160 --> 00:48:02,400

you, as you create a project,

you write up a description.

993

00:48:02,400 --> 00:48:03,910

We make it easy to edit that.

994

00:48:03,910 --> 00:48:06,090

We made it easy to create

them because we think

995

00:48:06,090 --> 00:48:08,130

making it easy to

do the right thing

996

00:48:08,130 --> 00:48:10,770

helps us get a better

understanding of what you're

997

00:48:10,770 --> 00:48:13,900

doing and helps you

stay better on track.

998

00:48:13,900 --> 00:48:16,840

The researchers stay better on

track with what they're doing.

999

00:48:16,840 --> 00:48:18,570

And so one of the

things we've seen

1000

00:48:18,570 --> 00:48:22,230

with other projects in the

world that we've learned from

1001

00:48:22,230 --> 00:48:24,430

is some of the things

that have gotten out there

1002

00:48:24,430 --> 00:48:26,980

that we wish people

wouldn't have published

1003

00:48:26,980 --> 00:48:30,700

has happened because

a researcher ended up

1004

00:48:30,700 --> 00:48:33,320

deviating from what they

said they were going to do.

1005

00:48:33,320 --> 00:48:35,470

And some of that is

because it can take a year

1006

00:48:35,470 --> 00:48:36,440

to make those changes.

1007

00:48:36,440 --> 00:48:37,940

And so we want to

make that easy.

1008

00:48:37,940 --> 00:48:40,000

So making it easy to

do the right thing

1009

00:48:40,000 --> 00:48:41,973

is one of the things

we try to do here.

1010

00:48:41,973 --> 00:48:44,390

And then another thing we do

is everything's in the cloud.

1011

00:48:44,390 --> 00:48:45,265

So we can audit it.

1012

00:48:45,265 --> 00:48:47,140

We have this thing called

the Resource Access

1013

00:48:47,140 --> 00:48:51,910

Board, which can look at any

workspace based on questions

1014

00:48:51,910 --> 00:48:52,660

that people--

1015

00:48:52,660 --> 00:48:55,270

and based on how people

fill out those forms of what

1016

00:48:55,270 --> 00:48:57,230

their project is.

1017

00:48:57,230 --> 00:49:01,935

They may take a look more

carefully at some than others.

1018

00:49:01,935 --> 00:49:02,810

It'll be more likely.

1019

00:49:02,810 --> 00:49:03,935

They also do random audits.

1020

00:49:03,935 --> 00:49:07,510

And we have participants

who do actually

1021

00:49:07,510 --> 00:49:12,847

flag projects from the research

project directory saying,

1022

00:49:12,847 --> 00:49:14,180

hey, take a closer look at this.

1023

00:49:14,180 --> 00:49:16,040

And so we'll do that as well.

1024

00:49:16,040 --> 00:49:18,160

And those actually

result in changes

1025

00:49:18,160 --> 00:49:20,200

to the project and

reformulations.

1026

00:49:20,200 --> 00:49:23,140

And some researchers

actually, in various ways

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00:49:23,140 --> 00:49:25,150

based on their

topic, will actually

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00:49:25,150 --> 00:49:27,220

have their papers go

through and looked at

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00:49:27,220 --> 00:49:29,320

by the Resource Access Board.

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00:49:29,320 --> 00:49:31,370

This is something we're

learning about in time.

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00:49:31,370 --> 00:49:33,850

I think some of the

people listening

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00:49:33,850 --> 00:49:40,570

may know that we had a paper

that came out in February that

1033

00:49:40,570 --> 00:49:43,310

didn't meet our best

standards for what we want,

1034

00:49:43,310 --> 00:49:44,840

how we wanted to

represent the data.

1035

00:49:44,840 --> 00:49:48,490

And so we're working slowly

through that process with nature

1036

00:49:48,490 --> 00:49:50,750

about changing one

of those figures.

1037

00:49:50,750 --> 00:49:57,640

But what we have done is

beefed up some of our processes

1038

00:49:57,640 --> 00:49:58,340

with that.

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00:49:58,340 --> 00:50:00,700

So our Resource Access

Board is a key part

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00:50:00,700 --> 00:50:07,900

of that, how we

look at those pieces

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00:50:07,900 --> 00:50:09,440

and educate our researchers.

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00:50:09,440 --> 00:50:12,683

And then, quite frankly, another

piece is talking to publishers

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00:50:12,683 --> 00:50:13,850

and working with publishers.

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00:50:13,850 --> 00:50:16,910

And so we help support

the NASN reports.

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00:50:16,910 --> 00:50:19,090

We were one of the

key funders of that

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00:50:19,090 --> 00:50:24,350

about how we talk about genetic

ancestry and genetic similarity,

1047

00:50:24,350 --> 00:50:26,272

race and ethnicity

and genomic studies.

1048

00:50:26,272 --> 00:50:28,480

So all those things trying

to promote the right thing

1049

00:50:28,480 --> 00:50:31,820

and make the community

better over time.

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00:50:31,820 --> 00:50:33,230

RACHELE PETERSON: Thanks, Josh.

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00:50:33,230 --> 00:50:36,110

That is in line with a

couple of the other questions

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00:50:36,110 --> 00:50:38,240

that we got around

the NASN report

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00:50:38,240 --> 00:50:41,540

and the nature of publication

and the kind of guidance

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00:50:41,540 --> 00:50:43,560

that the program, along

with the community,

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00:50:43,560 --> 00:50:45,980

can be working on for

researchers for those best

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00:50:45,980 --> 00:50:50,460

practices around labeling

and avoiding conflation.

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00:50:50,460 --> 00:50:53,030

So if you could perhaps talk a

little bit more about the work

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00:50:53,030 --> 00:50:55,640

that could be done

there in the future.

1059

00:50:55,640 --> 00:50:57,420

And then I have

one last question.

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00:50:57,420 --> 00:50:59,045

And then we'll wrap

it up because we're

1061

00:50:59,045 --> 00:51:00,620

over time for the session.

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00:51:00,620 --> 00:51:03,120

JOSH DENNY: So this is

a community problem.

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00:51:03,120 --> 00:51:05,050

It's not just about All of Us.

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00:51:05,050 --> 00:51:07,680

It is about genetics worldwide.

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00:51:07,680 --> 00:51:09,920

And I mentioned

that worldwide part

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00:51:09,920 --> 00:51:14,930

because I think we are, in

this country as geneticists

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00:51:14,930 --> 00:51:20,360

and genetic communities, growing

more aware, more familiar, more

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00:51:20,360 --> 00:51:21,150

in tune with this.

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00:51:21,150 --> 00:51:23,910

But it's something that

we have to work on.

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00:51:23,910 --> 00:51:28,850

And I think how the publishers

look at it is one piece of that

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00:51:28,850 --> 00:51:32,630

and how we think about

it in peer review

1072

00:51:32,630 --> 00:51:36,890

and then how each of us has

a genetic resource thinks

1073

00:51:36,890 --> 00:51:39,830

about educating researchers

in part of this.

1074

00:51:39,830 --> 00:51:41,550

These all play into it.

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00:51:41,550 --> 00:51:44,178

So I think it's such a

multifaceted problem.

1076

00:51:44,178 --> 00:51:46,220

I think one of the things

to do is admit when you

1077

00:51:46,220 --> 00:51:47,470

could have done things better.

1078

00:51:47,470 --> 00:51:49,830

And hopefully, you

felt like I just did.

1079

00:51:49,830 --> 00:51:52,490

I think we as a

program, it wasn't--

1080

00:51:52,490 --> 00:51:56,850

we as a program could have done

better with that publication.

1081

00:51:56,850 --> 00:52:01,670

And so that's why

we're revising it.

1082

00:52:01,670 --> 00:52:05,430

I think that another

process is, again,

1083

00:52:05,430 --> 00:52:07,980

education and things like

[INAUDIBLE] in the process.

1084

00:52:07,980 --> 00:52:10,490

So I think this

is a big problem.

1085

00:52:10,490 --> 00:52:14,720

Fortunately, I feel

like it's one where we

1086

00:52:14,720 --> 00:52:16,890

have a positive trajectory on.

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00:52:16,890 --> 00:52:19,130

And I think we're hopefully

making a difference

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00:52:19,130 --> 00:52:20,870

as a community.

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00:52:20,870 --> 00:52:23,760

It's important.

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00:52:23,760 --> 00:52:27,270

It comes back also to inclusion.

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00:52:27,270 --> 00:52:30,810

If you don't have inclusion,

you don't have this problem.

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00:52:30,810 --> 00:52:33,210

But that's not the right answer.

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00:52:33,210 --> 00:52:35,940

We really have to include

and close these gaps.

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00:52:35,940 --> 00:52:38,280

And I'm glad that

we can hopefully

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00:52:38,280 --> 00:52:41,580

be part of the

maybe solution, not

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00:52:41,580 --> 00:52:45,000

always in the most painless

way, but we can hopefully

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00:52:45,000 --> 00:52:46,710

be part of the solution.

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00:52:46,710 --> 00:52:47,290

RACHELE PETERSON: Thanks, Josh.

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00:52:47,290 --> 00:52:49,082

And then our last

question from an attendee

1100

00:52:49,082 --> 00:52:52,330

is, given that underrepresented

in biomedical research

1101

00:52:52,330 --> 00:52:55,890

participants are more likely

to have barriers to accessing

1102

00:52:55,890 --> 00:52:58,020

quality health care,

has the program

1103

00:52:58,020 --> 00:53:01,380

tested the amount and quality

of the electronic health record

1104

00:53:01,380 --> 00:53:05,490

data between those UBR

and non-UBR participants

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00:53:05,490 --> 00:53:08,640

to ensure both groups are

being equitably represented

1106

00:53:08,640 --> 00:53:09,670

in the dataset?

1107

00:53:09,670 --> 00:53:12,780

And what efforts are being made

to collect alternative data

1108

00:53:12,780 --> 00:53:16,260

sources longitudinally to

ensure all participants are well

1109

00:53:16,260 --> 00:53:18,150

represented in the health data?

1110

00:53:18,150 --> 00:53:19,570

JOSH DENNY: Yeah,

great questions.

1111

00:53:19,570 --> 00:53:22,923

So the first thing is

starting to collect data.

1112

00:53:22,923 --> 00:53:24,340

I mentioned some

of the challenges

1113

00:53:24,340 --> 00:53:25,960

in getting electronic health

records in this country.

1114

00:53:25,960 --> 00:53:28,377

And no one will be surprised

with all the different health

1115

00:53:28,377 --> 00:53:29,750

systems we have a part of.

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00:53:29,750 --> 00:53:32,390

I think we've made great

efforts towards doing that.

1117

00:53:32,390 --> 00:53:38,260

If you look at the highest level

representation of different UBR

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00:53:38,260 --> 00:53:41,110

categories,

typically, there's not

1119

00:53:41,110 --> 00:53:45,100

much difference between those

who identify as UBR and not

1120

00:53:45,100 --> 00:53:47,270

in having an electronic

health record.

1121

00:53:47,270 --> 00:53:49,100

You do see differences.

1122

00:53:49,100 --> 00:53:51,640

So a federally

qualified health center

1123

00:53:51,640 --> 00:53:54,710

doesn't have an

inpatient capability.

1124

00:53:54,710 --> 00:53:58,150

So an FQHC delivering

EHRs information

1125

00:53:58,150 --> 00:54:00,460

has a different slice

of the EHR information

1126

00:54:00,460 --> 00:54:04,120

than a larger academic

medical center would have.

1127

00:54:04,120 --> 00:54:05,890

But likewise, an

academic medical center

1128

00:54:05,890 --> 00:54:08,710

may have some fragmentation

between their primary care

1129

00:54:08,710 --> 00:54:11,000

clinic, maybe even

FQHC and that.

1130

00:54:11,000 --> 00:54:13,030

So one of the things

we just try to do

1131

00:54:13,030 --> 00:54:15,800

is try to just get as

many sources as we can.

1132

00:54:15,800 --> 00:54:16,990

We're not done.

1133

00:54:16,990 --> 00:54:19,060

It's a journey.

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00:54:19,060 --> 00:54:22,570

To my knowledge, we had the

first harmonized multi-vendor

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00:54:22,570 --> 00:54:24,353

national EHR dataset.

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00:54:24,353 --> 00:54:25,270

We've been growing it.

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00:54:25,270 --> 00:54:26,280

We've been plugging holes.

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00:54:26,280 --> 00:54:27,780

And there's still

holes that remain.

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00:54:27,780 --> 00:54:29,340

And we'll just keep going.

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00:54:29,340 --> 00:54:32,088

And so we have

several efforts like--

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00:54:32,088 --> 00:54:33,630

which I didn't talk

about this effort

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00:54:33,630 --> 00:54:36,090

called CLAD, which is testing

a couple different ways

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00:54:36,090 --> 00:54:41,040

to get at other EHR data

as well as claims data.

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00:54:41,040 --> 00:54:44,795

We are working with

other types of ways

1145

00:54:44,795 --> 00:54:47,370

of getting health data without

going into too much detail.

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00:54:47,370 --> 00:54:49,360

We're working on some

national projects.

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00:54:49,360 --> 00:54:53,970

Many of you may know

that there was a--

1148

00:54:53,970 --> 00:54:58,740

NIH director Monica Bertagnolli

has talked a lot about an effort

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00:54:58,740 --> 00:55:02,850

that she's been promoting about

trying to get some more data

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00:55:02,850 --> 00:55:05,920

liquidity across the country,

across different EHR systems.

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00:55:05,920 --> 00:55:07,390

So we're working

on that as well.

1152

00:55:07,390 --> 00:55:10,842

We are hopefully a

great test case for it.

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00:55:10,842 --> 00:55:12,300

So we're working

on all the avenues

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00:55:12,300 --> 00:55:15,510

we can to plug those

holes, as we will continue

1155

00:55:15,510 --> 00:55:16,780

to get better over time.

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00:55:16,780 --> 00:55:19,853

And what I encourage

researchers to do is really

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00:55:19,853 --> 00:55:21,270

think about best

practices, to ask

1158

00:55:21,270 --> 00:55:23,400

the very questions you asked.

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00:55:23,400 --> 00:55:27,100

Are the data less longitudinal

for certain populations

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00:55:27,100 --> 00:55:27,770

than others?

1161

00:55:27,770 --> 00:55:28,640

They are.

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00:55:28,640 --> 00:55:31,460

But they're not always in the

same way as you might expect.

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00:55:31,460 --> 00:55:35,050

So it requires addressing

and thinking about that

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00:55:35,050 --> 00:55:36,913

when you do your analysis.

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00:55:36,913 --> 00:55:39,330

RACHELE PETERSON: Thank you

so much, Josh, for joining us.

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00:55:39,330 --> 00:55:41,550

And thanks to the attendees

and participants as well.

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00:55:41,550 --> 00:55:44,220

And this concludes

our open session.

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00:55:44,220 --> 00:55:45,540

Have a great rest of the day.

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00:55:45,540 --> 00:55:47,350

JOSH DENNY: Thank you.