T1D Exchange

Data Science Committee Meeting

October 2023

Co-chairs: Joyce Lee, Marina Basina

Agenda

- Welcome and introductions- Dr. Lee & Dr. Basina
- Mapped sites and scorecard update- Anton, Maggie, T1D Exchange
- Review data spec change request process map- Emma, T1D Exchange
- Diagnosis stages 1&2 discussion- Dr. Alonso, BDC Peds
- Pregnancy and type 2, pre-conception A1c- Dr. Basina

Mapping Updates

- 32 sites fully mapped (from 31 sites in Q3)
- 4 in validation phase
- Data completeness scorecards
  - Mid-year scorecards have been distributed

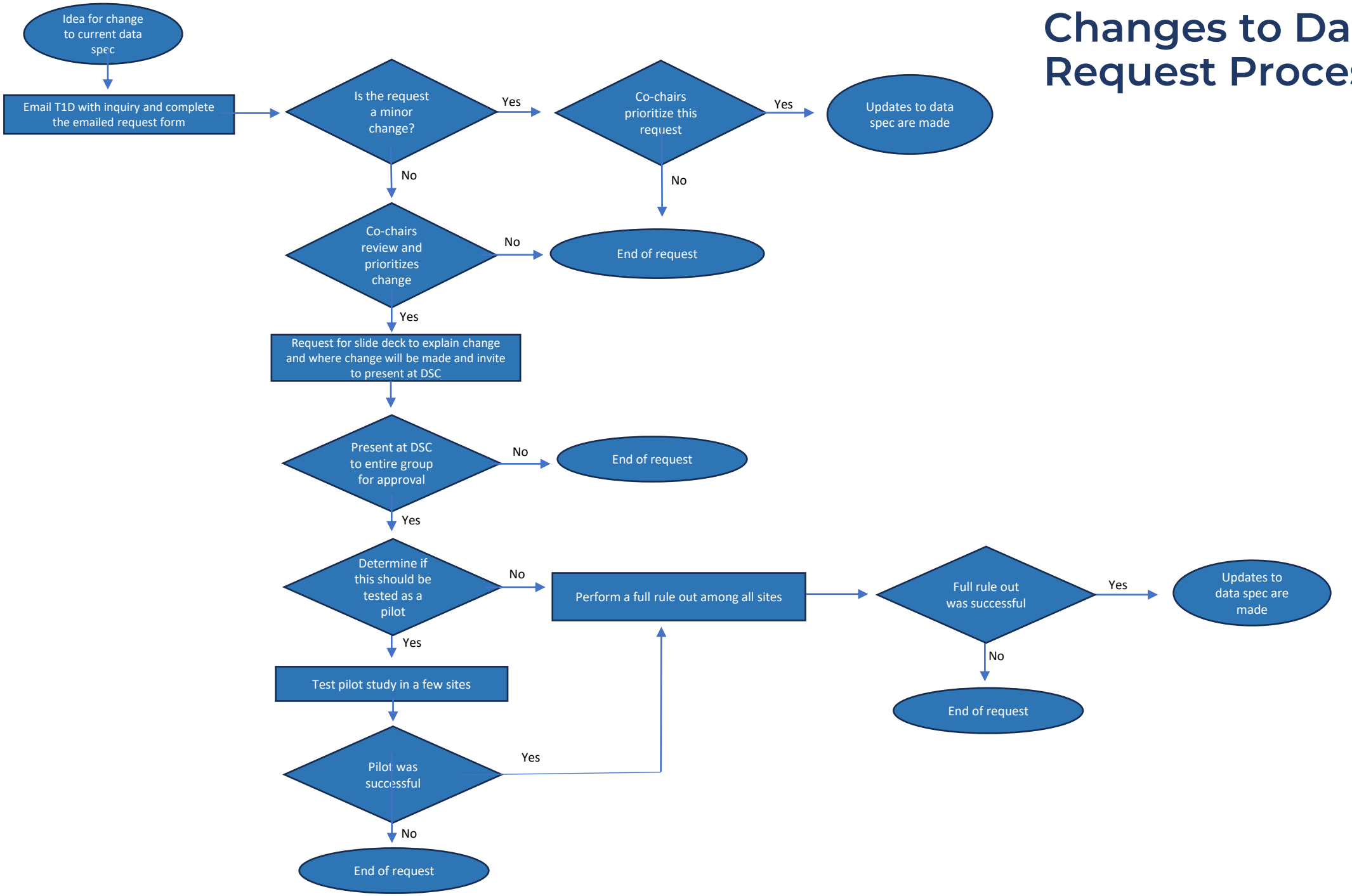
Scorecards

- Variables with yellow for meets mapping expectation need improvement.
- Cgm_st_dt only 54% of sites are providing. Only 49% data availability for collaborative average.
- Pump_st_dt only 54% of sites are providing. Only 39% data availability for collaborative average.
- DKA variables have low data availability (7-15%)for collaborative average.
- SDOH only has 15% of sites providing.

T1Dx Phase 1 Measures	Codes from T1DX data spec	Collaborative Average	% of T1DX sites providing	Meets Mapping Expectations
Demographic data	birth_date	100%	100%	
	t1d_dx_dt	80%	85%	
	Race	98%	100%	
	Ethnicity	100%	100%	
	primary_insurance_type	99%	100%	
	39156-5 (BMI)	93%	92%	
A1c data	4548-4, 17856-6	90%	100%	
CGM Use data	cgm_binary=1	82%	46%	
	cgm_st_dt	49%	54%	
	cgm_company	68%	81%	
	cgm_model	64%	69%	
BG check data	bgm_test_freq	37%	69%	
Pump Use data	ins_regimen=1	49%	73%	
	pump_st_dt	39%	54%	
	pump_company	35%	69%	
	pump_model	34%	77%	
HCLS	ins_pump_delivery==4	26%	31%	
MDI Use data	ins_regimen !=1	45%	73%	
Depression screening data	55758-7, 44261-6	51%	73%	
T1Dx Phase 2 Measures				
Time in Range	time_in_range	55%	50%	
Time in Hypoglycemia	cgm_below_70	61%	35%	
Time in Severe Hypoglycemia	cgm_below_54	47%	23%	
DKA events	dka_events_inp	15%	46%	
	dka_events_amb	8%	42%	
	dka_events_inp_pro	17%	39%	
	dka_events_amb_pro	7%	35%	
Bolus 3X among Pump users	bolus_ins_daily_inj	45%	50%	
SDOH	88124-3, 88122-7, 88123-5	43%	15%	
Change in medication file format				
	drug_name	NA	65%	
	drug_name_generic	NA	54%	
	drug_sub_class	NA	46%	

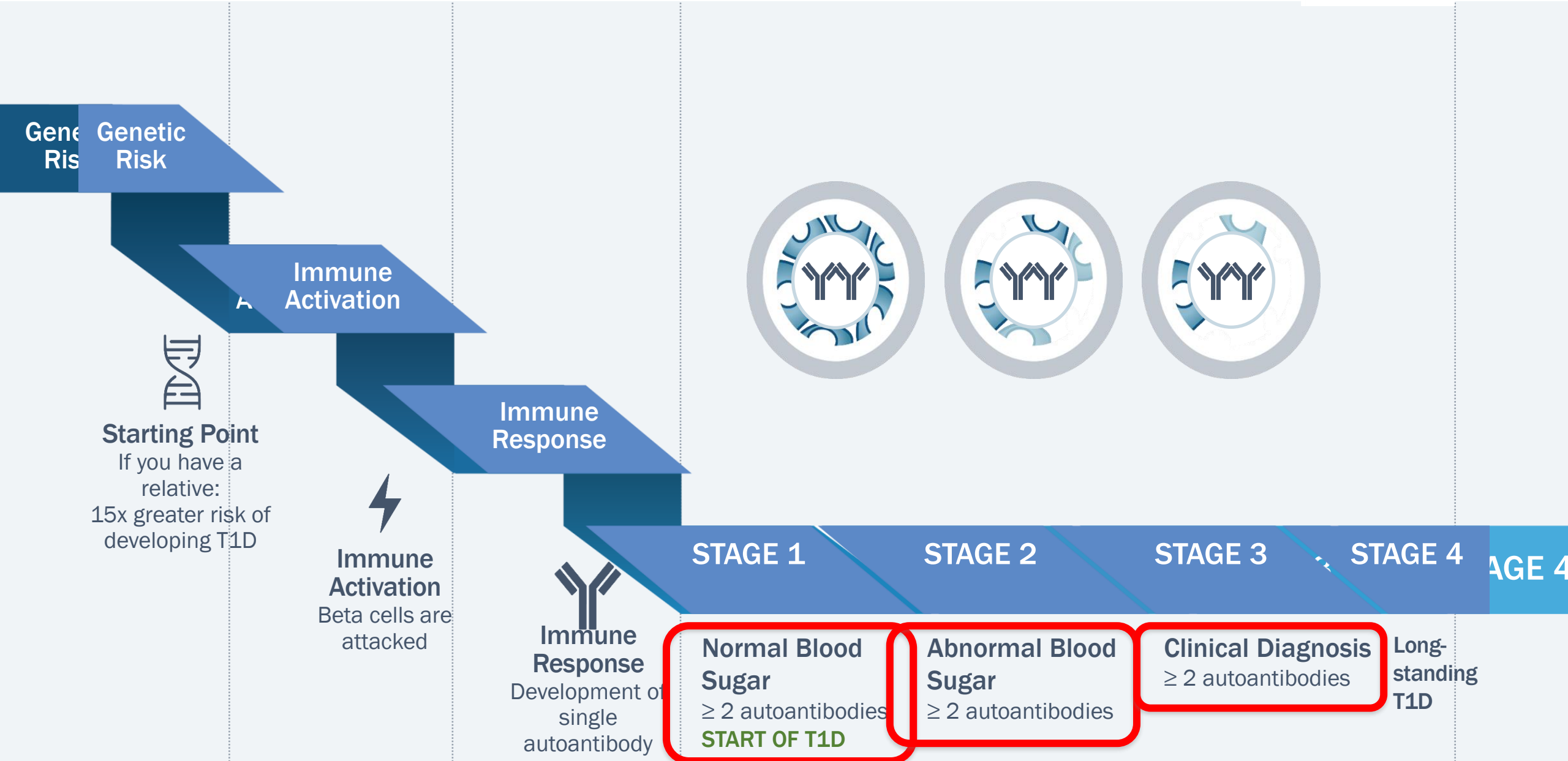
Collaborative Scorecard: Averages based on 26 clinics who received scorecards for data from 7/01/2022-6/30/2023.

Changes to Data Spec Request Process Map

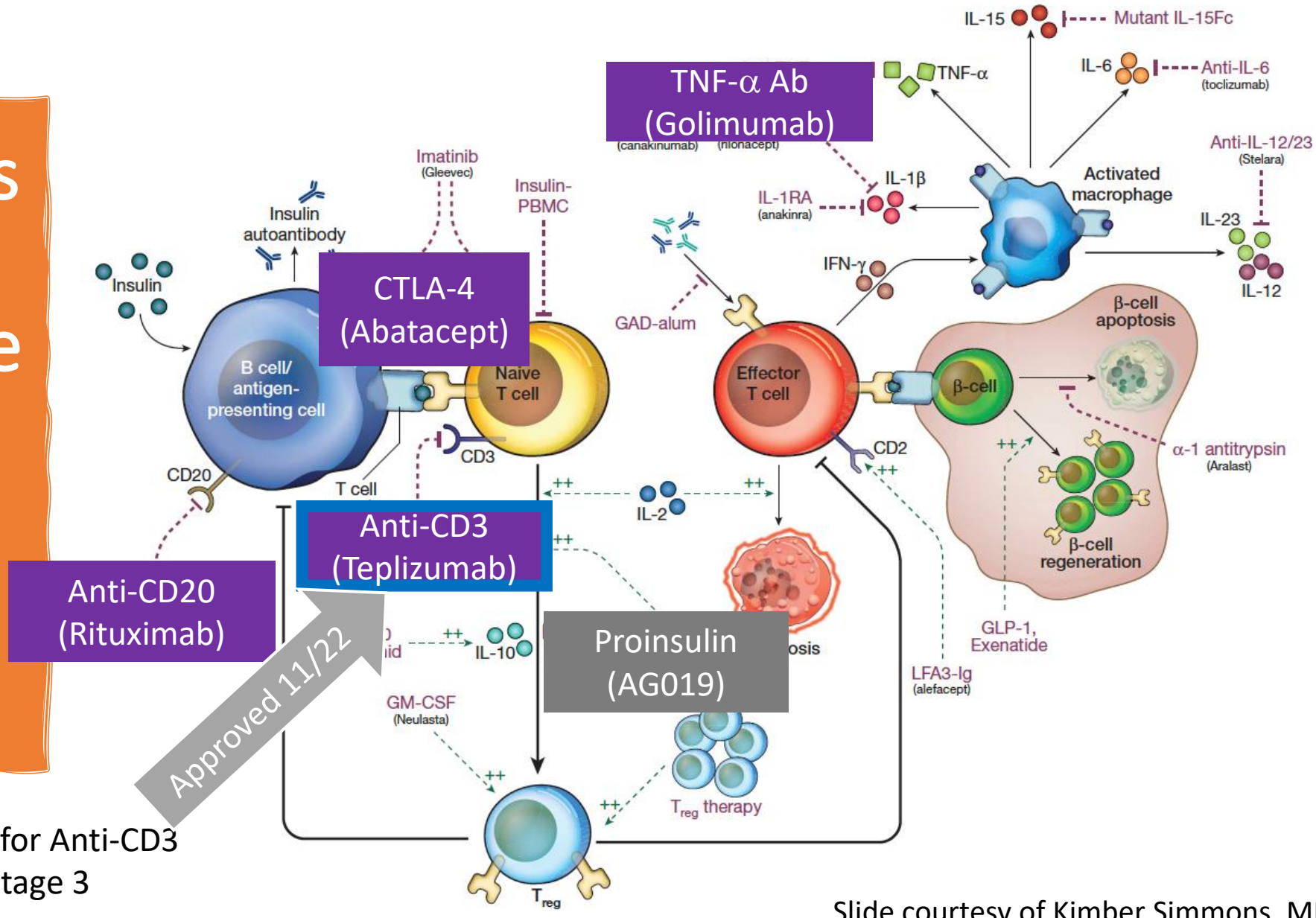


Type 1 diabetes develops in stages.

Type 1 Diabetes TrialNet



New therapies will prevent and delay type 1 diabetes.



Results all in Stage 3 except for Anti-CD3 which is Stage 2 and Stage 3

Slide courtesy of Kimber Simmons, MD MS

Our field is changing.

- Universal screening to identfiy those who may benefit from interventions?
- New ICD-10 codes?
  - Current definition of “Prediabetes” is based on evolution of type 2 diabetes
  - Type 1 diabetes “stage 2” definition is similar but distinct.
- New care models for education and monitoring those with presymptomatic T1D
  - Use of technology (Continuous glucose monitoring - CGM)

tess
THE EARLY START STUDY
FOR PRE-SYMPTOMATIC T1D

Slide courtesy of Brigitte Frohnert MD, PhD

Type 1 diabetes stages

Display Diagnosis Name	ADA status	ICD10 code	ICD10 name	Synonyms	Patient friendly display name
Persistent single high-affinity islet autoantibody	(none)	R76.8	Other specified abnormal immunological findings in serum	Islet autoimmunity to a single autoantigen Single islet autoantibody positive Single type 1 diabetes associated antibody positive	Increased risk of type 1 diabetes
Type 1 diabetes (presymptomatic, stage 1)	Stage 1	R76.8	Other specified abnormal immunological findings in serum	Islet autoimmunity to multiple autoantigens Mulitple islet autoantibody positive Multiple type 1 diabetes associated antibody positive	Very high risk of type 1 diabetes
Type 1 diabetes (presymptomatic, prediabetes, stage 2)	Stage 2	R73.03	Prediabetes	Islet autoimmunity and dysglycemia Prediabetes with islet autoimmunity Type 1 diabetes autoimmunity and dysglycemia	Early type 1 diabetes

New IMO codes (2022)

CHCO Custom Text	CHCO code	New IMO text	New IMO Code
Persistent single high-affinity islet autoantibody	2120001	Persistent single high-affinity islet autoantibody	1676360
Type 1 diabetes (presymptomatic, stage 1)	2120002	Stage 1 presymptomatic normoglycemic type 1 prediabetes	1676361
with synonym term of "stage 1 type 1 prediabetes"		Stage 1 type 1 prediabetes	1676370
Type 1 diabetes (presymptomatic, prediabetes, stage 2)	2120003	Stage 2 presymptomatic dysglycemic type 1 prediabetes	1676362
with synonym term of "stage 2 type 1 prediabetes"		Stage 2 type 1 prediabetes	1676371

DM 2, PREGNANCY, PRECONCEPTION

Introduction

- Pre-gestational DM in 1-2% of pregnancies
- DM 2 in 30-50% of the pregnancies
- ***Risks for mothers***: miscarriage, preeclampsia, gestational hypertension, maternal birth trauma, and caesarean delivery, preterm delivery (<37 weeks) x 4 times more often than in non-DM,
- ***Neonates***: LGA (birth trauma), hypertrophic cardiomyopathy, neonatal respiratory problems, and metabolic complications (hypoglycaemia, hyperbilirubinemia, hypocalcaemia, and polycythaemia).
- Lower DM duration and A1C comparing to T1D – risk of complications is the same as in T1D
- **Possible explanations**:
- Increased prevalence of obesity, hypertension and the metabolic syndrome
- Higher rate of perinatal mortality,
- Offspring of mothers with T2DM are also at increased risk for metabolic complications (such as T2DM and obesity) later in life

Stats

1. Despite the beneficial effects of preconception care, women with T2DM are less likely to follow preconception programs compared to women with T1DM (32% vs. 54% with T1DM), which is a missed opportunity to improve pregnancy outcomes.
2. Incidence of congenital malformations is linearly associated with increasing HbA1c values in early pregnancy
3. Glycaemic control should be optimized before conception.
4. Studies showed a risk reduction of congenital malformations by 71% and reduction of the perinatal mortality risk by 54% with improved glycemic control pre-conception
5. Pre-pregnancy care was associated with a reduction in preterm delivery rate of 15%, a risk reduction of 48% for small-for-gestational age (SGA) infants and a risk reduction of 25% for neonatal intensive care unit (NICU) admissions

(Wahabi et al. Systematic review and meta-analysis of the effectiveness of pre-pregnancy care for women with diabetes for improving maternal and perinatal outcomes. PloS One (2020))

Stats (cont)

- The National Institute for Health and Care Excellence (NICE) and the American Diabetes Association (ADA) guidelines advise therefore to aim for HbA1c values < 6,5%

- Women with T2DM are therefore in generally advised not to get pregnant until the HbA1c value is <7.0% because of the associated risks for congenital malformations, LGA, SGA, preterm deliveries and NICU admissions

Committee ADAPP. 15. Management of Diabetes in Pregnancy: Standards of Medical Care in Diabetes—2022. Diabetes Care (2022) 45:S232–S43; National Institute for Health and Care Excellence: Guidelines. Diabetes in pregnancy: management from preconception to the postnatal period Vol. 2020 London: National Institute for Health and Care Excellence (NICE (2020).

Stanford Data

- **Question**
- How many women aged 18-45 years, who have been diagnosed with T2D and have been on multiple daily injections of insulin
- treatment for a minimum of 6 months, are being followed in the Stanford outpatient clinics?
- **Summary**
- We identified 812 female patients between ages 18-45 years old with a history of type II diabetes during an office visit.
- They also had continuous insulin for at least 6 months any time after this office visit.
- The average age was 34.5 years old and the overall comorbidity score of this cohort was 2.9.
- Within 3 months of the inclusion date, 39.9% of the cohort was also on metformin.
- The baseline a1c was 8.5, and the average a1c within 6 months after inclusion was 7.8%.
- **Conclusions**
- In female patients aged 18-45 years old with type II diabetes and insulin use, the average a1c within 6 months was 7.8 and 40% of the cohort was taking metformin.

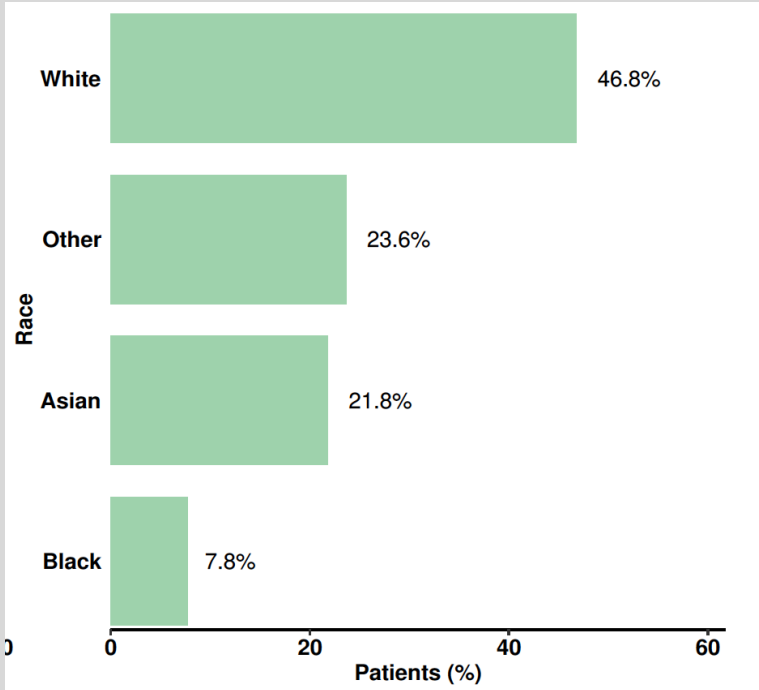
Population	Female Adults Age 18-45 History of type II Diabetes, at an outpatient visit Start of insulin anytime after this visit (duration of at least 6 months)
Intervention	Case series

Outcome	baseline a1c outcome a1c within 6 months metformin +/- 3 months of inclusion time, as surrogate of co-administered metformin with insulin
Timeframe	2010-2023

Baseline (sd or %)	
Baseline A1c	8.5 (2.3)
Outcomes (sd or %)	
Metformin Within 3 Months	324 (39.9%)
Outcome A1c 6 Mo	7.82 (1.96)

Demographic Table

	COHORT
N	**812**
Female (%)	812 (100%)
Mean age (sd)	34.5 (7)
<18 yr	0 (0%)
18-29 yr	215 (26.5%)
30-39 yr	387 (47.7%)
40-49 yr	210 (25.9%)
50-59 yr	0 (0%)
60-69 yr	0 (0%)
70-79 yr	0 (0%)
80-89 yr	0 (0%)
>=90 yr	0 (0%)
Race (%)	
White	380 (46.8%)
Other	192 (23.6%)
Asian	177 (21.8%)
Black	63 (7.8%)
Hispanic (%)	232 (28.6%)



Comorbidity score (sd)	**2.9 (2.5)**
Malignancy	61 (7.51%)
Metastatic Solid Tumor	19 (2.34%)
Diabetes	806 (99.26%)
Diabetes with Complications	269 (33.13%)
Congestive Heart Failure	74 (9.11%)
Myocardial Infarction	29 (3.57%)
Peripheral Vascular Disease	25 (3.08%)
Chronic Pulmonary Disease	183 (22.54%)
Cerebrovascular Disease	34 (4.19%)
Dementia	2 (0.25%)
Hemiparaplegia	16 (1.97%)
Mild Liver Disease	152 (18.72%)
Severe Liver Disease	19 (2.34%)
Renal Disease	98 (12.07%)
Peptic Ulcer Disease	11 (1.35%)
Rheumatic Disease	21 (2.59%)
Hiv	1 (0.12%)