SID e AMD Lombardia

LA TECNOLOGIA – oggi e domani

Grande Ospedale Metropolitano Niguarda, Milano, 7 Giugno 2025

Screening e predizione del diabete di tipo 1

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Non c'è cura, senza ricerca.

Diabetes Research Institute

UniSR

Università Vita-Salute San Raffaele

Disclosures

Emanuele Bosi

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Abbott

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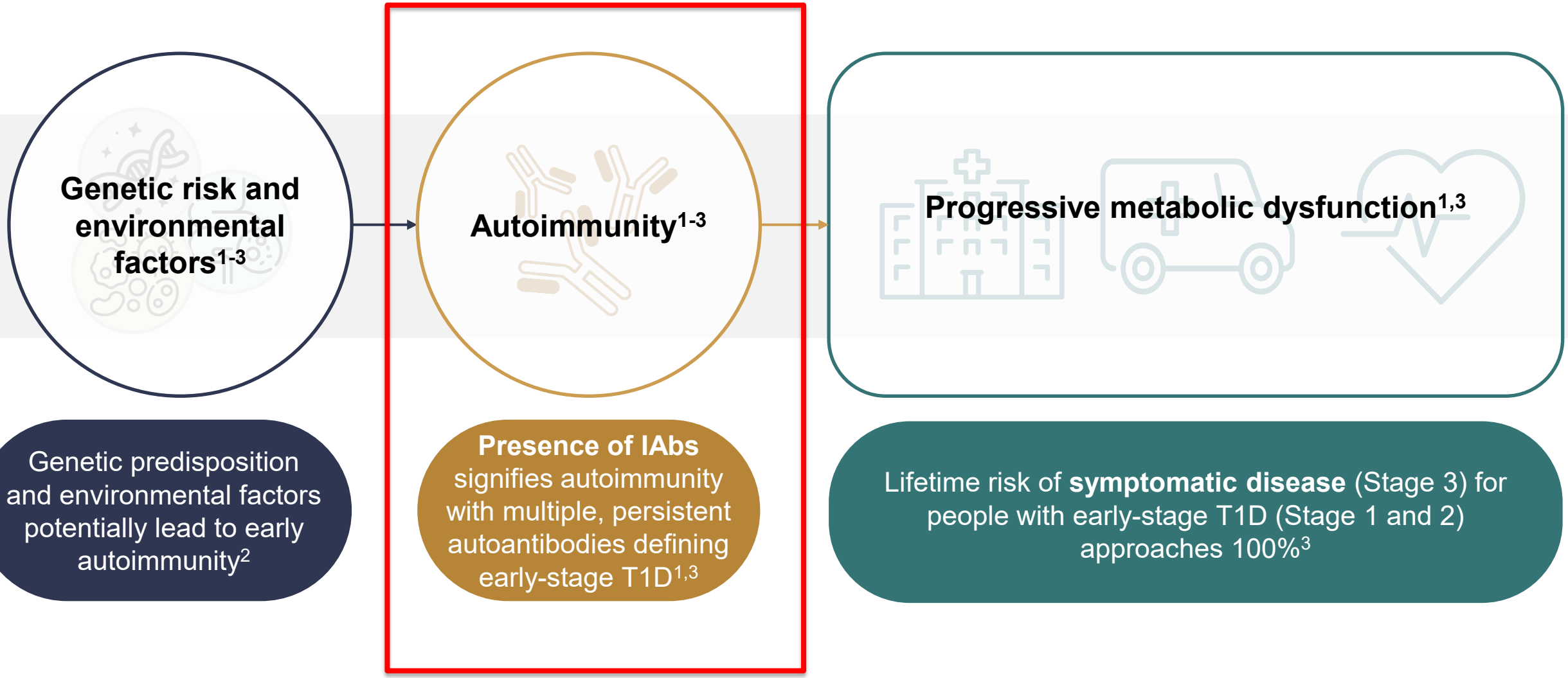
Medtronic

Roche

Sanofi

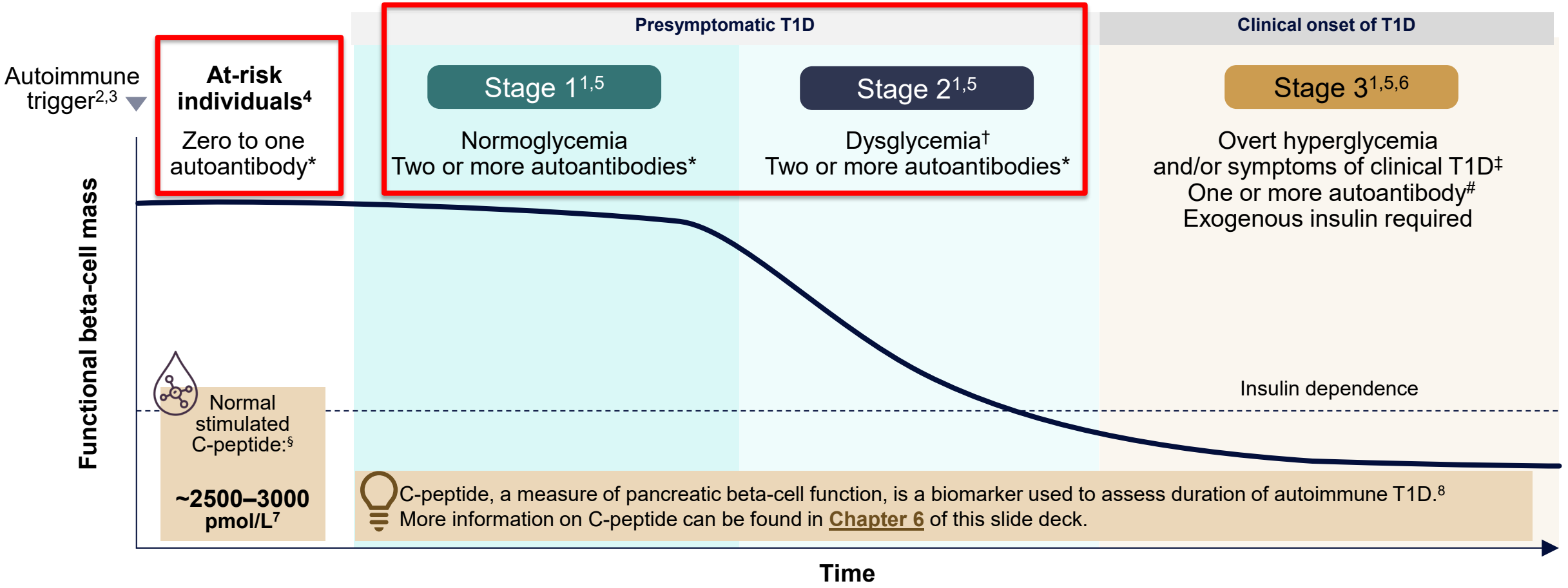
Autoimmune Type 1 diabetes Is a Continuum from Genetic Risk and Environmental Factors to Autoimmunity and Ultimately, Metabolic Disease[1]



IAb, islet autoantibody; T1D, type 1 diabetes.

1. Phillip M, et al. Diabetes Care. 2024;47(8):1276-98. 2. Primavera M, et al. Front Endocrinol (Lausanne). 2020;11:248. 3. Insel RA, et al. Diabetes Care. 2015;38(10):1964-74.

Following Immune Activation, Autoimmune T1D Progresses in Three Distinct Stages[1]

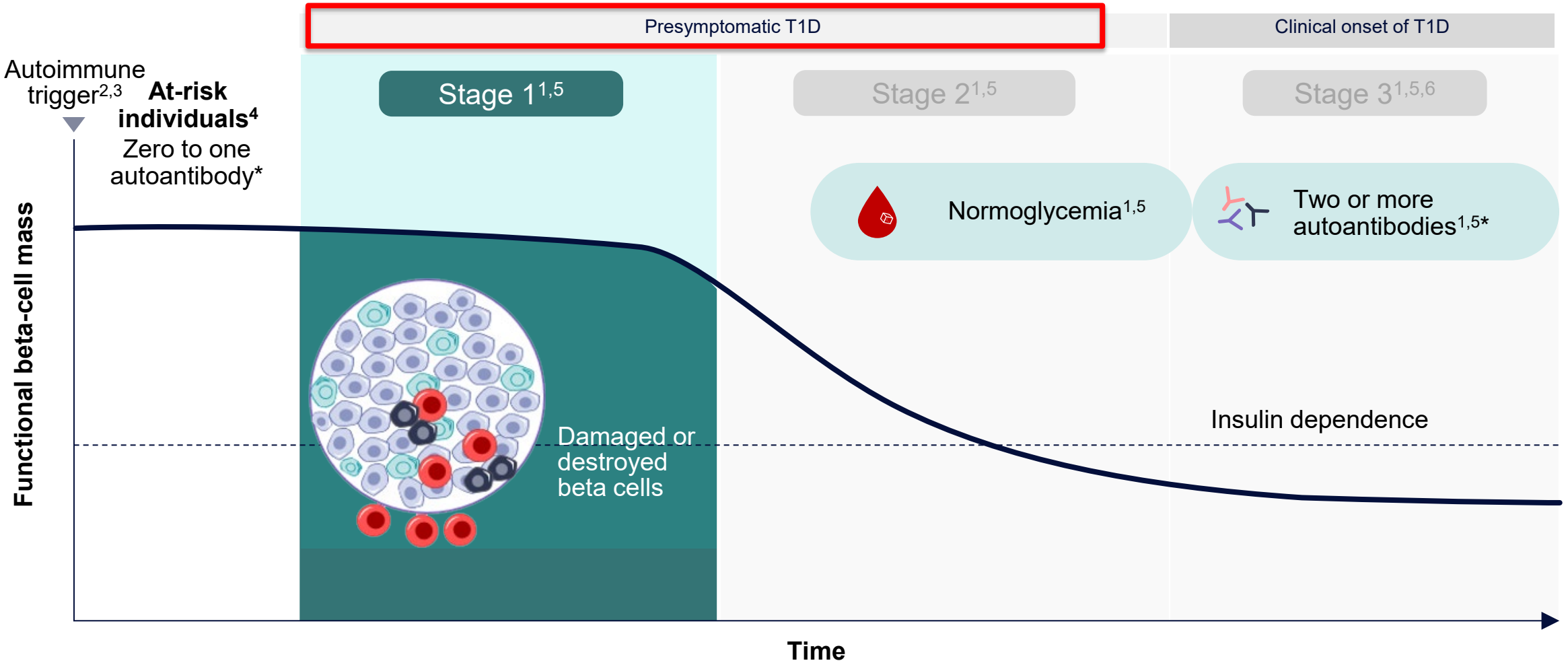


*Autoantibodies to beta-cell autoantigens (insulin, GAD, IA-2, ZnT8) or ICA.[1,5,9] †FPG of 100 to 125 mg/dl, 2-hour PG during OGTT of 140 to 199 mg/dl, HbA1c of 5.7% to 6.4% (39–47 mmol/mol), or ≥10% increase in HbA1c is observed.[5] ‡Common symptoms include polydipsia, polyuria, fatigue, and weight loss.[1] #Some patients who develop Stage 3 T1D may only have single autoantibody positivity,[10] or autoantibodies may become absent.[5] §Variability between C-peptide tests primarily derives from the physiological differences between fasting, random or stimulated C-peptide.[11]

FPG, fasting plasma glucose; GAD, glutamic acid decarboxylase; HbA1c, glycosylated hemoglobin; IA-2, insulinoma-associated antigen-2; ICA, islet cell cytoplasmic autoantibody; OGTT, oral glucose tolerance test; PG, plasma glucose; T1D, type 1 diabetes; ZnT8, zinc transporter 8.

1. Insel RA, et al. Diabetes Care. 2015;38(10):1964-74. 2. DiMeglio LA, et al. Lancet. 2018;391(10138):2449-62. 3. Buzzetti R, et al. Nat Rev Dis Primers. 2022;8(1):63. 4. Philip M, et al. Diabetologia. 2024;67:1731-59. 5. ADA Professional Practice Committee. Diabetes Care. 2024;47:S20-42. 6. Redondo MJ, et al. Diabetes Care. 2018;41(2):311-7. 7. Galderisi A, et al. J Clin Endocrinol Metab. 2021;106(9):2660-69. 8. Leighton E, et al. Diabetes Ther. 2017;8(3):475-87. 9. Peters A. J Fam Pract. 2021;70(6S):S47-52. 10. Redondo MJ, et al. J Clin Endocrinol Metab. 2020;105(5):1629-40.11. Maddaloni E, et al. Diabetes Obes Metab. 2022;24(10):1912-26.

Stage 1 Is Characterized by Two or more Islet Autoantibodies and Normal Blood Glucose[1-4]



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GAD, glutamic acid decarboxylase; IA-2, insulinoma-associated antigen-2; ICA, islet cell cytoplasmic autoantibody; T1D, type 1 diabetes; ZnT8, zinc transporter 8.

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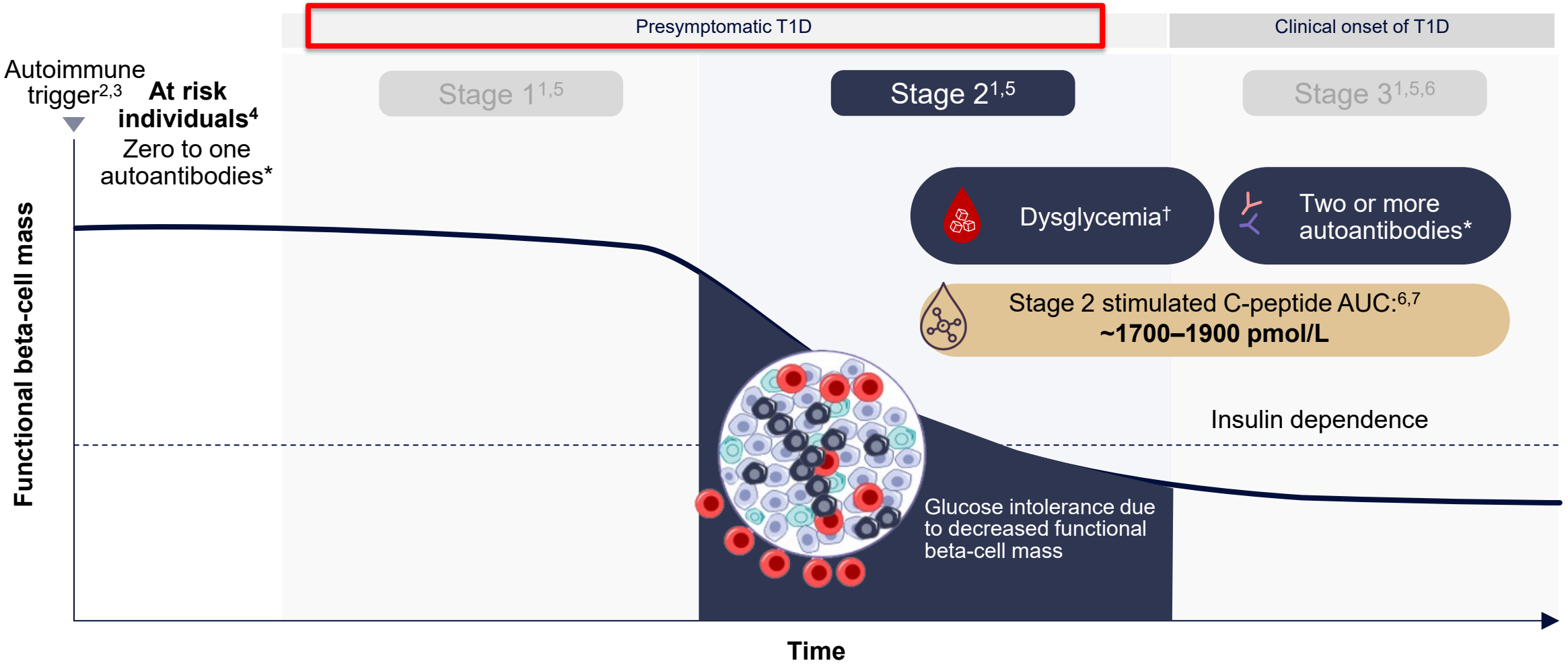
Stage 2 Is Characterized by Two or more Islet Autoantibodies and Dysglycemia[1-5]

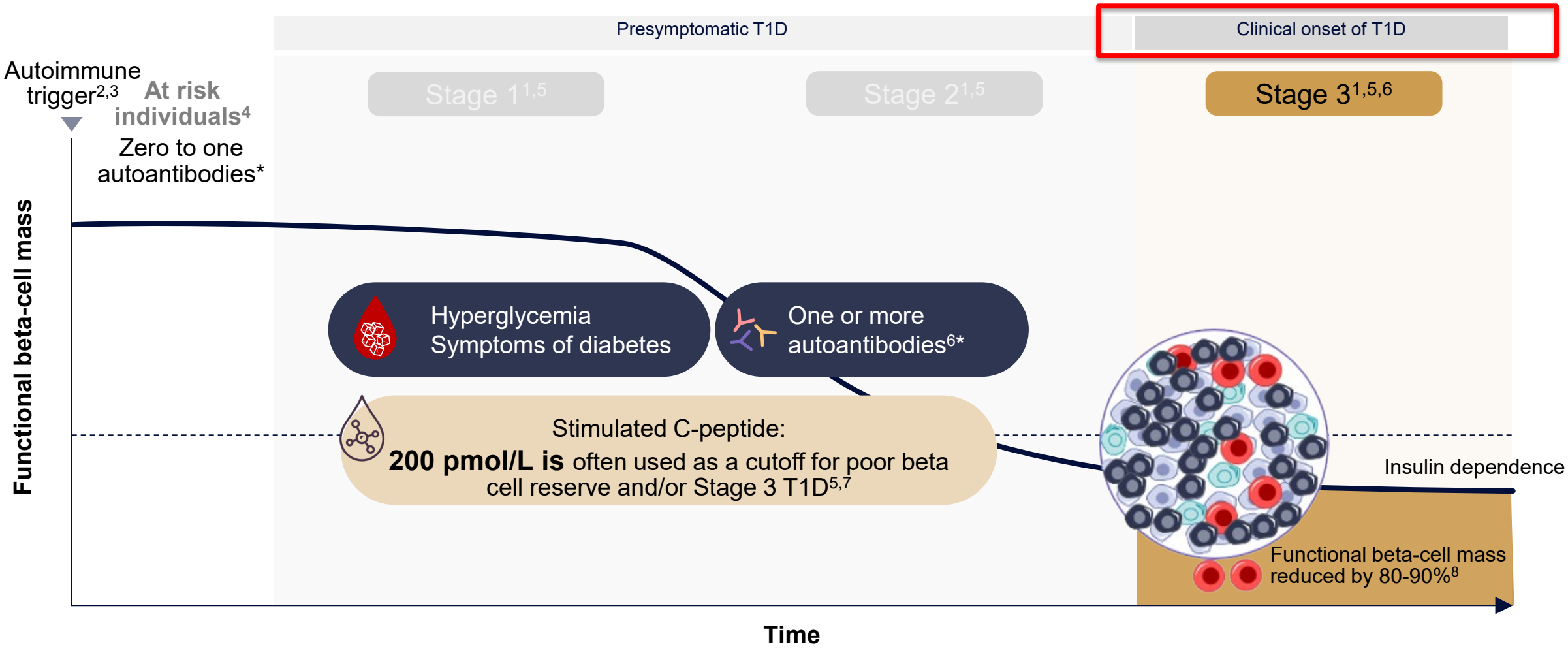


*Autoantibodies to beta cell autoantigens (insulin, GAD, IA-2, ZnT8) or ICA.[1,5,8] †FPG of 100 to 125 mg/dl, 2-hour PG during OGTT of 140 to 199 mg/dl, HbA1c of 5.7% to 6.4% (39–47 mmol/mol), or ≥10% increase in HbA1c is observed.[5]

AUC, area under curve; FPG, fasting plasma glucose; GAD, glutamic acid decarboxylase; HbA1c, glycosylated hemoglobin; IA-2, insulinoma-associated antigen-2; ICA, islet cell cytoplasmic autoantibody; OGTT, oral glucose tolerance test; PG, plasma glucose; T1D, type 1 diabetes; ZnT8, zinc transporter 8.

1. Insel RA, et al. Diabetes Care. 2015;38(10):1964-74. 2. DiMeglio LA, et al. Lancet. 2018;391(10138):2449-62. 3. Buzzetti R, et al. Nat Rev Dis Primers. 2022;8(1):63. 4. Philip M, et al. Diabetologia. 2024;67:1731-59. 5. ADA Professional Practice Committee. Diabetes Care. 2024;47:S20-42. 6. Sims EK, et al. Sci Transl Med. 2021;13(583):eabc8980. 7. Sims EK, et al. Sci Transl Med. 2021;13(583):eabc8980. Supplement. 8. Peters A. J Fam Pract. 2021;70(6S):S47-52.

Stage 3 Corresponds with Hyperglycemia and the Onset of Symptomatic Disease[1]



*Autoantibodies to beta cell autoantigens (insulin, GAD, IA-2, ZnT8) or ICA.[1,5,9] ~15% of the National Institutes of Health-sponsored Type 1 Diabetes TrialNet Pathway to Prevention participants who develop T1D have single autoantibody positivity at diagnosis.[10]

GAD, glutamic acid decarboxylase; IA-2, insulinoma-associated antigen-2; ICA, islet cell cytoplasmic autoantibody; T1D, type 1 diabetes; ZnT8, zinc transporter 8.

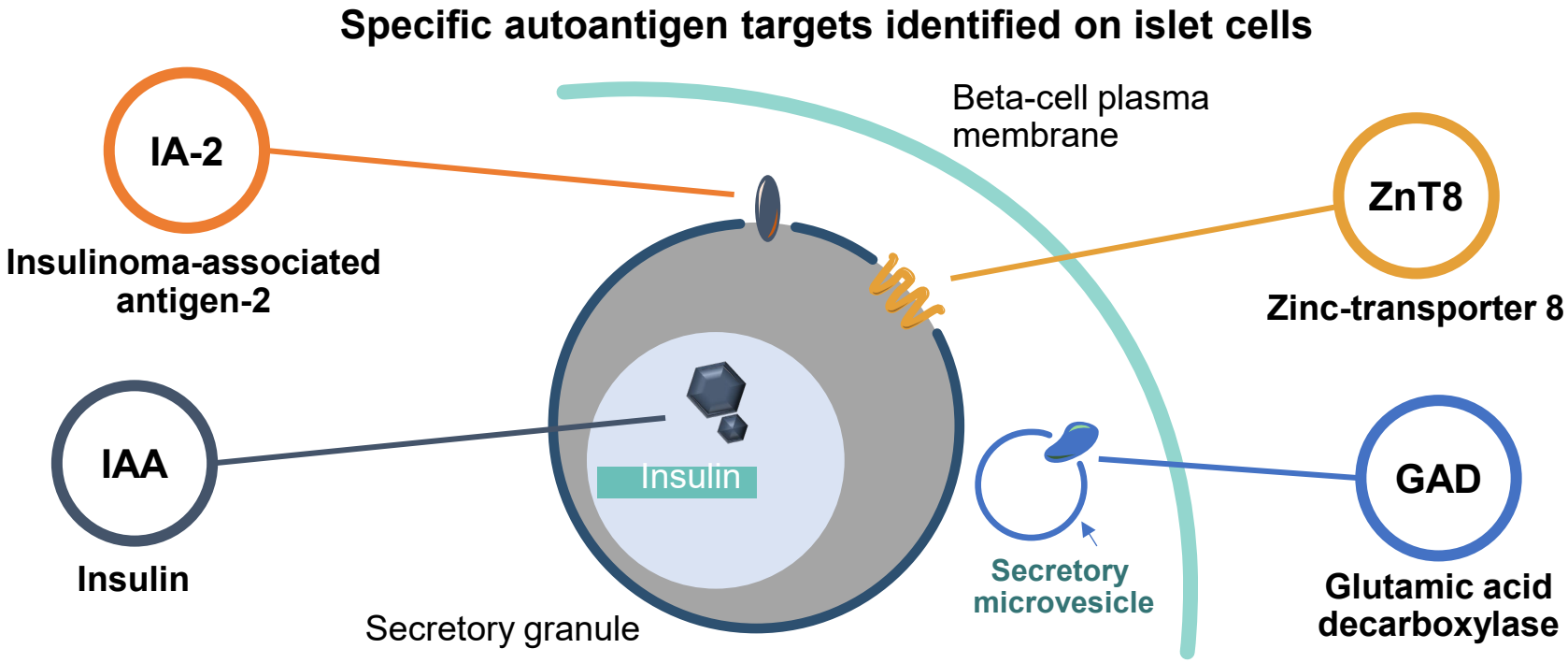
1. Insel RA, et al. Diabetes Care. 2015;38(10):1964-74. 2. DiMeglio LA, et al. Lancet. 2018;391(10138):2449-62. 3. Buzzetti R, et al. Nat Rev Dis Primers. 2022;8(1):63. 4. Philip M, et al. Diabetologia. 2024;67:1731-59. 5. ADA Professional Practice Committee. Diabetes Care. 2024;47:S20-S42. 6. Redondo MJ, et al. Diabetes Care. 2018;41(2):311-7. 7. Leighton E, et al. Diabetes Ther. 2017;8(3):475-87. 8. Meier JJ. Diabetologia 2008;51:703–13. 9. Peters A. J Fam Pract. 2021;70(6S):S47-52. 10. Redondo MJ, et al. J Clin Endocrinol Metab. 2020;105(5):1629-40.

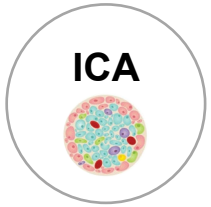
HOW DO WE FIND PEOPLE IN EARLY STAGES of T1D?

By islet autoantibody screening

Prevalence of T1D amongst the general population is ~0.3% by age 20

ISLET AUTO-ANTIBODIES (IAb) and T1D



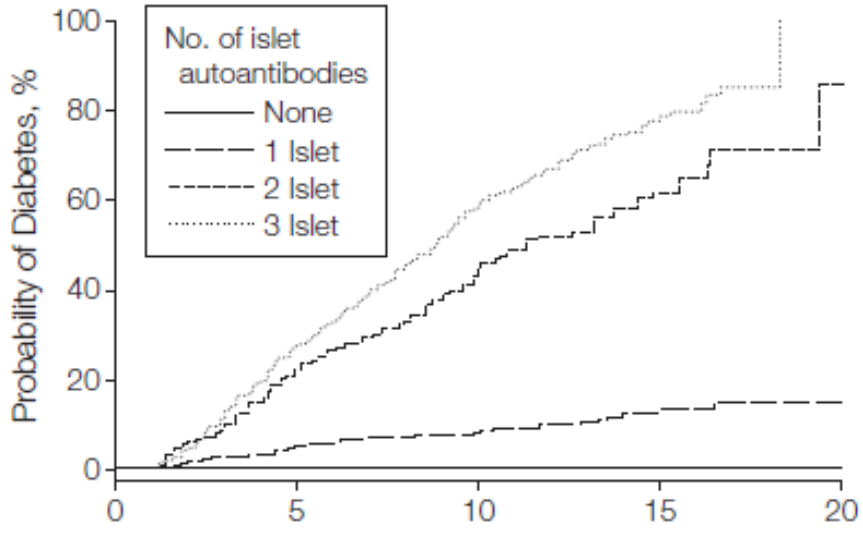


Islet Cell Cytoplasmatic Autoantibodies (ICAs) are not generally used for screening as they lack specificity and are technically challenging to detect

The presence of ≥2 confirmed IAb identifies people with autoimmunity, many of whom may be **presymptomatic** (Stages 1 and 2)

Increased incidence of type 1 diabetes is associated with increased number of autoantibodies in children screened both in families and in the general population

Figure 1. Development of Diabetes in Children Stratified for Islet Autoantibody Outcome



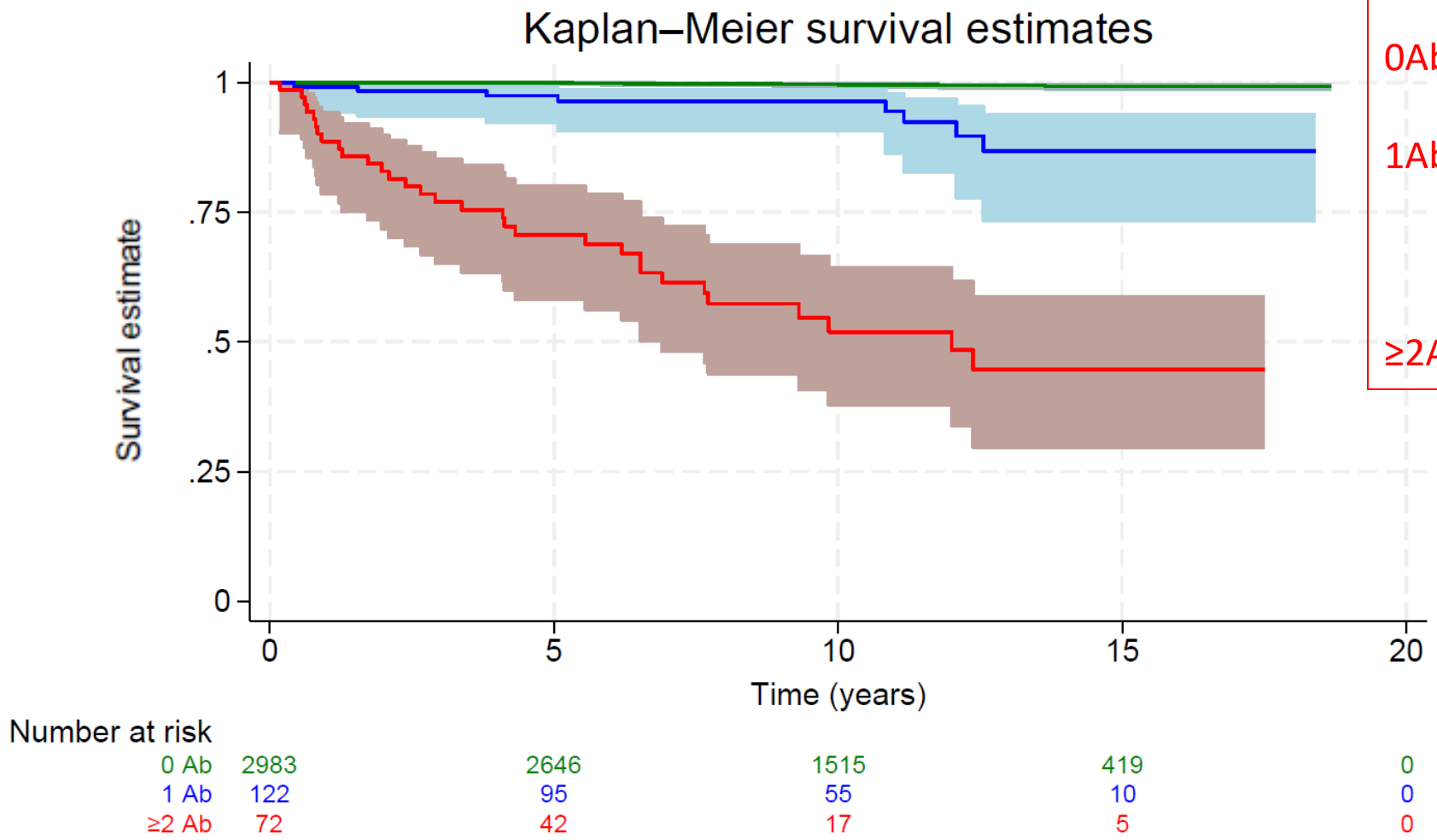
No. at risk Islet autoantibodies, No.					
3 Islet	358	250	112	20	
2 Islet	227	168	82	19	1
1 Islet	474	430	272	118	9
None	12318	8875	5253	1161	44

The numbers at risk represent the children receiving follow-up at age 0, 5, 10, 15, and 20 years.

Ziegler AG et al. JAMA. 2013;309(23):2473-2479

San Raffaele TrialNet Center 2003-2024
Survival free of stage 3 type 1 diabetes after the first autoantibody screening test.

Green line, autoantibody-negative; blue line, positive for a single autoantibody; red, positive for ≥2 autoantibodies



Survival free of clinical diabetes at 15 years:

0Ab: 99.5%

1Ab: 87.3%

≥2Ab: 45.9%

Martinenghi S et al. Diabetologia. 2025 May 29. Epub ahead of print.

Accurate prediction by islet autoantibodies both in families and in the general population

Risk for future type 1 diabetes according to autoantibody status (anti-GAD, anti-insulin, anti-IA2, anti-ZnT8)

- No autoantibodies: risk 0
- 1 autoantibody: risk 10-20% in 10 years
- ≥ 2autoantibodies: risk > 80% in 10 years (almost certainty of progression to clinical diabetes, at least in children and adolescents)

Rational for screening of type 1 diabetes (T1D) in the general population

Studies in families established islet autoantibody screening as highly predictive of T1D;

However, most people developing T1D (95%) have no family history, therefore disease burden reduction at the public health level requires screening in the general population;

Pre-symptomatic type 1 diabetes is similar in relatives and in the general population;

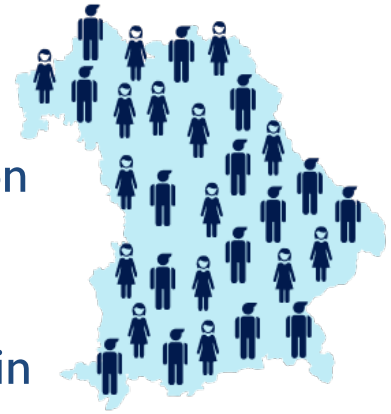
Therefore, islet autoantibodies can be used for screening in the general population as well.

Is T1D autoantibody screening in general population feasible?

The Fr1da model

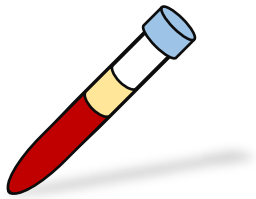
Fr1da

Typ 1 Diabetes: Früh erkennen – Früh gut behandeln



In cooperation with > 600 primary care pediatricians in Bavaria, Germany

Capillary blood



Since 2015:
160,631 participants;
Age 1.75 – 10.99 years

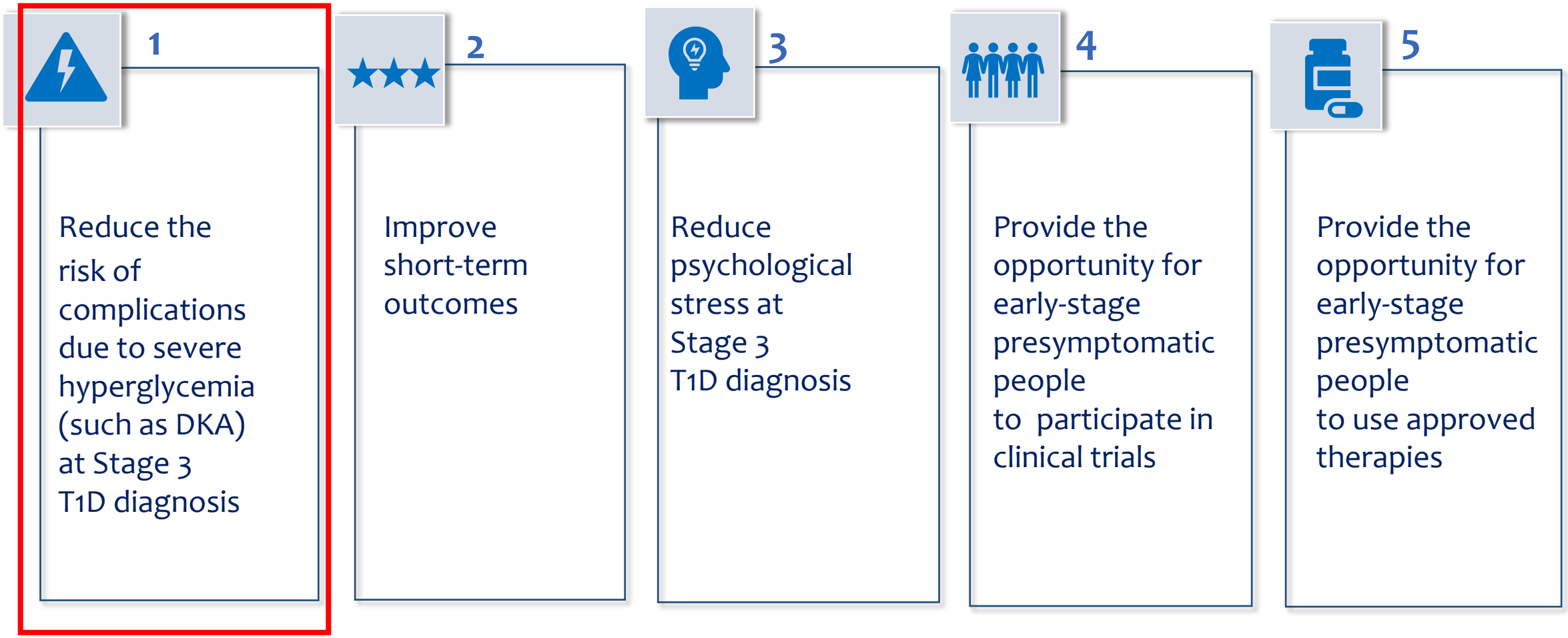
461 children (**0.3** %) with multiple islet autoantibodies

T1D
Stage 1 (0.19%)
Stage 2 (0.019%)
Stage 3 (0.027%)

Ziegler, JAMA 2020;
Raab, BMJ open 2016
Ziegler, Diabetes Technol Ther 2016

Courtesy of A. Ziegler

WHY SHOULD PEOPLE PARTICIPATE IN SCREENING PROGRAMS?



ISPAD Guidelines 2024. Horm Res Paediatr. 2024;97(6):529-545

Prevention of diabetic ketoacidosis in relatives screened for islet autoantibodies and followed up in the TrialNet Pathway to Prevention study at a single institution in Italy

Population

4046 Italian relatives of T1D patients

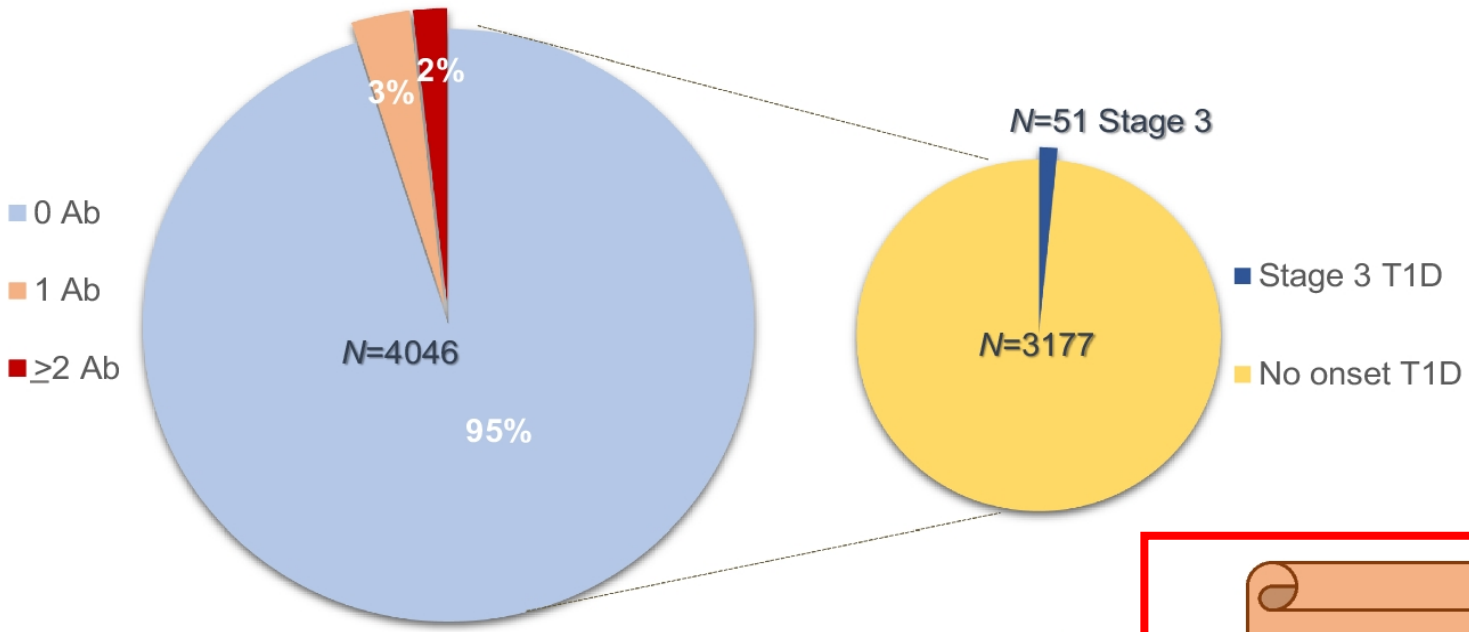
Purpose?

Identification of people at risk of T1D for DKA prevention

Methods

- Ab testing
- Metabolic screening
- Phone recall

~ 20 years of follow-up
July 2005–June 2024



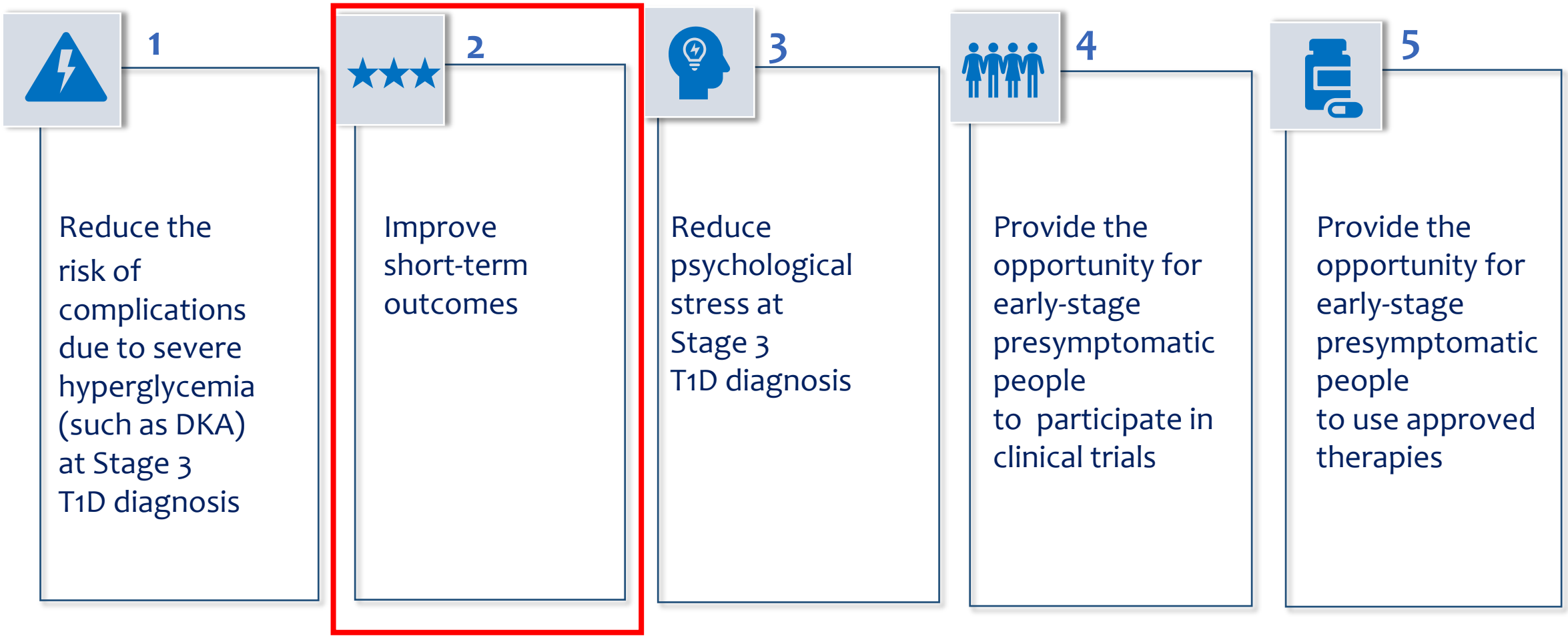
	Overall	0 Ab	1 Ab	≥2 Ab
T1D events, *n*	51	12	8	31
Time to onset (years), median (IQR)	5.1 (1.8-8.9)	7.8 (5.4-10.4)	7.9 (2.1-11.8)	2.9 (0.9-6.5)
Adults at onset, *n* (%)	16 (31.4)	4 (33.3)	4 (50.0)	8 (25.8)
Adults at first screening, *n* (%)	10 (19.6)	2 (16.7)	2 (25.0)	6 (19.4)
HbA_{1c} (mmol/mol) at onset, median (IQR)	64 (52-86)	79 (52-86)	74 (61-86)	62 (52-69)

Ab autoantibodies; DKA diabetic ketoacidosis; T1D type 1 diabetes

0 incidence of DKA at stage 3 T1D

Martinenghi S et al. Diabetologia. 2025 May 29. Epub ahead of print.

WHY SHOULD PEOPLE PARTICIPATE IN SCREENING PROGRAMS?



ISPAD Guidelines 2024. Horm Res Paediatr. 2024;97(6):529-545

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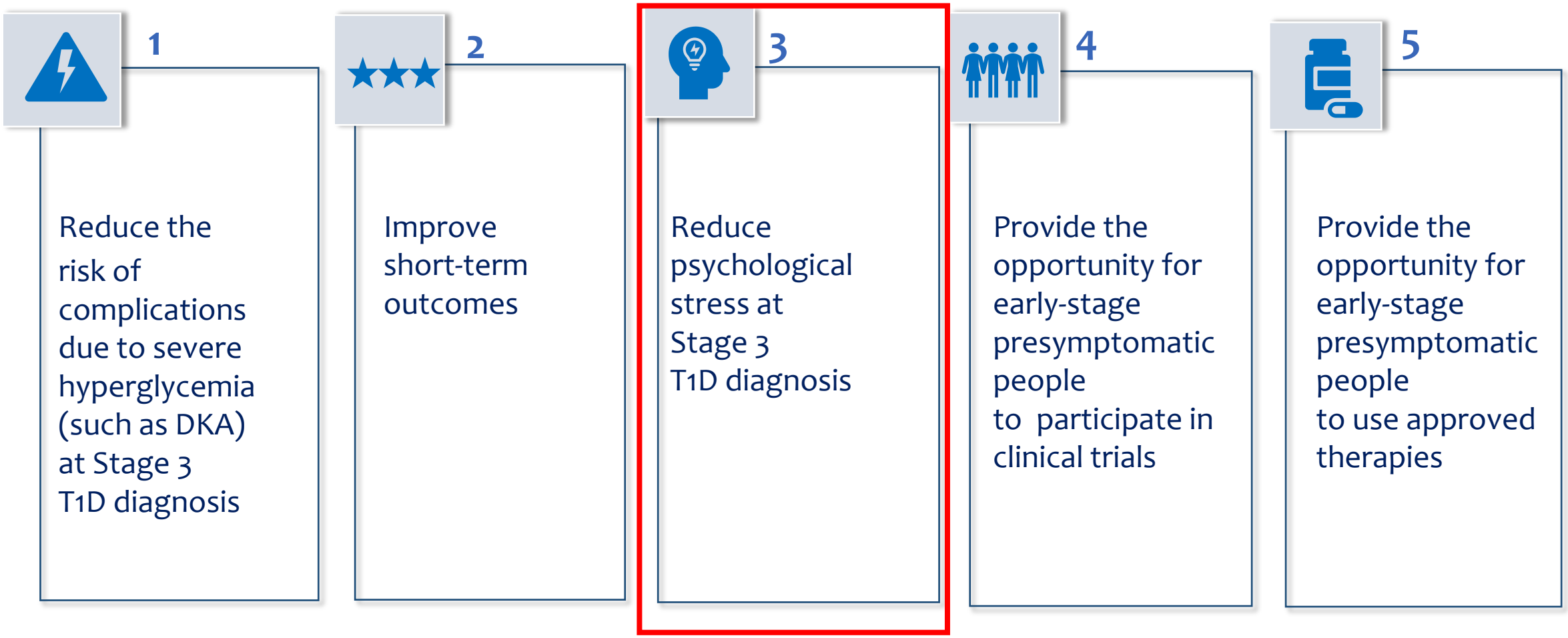

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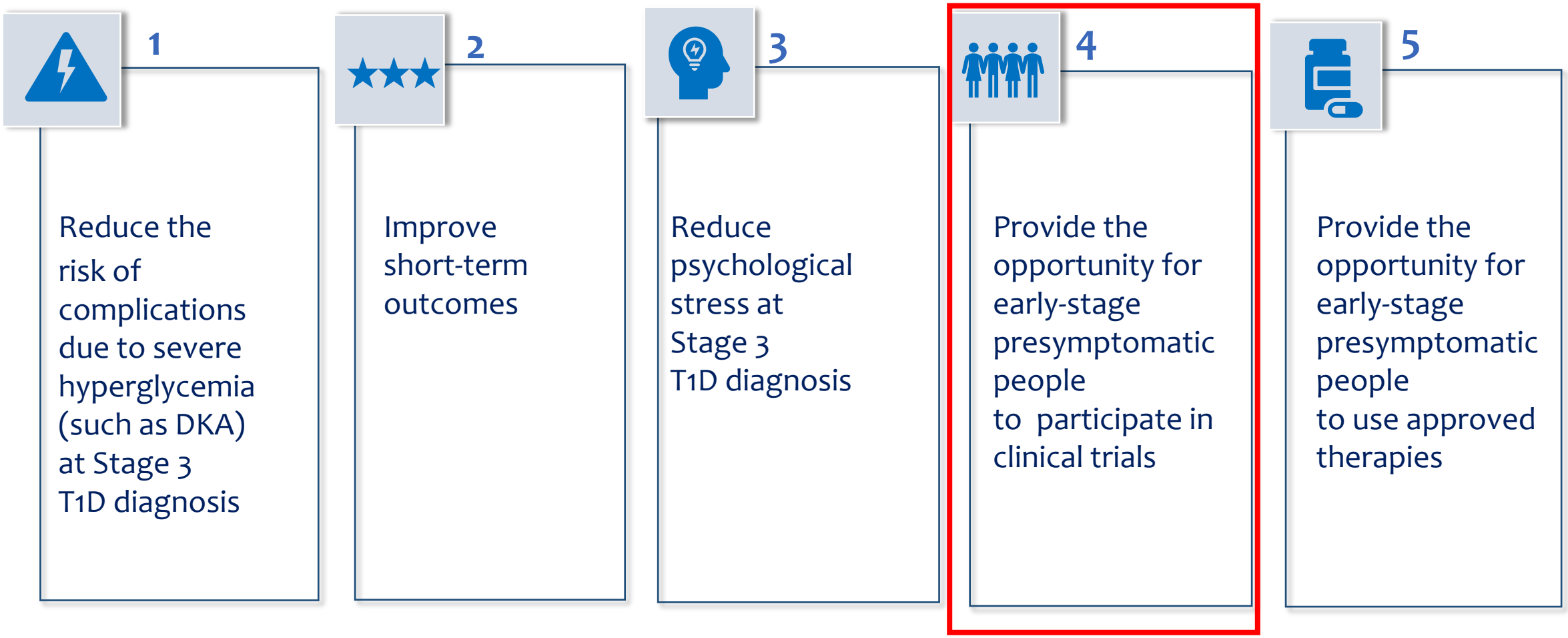

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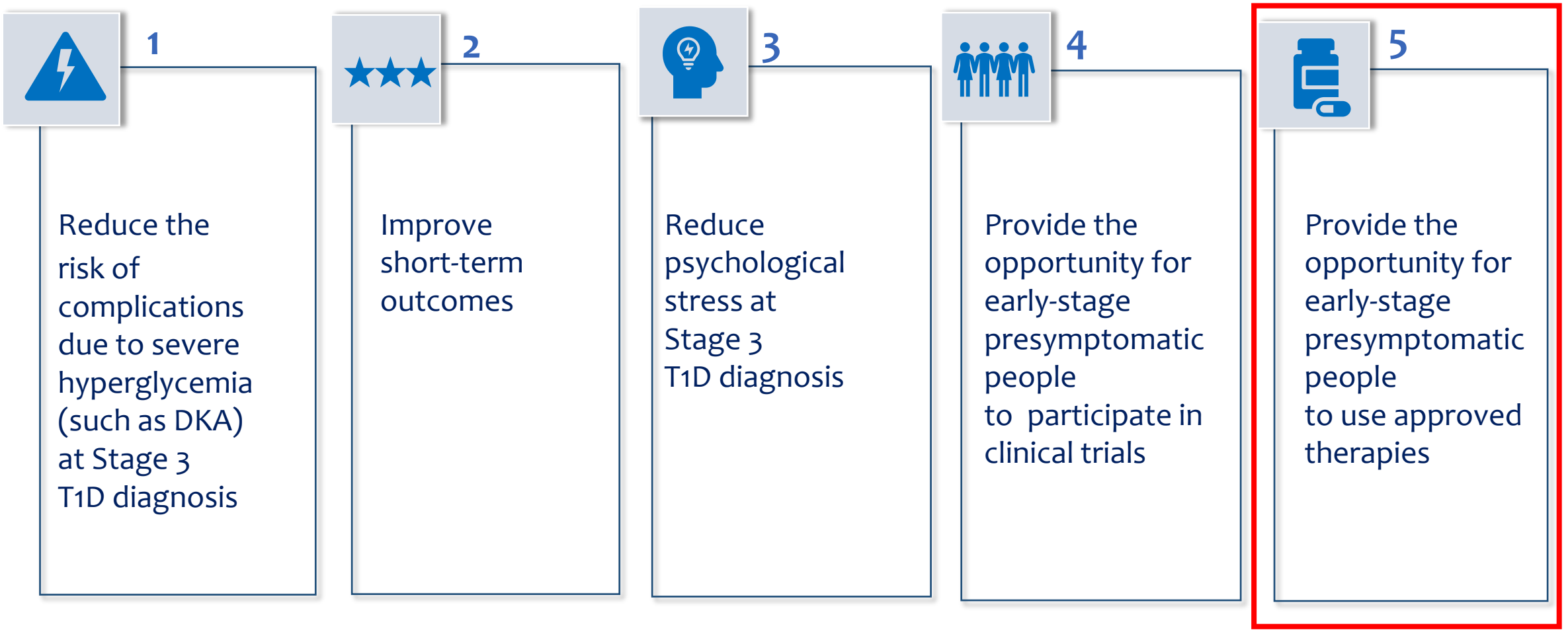
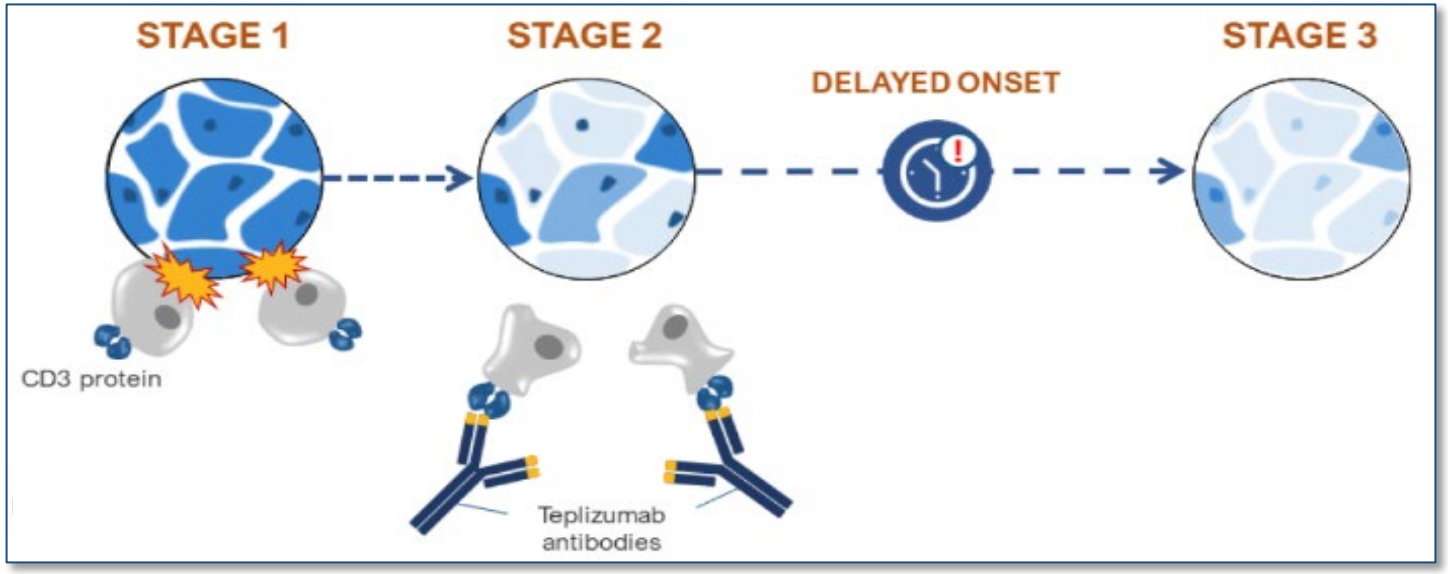


ISPAD Guidelines 2024. Horm Res Paediatr. 2024;97(6):529-545

5. ACCESS TO APPROVED THERAPIES

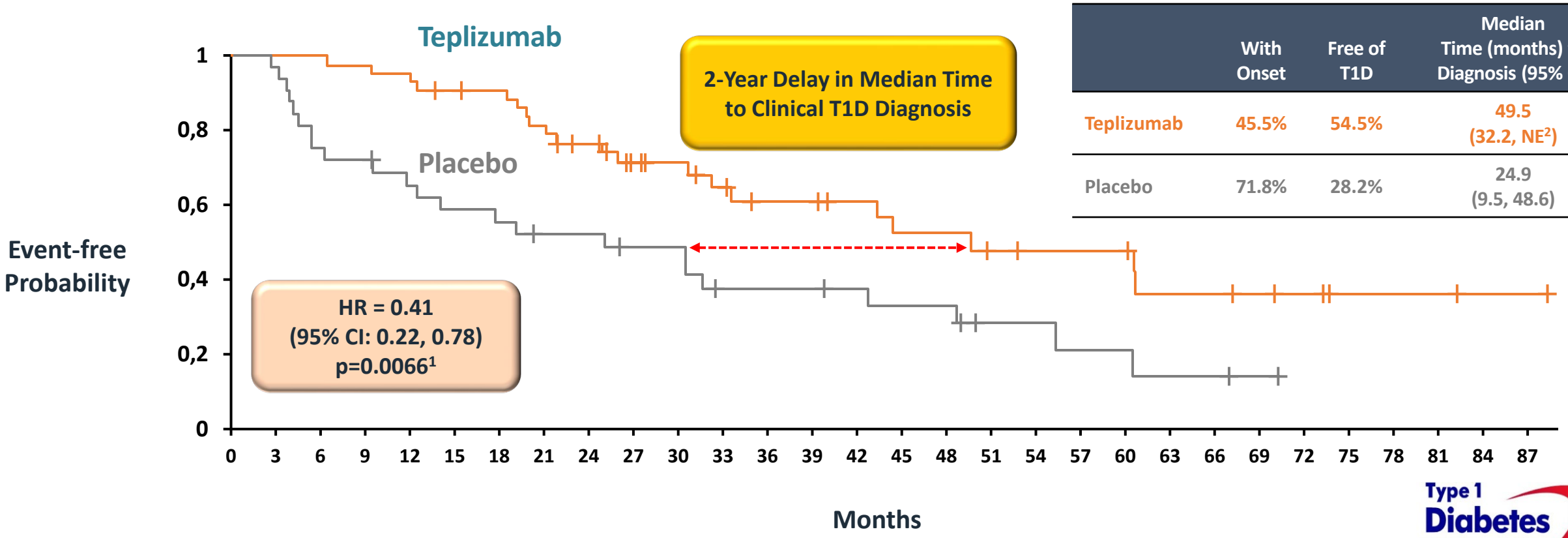
Teplizumab humanized anti-CD3 monoclonal antibody, is the first immunotherapy approved for Stage 2 T1D in the USA and in Europe.

The approval of this drug represents a significant breakthrough in the management of T1D.



Teplizumab antibodies target T cells, some of which are responsible for the destruction of islet beta cell slowing down T1D progression from Stage 2 to Stage 3.

Teplizumab Prevention Study
Significantly Delayed Onset of Stage 3 Clinical T1D vs Placebo



	With Onset	Free of T1D	Median Time (months) to Diagnosis (95% CI)
Teplizumab	45.5%	54.5%	49.5 (32.2, NE[2])
Placebo	71.8%	28.2%	24.9 (9.5, 48.6)

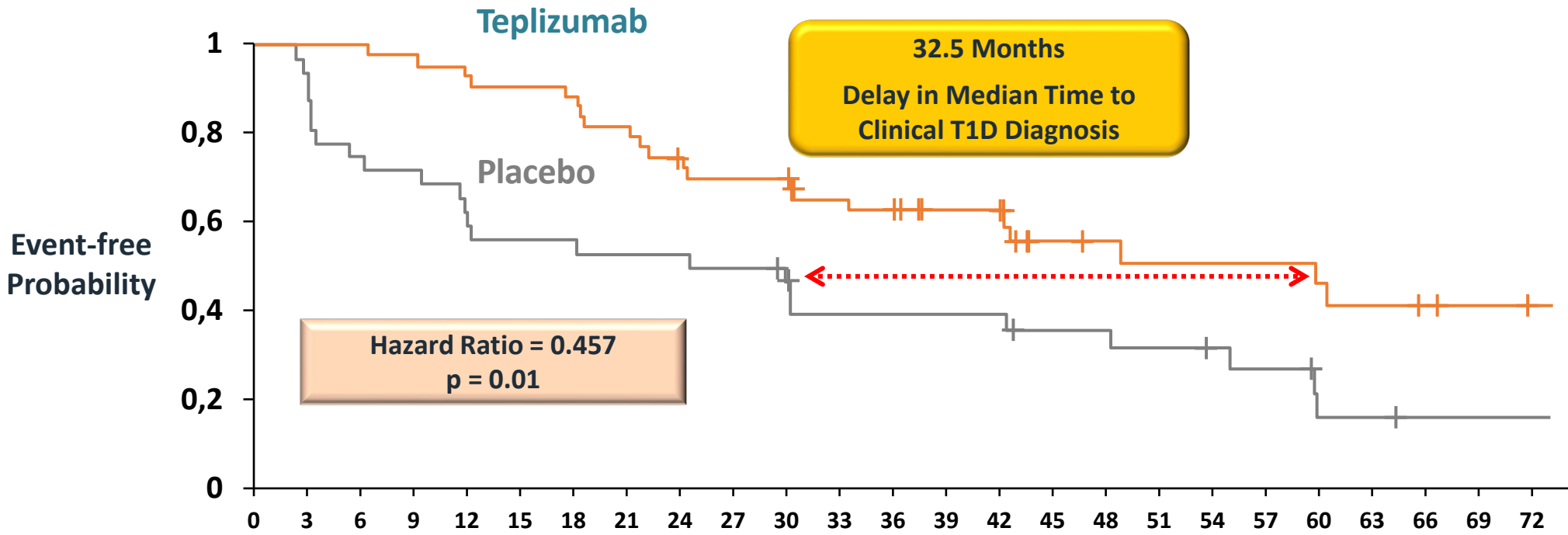
Number of Patients at Risk

Teplizumab	44	44	44	43	41	39	38	34	30	24	22	19	16	16	14	12	12	10	9	9	9	6	6	5	4	2	2	2	1	1
Placebo	32	31	24	23	20	18	17	15	15	13	13	9	9	9	8	7	7	4	4	3	3	2	2	1	0					

1. Cox Proportional Hazards model ; 2. Not Estimable

Herold et al. N Engl J Med 2019; 381:603-613

Teplizumab Prevention Study
Sustained Delay over Extended Follow-Up



	% With Onset	% Free of T1D	Median Time to Diagnosis
Teplizumab	50%	50%	59.6 months
Placebo	78%	22%	27.1 months

Number of Patients at Risk

Teplizumab	44	44	41	39	32	29	23	19	12	11	10	8	4
Placebo	32	24	19	18	17	14	11	11	9	7	3	2	2

Type 1 Diabetes TrialNet

Sims et al. Sci Trans Med 2021;13,eabc8980

Italian Republic National Law on type 1 diabetes and celiac disease screening in infants and adolescents: a summary

Ministero della Salute

Sponsor

- Ministry of Health

General Objective

- Nationwide, Public Health Program in the childhood and adolescent general population (age 1-17 yr) in Italy to identify individuals at risk for type 1 diabetes and/or undiagnosed celiac disease, in order to reduce the complications associated with lat diagnosis of these diseases.

Specific Aims

- Prevention of diabetic keto-acidosis (DKA) at the clinical onset of type 1 diabetes;
- Identification of pre-symptomatic type 1 diabetes suitable to disease modifying therapies.
- Prompt treatment of newly diagnosed celiac disease by gluten free diet;
- Prevention of non gastrointestinal complications of celiac disease including impaired growth or short stature, iron deficiency, osteopenia, delayed puberty, etc.;

Comment

Screening type 1 diabetes and celiac disease by law

On Sept 17, 2023, the Italian Parliament approved with unanimous vote a law (Italian Republic Law 130/2023) introducing a nationwide screening for type 1 diabetes and coeliac disease in the general population aged 1–17 years as part of the public health program aimed at reducing the effects of these chronic diseases. This law was successfully passed because of the commitment of many people from the diabetes and scientific community and was advocated for by Fondazione Italiana Diabete.

Type 1 diabetes and coeliac disease are two distinct, but sometimes coexisting, autoimmune conditions that share some common features, including an underlying immune-mediated pathogenetic mechanism; a partially shared genetic predisposition associated with HLA polymorphisms; associations with disease-specific autoantibodies, being detectable in the circulation years before clinical onset; an identifiable long presymptomatic phase; and progression to clinical stage that can be predicted.[1,2] In addition, both conditions have continuously increased in incidence over the past five decades in high-income countries.[1,2]

There are two specific aims of the new Italian law. First is the identification of children and adolescents during the presymptomatic phase of type 1 diabetes. children and adolescents, positivity for two or more islet autoantibodies is associated with the greatest risk (almost certainty) of future disease; positivity for one autoantibody indicates an intermediate risk, and a negative autoantibody status is associated with no risk. Similarly, the development of coeliac disease—either typical or clinically silent—is associated with IgA class transglutaminase and endomysial autoantibodies that are also easily measurable and are sensitive and specific markers of the disease.[4] Type 1 diabetes and coeliac disease-specific autoantibodies can be tested together in combined screening procedures, as indicated in the new law.

Available information on presymptomatic type 1 diabetes and its natural history derives from screening programmes done in relatives or other groups of genetically predisposed individuals, for reasons of higher efficiency and feasibility. However, since most people developing type 1 diabetes have no family history, any action aiming at reducing disease burden at the public health level requires moving to screening in the general population.[5] In the general childhood and adolescent population, the prevalence of islet antibodies is around 1–2%, with 0·3–0·5% of the population deemed high risk due to having two or more autoantibodies.[6] For coeliac

studioportobello/Getty Images

Lancet Diabetes Endocrinol 2023
Published Online December 1, 2023
https://doi.org/10.1016/S2213-8587(23)00354-6

For the **Italian Republic Law 130/2023** see https://www.gazzettaufficiale.it/eli/gu/2023/09/27/226/sg/pdf

Bosi E, Catassi C. Lancet Diabetes Endocrinol. 2024 Jan;12(1):12-14

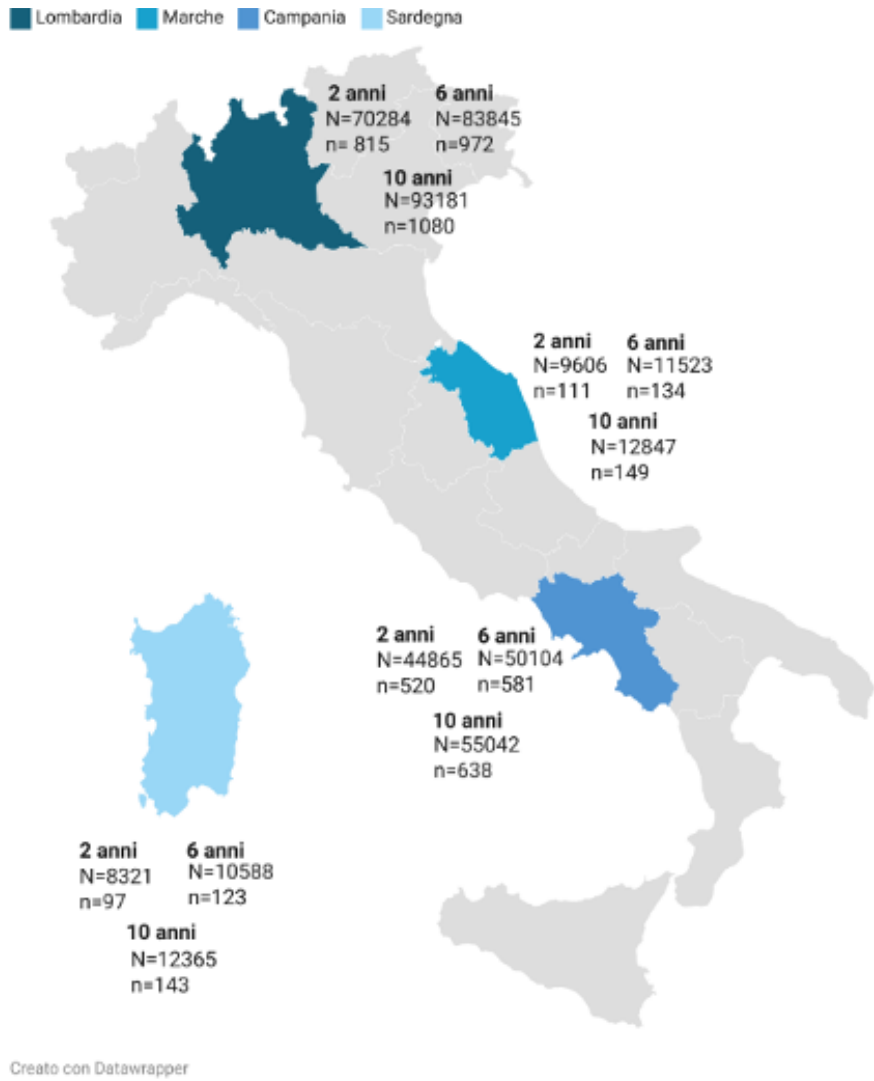
Law implementation pilot project: the D1CE SCREEN

Participating Regions and Children

April 2024 – March 2025

3 pillars:
The Family Pediatricians Nationwide Network
Capillary blood sampling
Centralized laboratory assays

Age (yr)	Lombardy	Marche	Campania	Sardinia	Total
2+1	815	111	520	97	1543
6+1	972	134	581	123	1810
10+1	1080	149	638	143	2010
total	2867	394	1739	363	5363



Law implementation Propaedeutic project: the D1CE SCREEN

The Family Pediatricians

Family Pediatricians are a public medical organization, part of the NHS and unique to Italy, extended as a nationwide network, responsible for prevention, cure and rehabilitation of children in the age ranges 0-6 years (mandatory) and 7-14 years (optional in alternative with adult GPs), sometime up to 16 yr.

In D1CE SCREEN Family Pediatricians are responsible for:

- direct contact of participants and families
- presentation of project rational and objectives
- administration of informed consent and informative materials
- execution of capillary blood drawing by fingerprick
- blood collection in microtubes and cards
- preservation of samples until shipping by courier
- communication to families of screening results and referral of positive cases to Regional centers
- questionnaires on feasibility and acceptability

D1Ce Screen study feasibility

Final enrollment (March 2025)

2736	2798

Region	Planned (n)	Enrolled (2+6+10 years)	Enrolled (other ages)	Total
Campania	1739	1502 (86,4%)	224	1726 (99,3%)
Lombardy	2867	2810 (98,0%)	186	2996 (104%)
Marche	394	363 (92,1%)	19	382 (97%)
Sardinia	363	369 (101,7%)	61	430 (118%)
Totale	5363	5044 (94,1%)	490	5534 (103%)

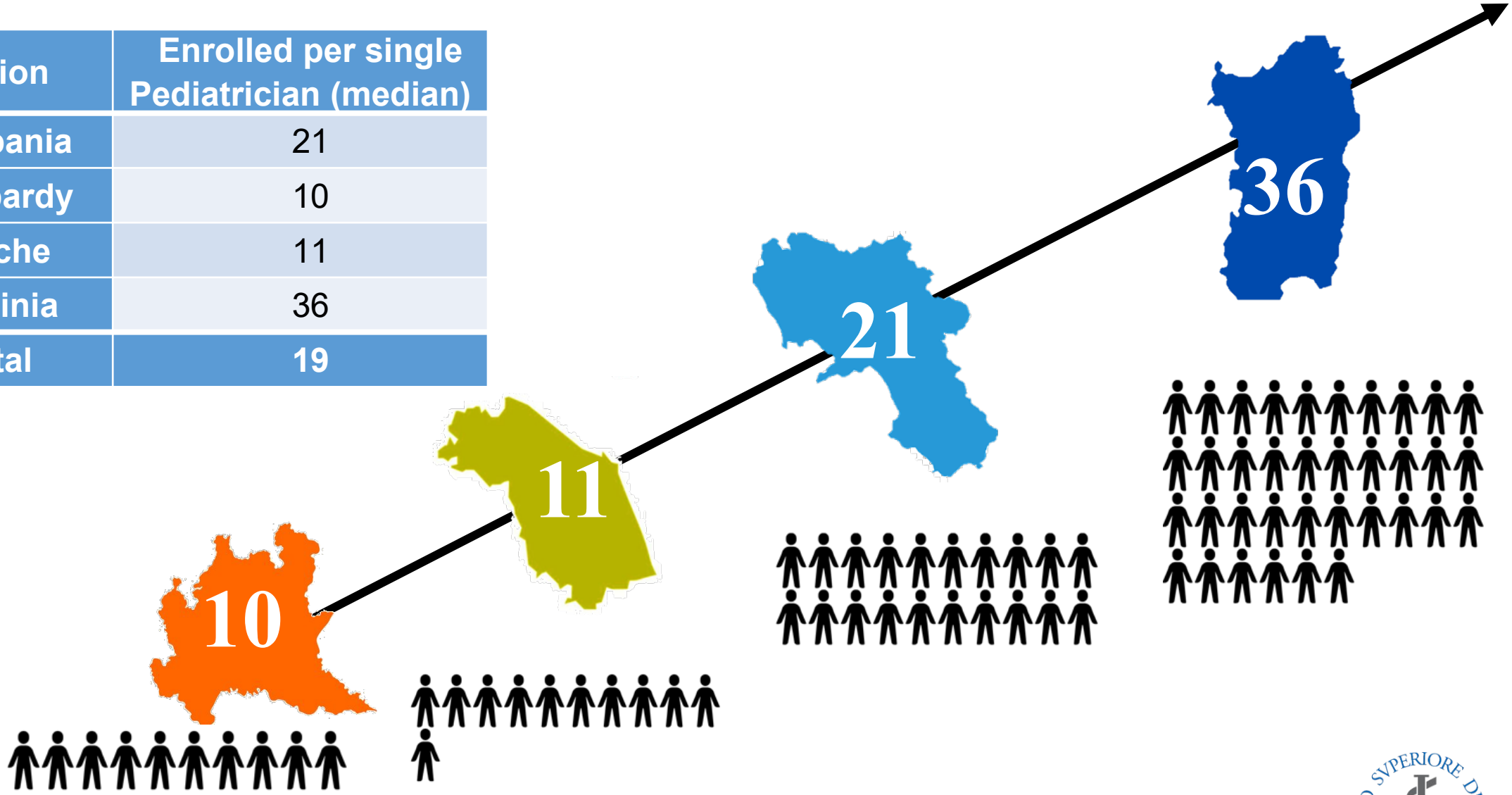
D1Ce Screen

Unpublished data-D1Cescreen steering committee

ISTITUTO SUPERIORE DI SANITÀ

D1Ce Screen study feasibility: enrollment per Pediatrician

Region	Enrolled per single Pediatrician (median)
Campania	21
Lombardy	10
Marche	11
Sardinia	36
Total	19



Law implementation Propaedeutic project: the D1CE SCREEN

Capillary blood Sampling and Assays

Capillary blood drawings from fingerprick was chosen vs venous sampling:

- Collected in Microvette (at least 25 µl) for autoantibody measurement:

  GAD, IA-2, ZnT8, insulin, transglutaminase-IgA and –IgG (6 specificities)
- Two drops on paper (Guthrie Cards) for HLA typing

Assays centralized at San Raffaele:

- Autoantibodies measured by LIPS and ELISA, with comparative evaluation
- HLA DQ2 and DQ8 typing by HLA typing by Reverse Dot Blot Hybridization

Acceptability and feasibility of capillary vs venous blood drawing in children and adolescents was evaluated in the former UNISCREEN study

D1Ce Screen study feasibility: serum samples adequacy for autoantibody assays (ELISA and/or LIPS)

Region	Adequate (n)	Absent (n)	Insufficient (n)	Partially sufficient (LIPS only) (n)	Total (n)
Campania	1321 (77,5%)	215 (12,6%)	12 (0,7%)	157 (9,2%)	1705
Lombardy	2559 (85,2%)	264 (8,8%)	17 (0,6%)	164 (5,5%)	3004
Marche	282 (74,8%)	31 (8,2%)	8 (2,1%)	55 (14,6%)	376
Sardinia	377 (83,9%)	43 (9,6%)	4 (0,9%)	25 (5,6%)	449
Total	4539 (82,0%)	553 (10,0%)	41 (0,7%)	401 (7,2%)	5534

Collected capillary samples were adequate for at least one autoantibody assay (LIPS) in 89.2% of cases

D1Ce Screen

Unpublished data-D1Cescreen steering committee

ISTITUTO SUPERIORE DI SANITÀ

Screening type 1 diabetes by autoantibodies: the performance of assays is crucial

- The measurement of islet autoantibodies is the foundation of screening strategies for type 1 diabetes
- A number of Standardization Programs (IDW, DASP and currently IASP) were developed and maintained over the years to improve the performance of immunoassays and the concordance of results across laboratories
- Capillary blood sampling proved to be equally suitable than venous blood sampling for autoantibody measurement, thus simplifying and facilitating large scale screening programs
- Significant advances have recently been achieved thanks to the development of novel techniques, applicable for multiple antigen detections and high-throughput performance

Islet Autoantibody Standardization Program

IASP

IDS IMMUNOLOGY OF DIABETES SOCIETY

A collaborative project of:

Immunology of Diabetes Society (IDS) IASP Committee

University of Florida Pathology Laboratories, Endocrine Autoantibody Laboratory

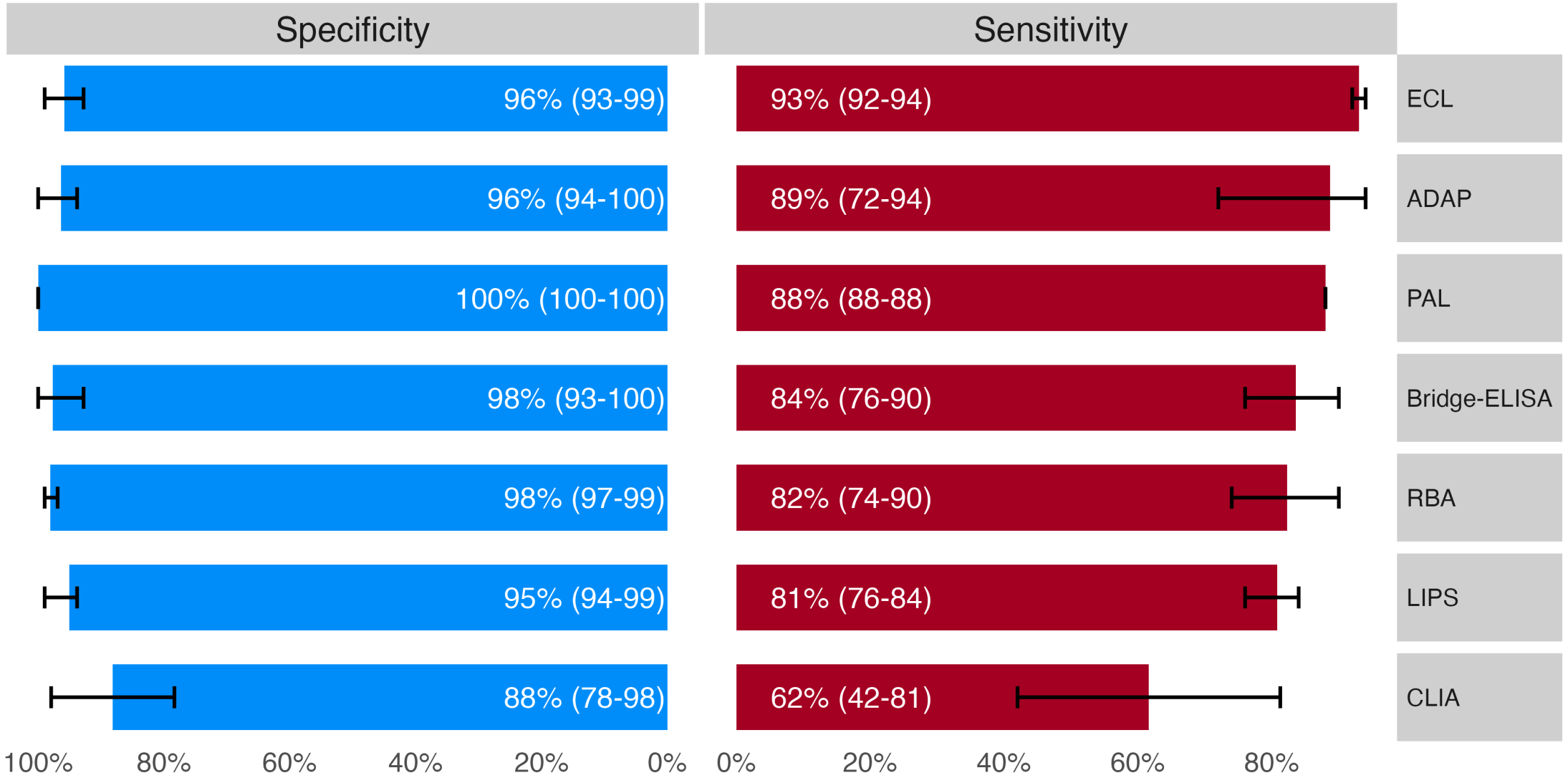
UF UNIVERSITY of FLORIDA College of Medicine

NATIONAL INSTITUTES OF HEALTH

NIH (TEDDY)

IASP2024: GADA Sensitivity and Specificity by Assay Format

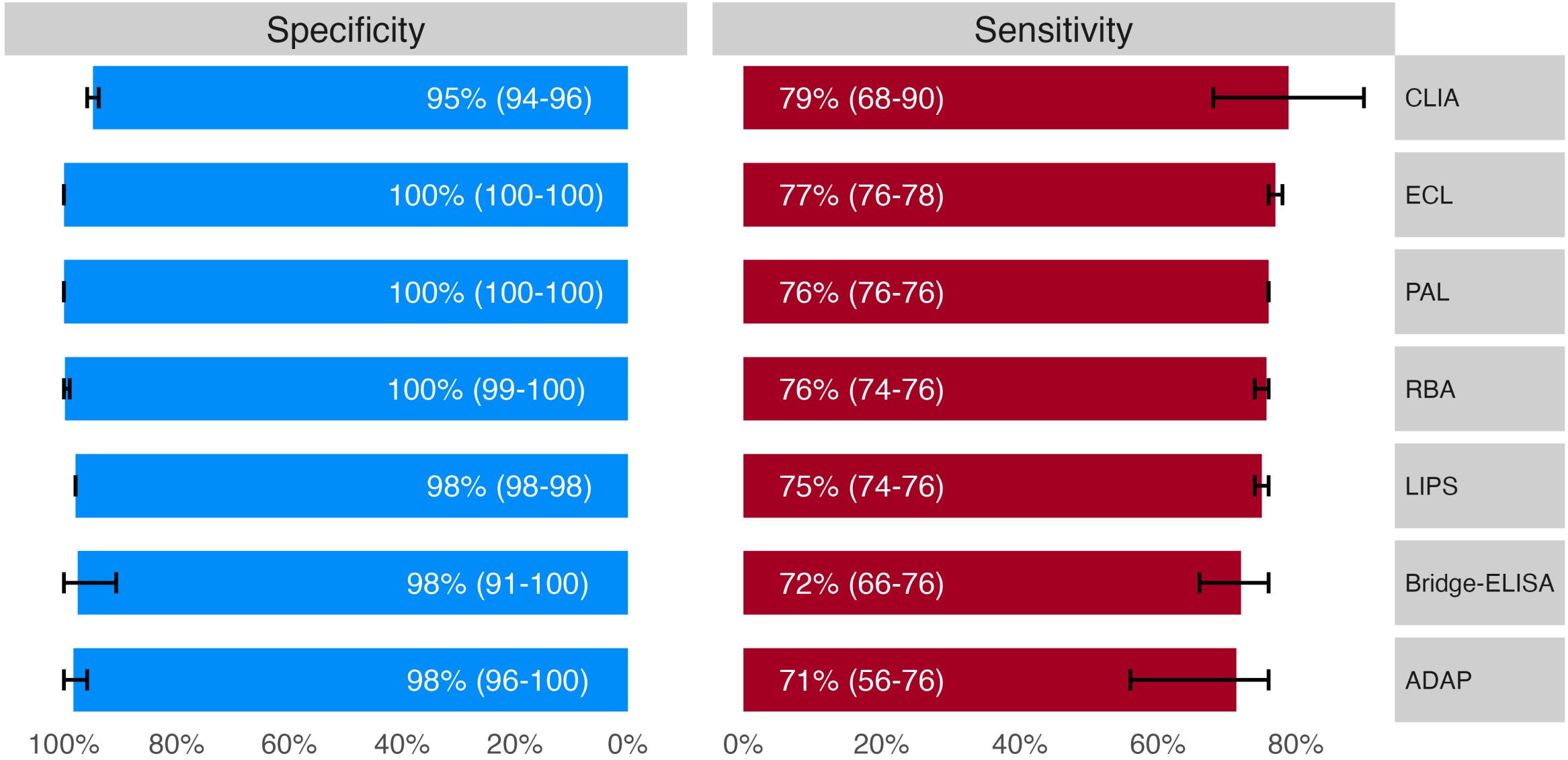
Values shown as mean% (range)



Lampasona V et al. IASP 2024 - Submitted

IASP2024: IA-2A Sensitivity and Specificity by Assay Format

Values shown as mean% (range)



Lampasona V et al. IASP 2024 - Submitted

IASP2024: ZnT8A Sensitivity and Specificity by Assay Format

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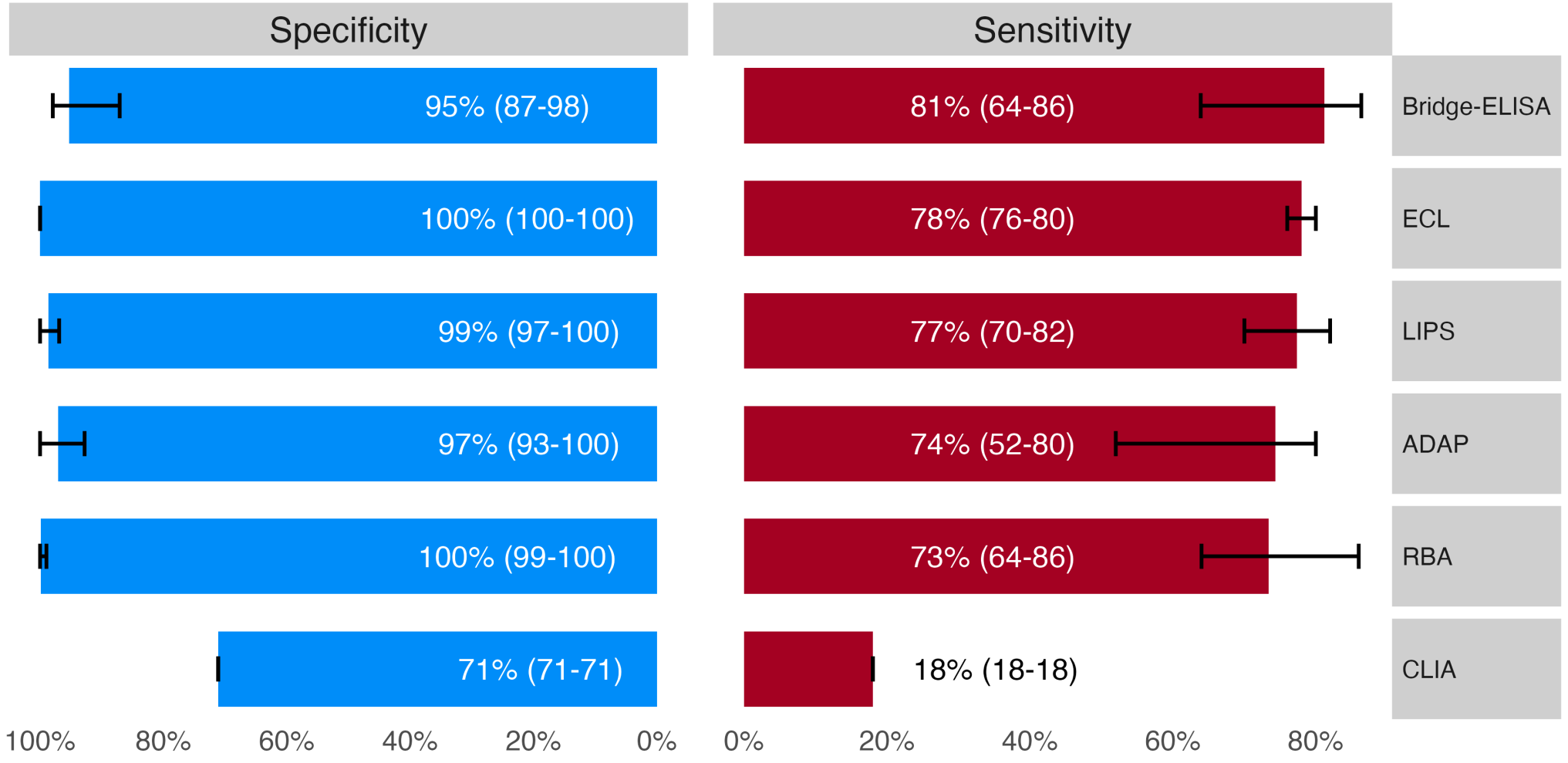

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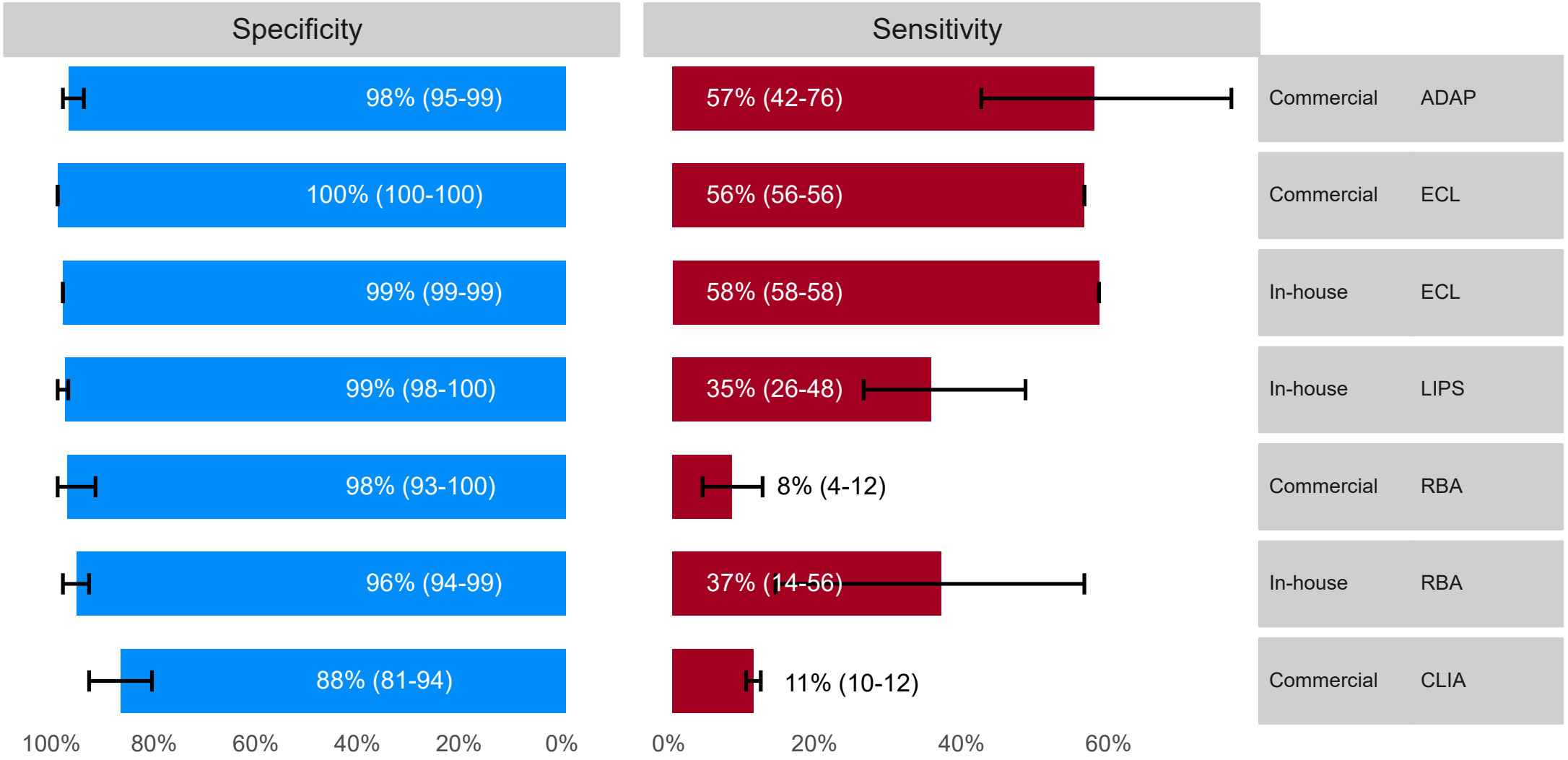
IASP2024: IAA Sensitivity and Specificity by Assay Format

Values shown as mean% (range)



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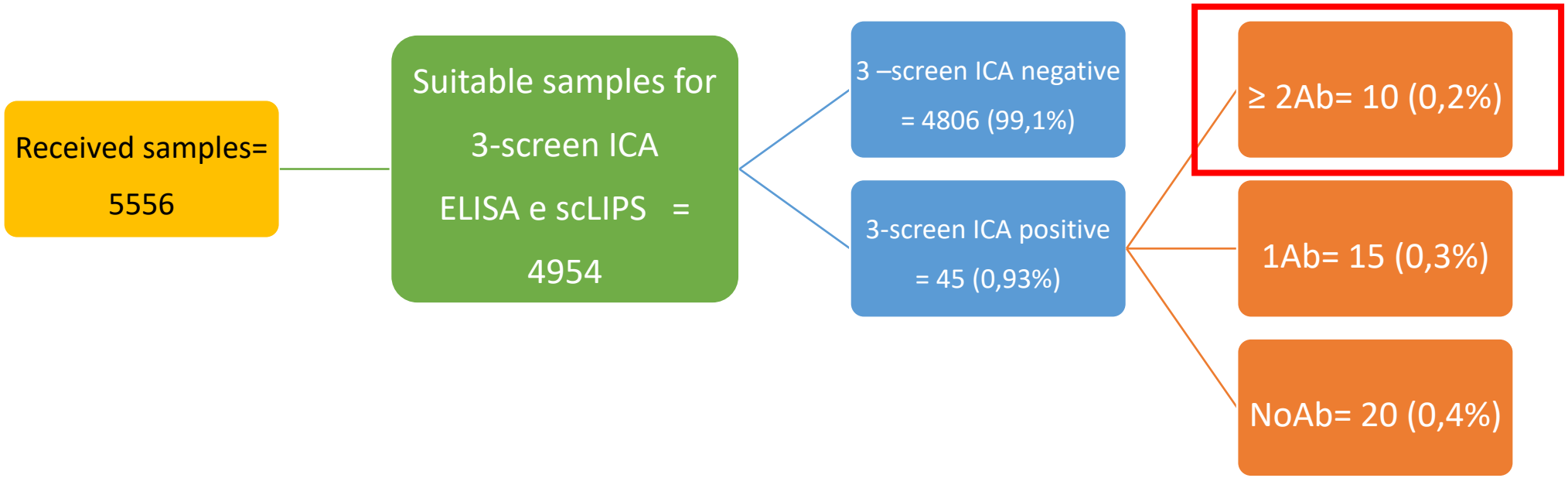
D1CE SCREEN

T1D autoantibody testing



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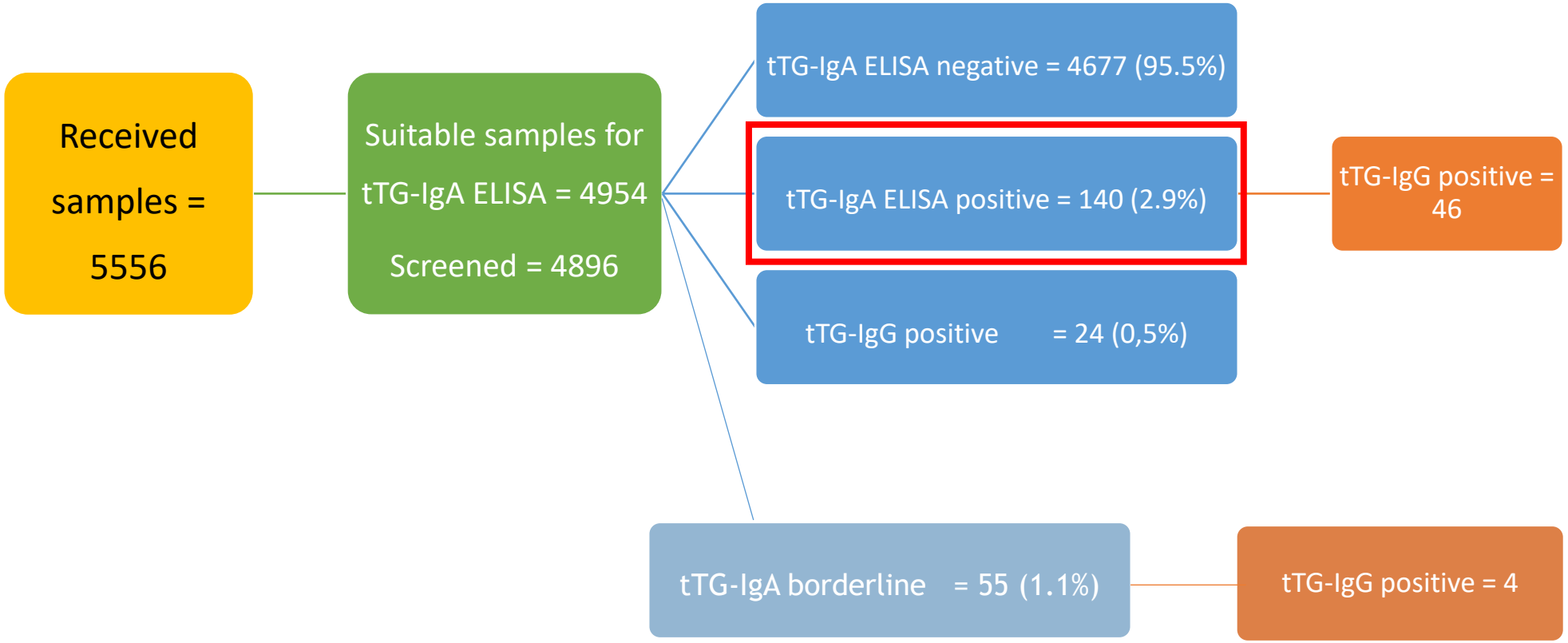
D1CE SCREEN

CD autoantibody testing



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Population screening of early stage type 1 diabetes

Is it worth?

- Yes, due to the disease impact

How?

- by islet autoantibodies

Is screening beneficial per se?

- Yes: DKA reduction, minimization of clinical symptoms at clinical onset, smoother transition to insulin therapy, potential access to disease modifying therapies

Is it feasible?

- Yes: many programs are ongoing around the world (Fr1da in Germany, ASK in Colorado, Dia-Union/TRIAD in Denmark and Sweden, DIPP in Finland, etc.), including the recent D1Ce, the pilot of the Italian Nationwide screening program

Are autoantibody assays accurate and affordable?

- Yes: by several assays

D1Ce Screen
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Non c'è cura, senza ricerca.

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Diabetes Research Institute

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Ospedale San Raffaele

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	Ilaria Formenti (piede diabetico)	Sara Angiulli	Loredana Bonisolli
			Rocco Pastore

I.R.C.C.S. Ospedale San Raffaele
Non c'è cura, senza ricerca.

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