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Professor of Pediatrics, Division Chief
@DoctorDiMeglio

Guidelines for Monitoring and Education in Pre-Symptomatic T1D



INDIANA UNIVERSITY
SCHOOL OF MEDICINE



Riley Children's Health
Indiana University Health

Disclosures

- Institutional support for research trials from:
 - Dompe, Lilly, Provention/Sanofi, Zealand
- Data Safety Monitoring Board
 - Lilly, Merck (non-diabetes indications)
- Consultant
 - Vertex, Abata
- Patent Application Co-author:
 - DFMO in new onset diabetes (through IU)



Guidance

~~Guidelines~~ for Monitoring and Education in (persons with) Pre- Symptomatic T1D

A glance into the draft - It is still a draft !!



Objectives

- **Discuss how the guidance was developed**
- **Present next step plans for document**



Consensus Guidance for Monitoring People with Antibody-Positive Pre-Stage 3 Type 1 Diabetes

Process began September 2022

Phone call/followed by email
from Dr. Albanese-O'Neill



Here is a brief summary of the initiative:

Working Group: Consensus Guidelines for Clinical Monitoring in Pre-symptomatic Type 1 Diabetes

Purpose: Develop and publish type 1 diabetes monitoring consensus guidelines for individuals who have participated in type 1 diabetes risk screening

Timeline: Draft Consensus Document: ATTD, February 2023, Berlin Germany
Working Group Meetings: Biweekly from February 2023 through May 2023
Finalize Consensus Document: ADA Sci Sessions, June 2023, San Diego, CA, USA








Chair: Moshe Phillip, MD

Associate Chair: Linda DiMeglio, MD, MPH

Thank you again for considering it and looking forward to hearing from you.

Anastasia

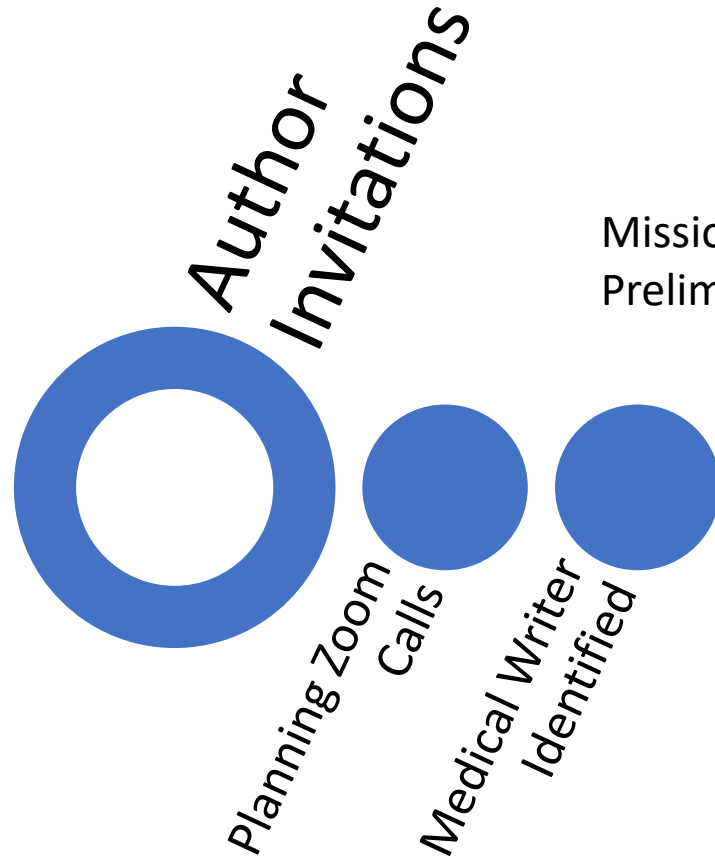
ISPAD Clinical Practice Consensus Guidelines 2022: Stages of type 1 diabetes in children and adolescents

Rachel E. J. Besser¹ | Kirstine J. Bell² | Jenny J. Couper^{3,4}  | Anette-G. Ziegler⁵ |
Diane K. Wherrett⁶ | Mikael Knip⁷  | Cate Speake⁸ | Kristina Casteels^{9,10}  |
Kimberly A. Driscoll¹¹  | Laura Jacobsen¹²  | Maria E. Craig¹³  |
Michael J. Haller¹² 

- Both general population and targeted screening should be coupled with education and monitoring programs for those identified with autoantibodies (B).



November 2022



Mission statement Drafted
Preliminary references pulled

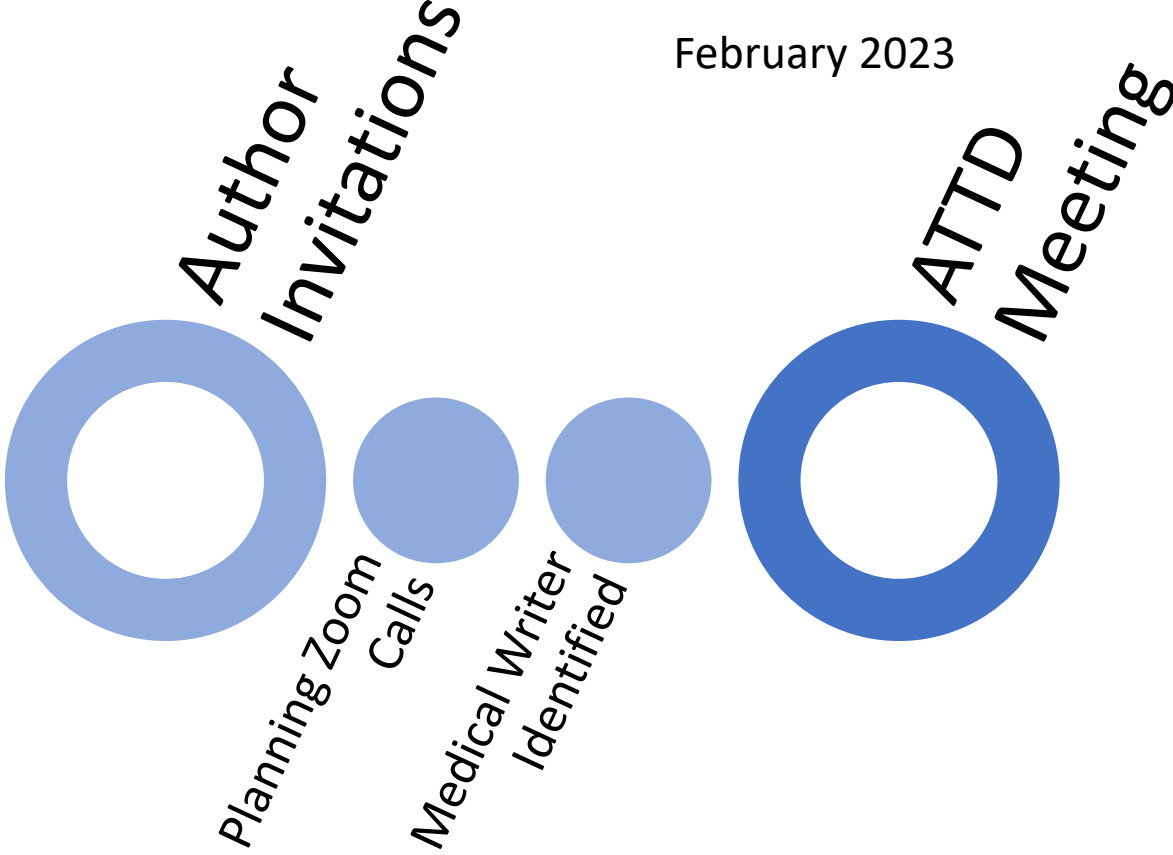
Mission Statement (Nov 2022)

- Even though T1D risk screening has taken place for over four decades, there are **no published clinical monitoring guidelines** available to clinicians to use in primary and specialty care.
- The recently-published ISPAD guidelines are the first consensus document to encourage ongoing monitoring to track disease progression.
- However, ISPAD guidance only addresses T1D progression in children and adolescents (not adults) and does not outline specific clinical practice steps.
- Without clear guidance for recommended next steps from healthcare professionals, individuals at risk for T1D will remain at increased risk for DKA at diagnosis and its related sequelae; continue to be unprepared at diagnosis; not be identified for participation in T1D prevention research, and miss opportunities to delay disease progression through therapeutic intervention.
- The urgency of the need for comprehensive monitoring guidance has risen with approval of the first disease modifying therapy, teplizumab.

Working group mission - develop

- Consensus document based on expert opinion and current evidence that specifies the **necessary monitoring guidance/a basic management approach for persons with Antibody-Positive Pre-Stage 3 T1D progression for use in clinical practice** to include
 - What endpoints to monitor
 - How to monitor
 - How frequently to monitor
 - How to provide psychosocial and educational support
 - Age/other biomarker and context-based contingencies and adaptations
 - What additional evidence is needed in this space (e.g. biomarkers, risk factors/assessment, efficacy of approaches)
- **Patient-facing educational materials** for use by individuals and clinical practices that include
 - Symptoms of T1D
 - T1D staging description
 - Description of monitoring plan
 - Customizable links to local resources





Author
Invitations

February 2023

ATTD
Meeting

Planning Zoom
Calls

Medical Writer
Identified

21st February 2023, ATTD-Berlin Germany

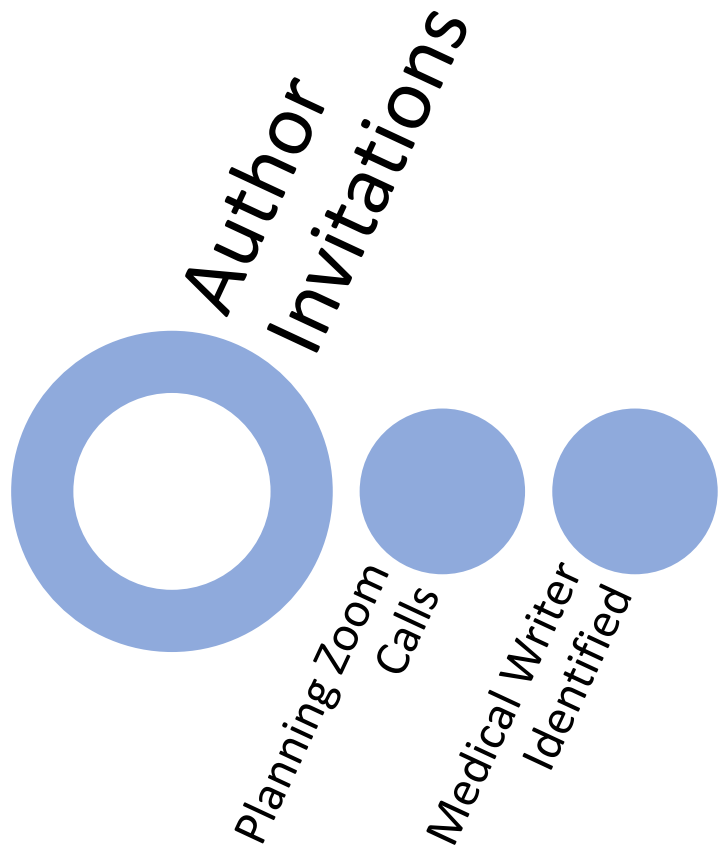


11:00 to 11:20	Welcome and Introductions – Dr. Sanjoy Dutta Summary of Working Group Mission – Dr. Moshe Phillip, Dr. Linda DiMeglio
11:20 to 12:30	What Have We Done in Monitoring? <ul style="list-style-type: none">• State of the Science in Monitoring – Dr. Marian Rewers• ISPAD Monitoring Guidelines – Dr. Rachel Besser• Insights from the INNODIA Monitoring Protocol – Dr. Chantal Mathieu• Insights from the TrialNet Monitoring Protocol – Dr. Emily Sims• Insights from the Fr1da Monitoring Protocol – Dr. Anette-Gabrielle Ziegler• Insights from the ASK/ASK the Experts Monitoring Protocol – Dr. Kimber Simmons
12:30 to 1:40	What Should We Do Next? Moderated Discussion Led by Dr. Moshe Phillip and Dr. Linda DiMeglio
1:40 to 1:55	Working Groups and Next Steps
1:55 to 2:00	Closing Remarks
2:00	Lunch and Networking at Café Madrid https://melia-berlin.firstview.us/en/cafe-madrid

21st February 2023, ATTD-Berlin Germany



- **Monitoring in children and adolescents (Besser/Griffin)**
 - **Subgroup leads: Veijola, Craig, Simmons, Couper**
- **Monitoring in adults (Schulman-Rosenbaum, Wentworth)**
- **Educational needs (Bell/Frohnert)**
- **Psychosocial interventions (Driscoll/Smith)**



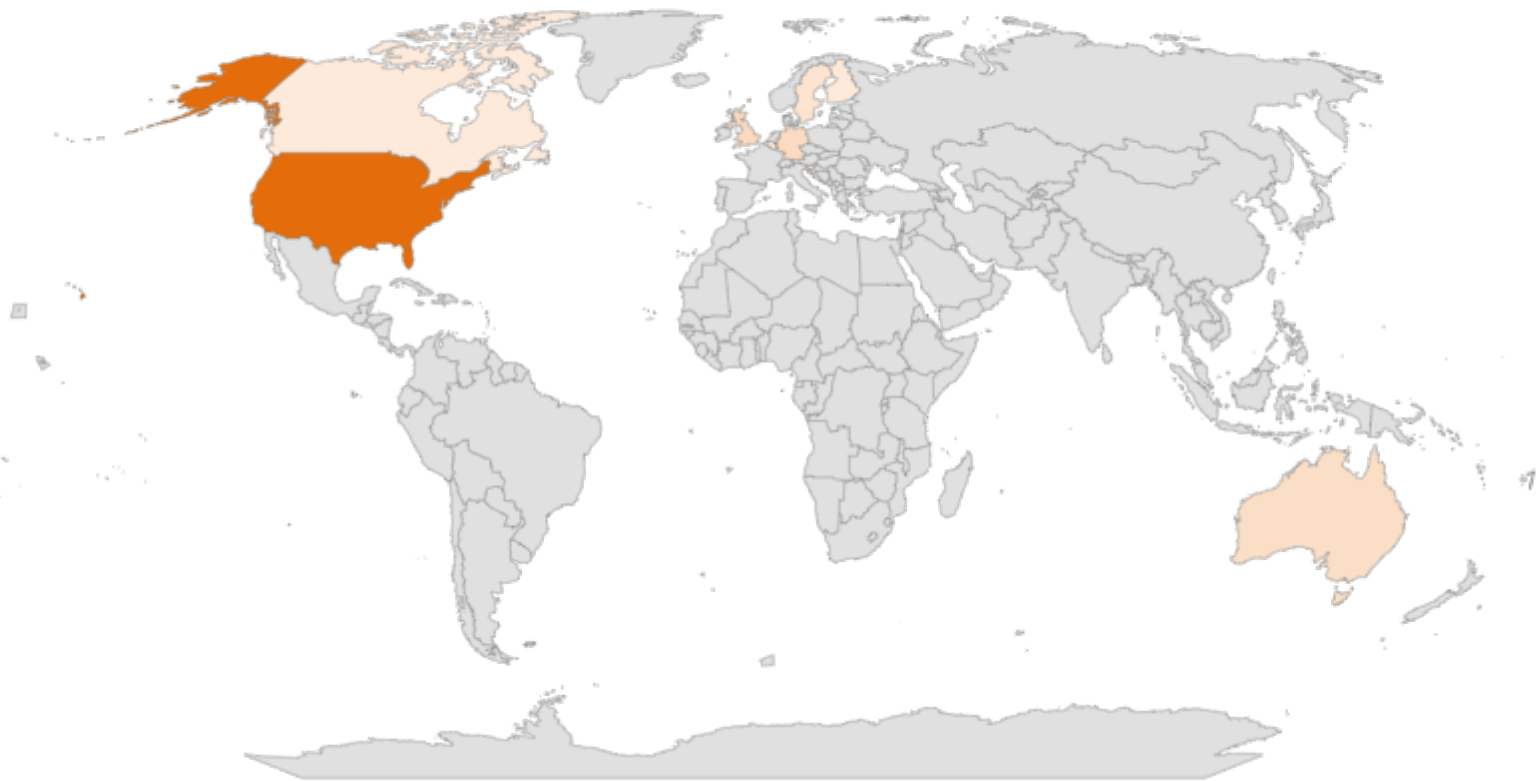
- 21 meetings
- Evidence reviewed
- ADA Grading of recommendations

Contributors

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		Helmholtz Munich, Institute of Diabetes Research
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Worldwide Authors



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A new clinical state to address



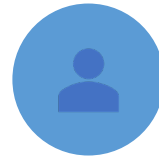
WHAT IS THE
PURPOSE OF
MONITORING?



HOW AND WHEN
SHOULD WE
MONITOR THESE
PERSONS?



WHAT DO WE DO
WITH SINGLE
ANTIBODY
POSITIVITY?



WHO SHOULD
MONITOR?



WHAT DEFINES
STAGE 2 T1D?



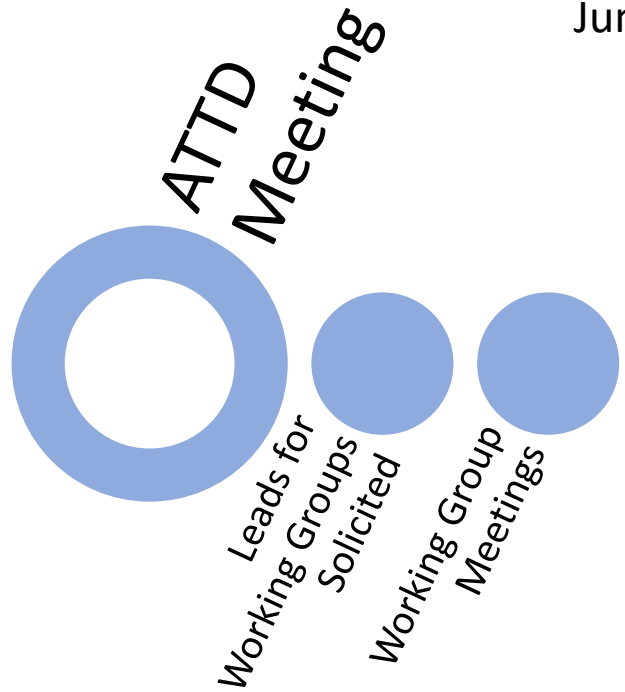
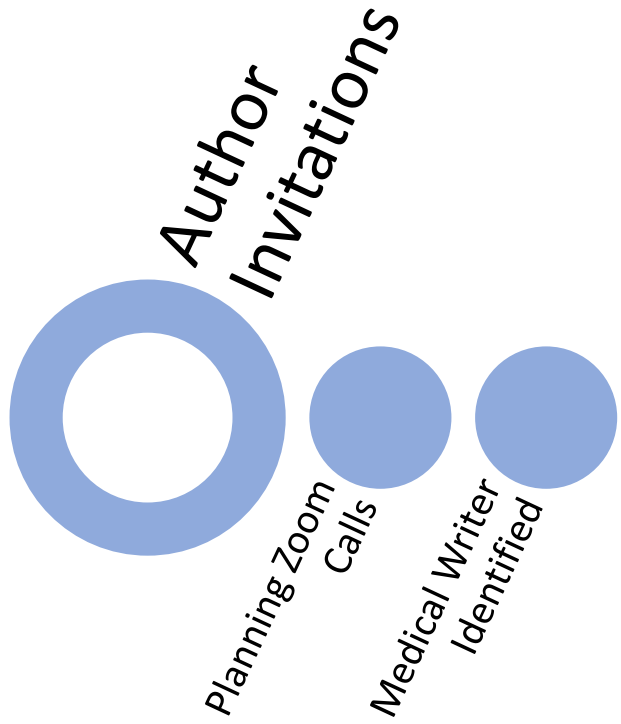
WHEN SHOULD WE
BEGIN TREATMENT?



EDUCATION



PSYCHOLOGICAL
SUPPORT

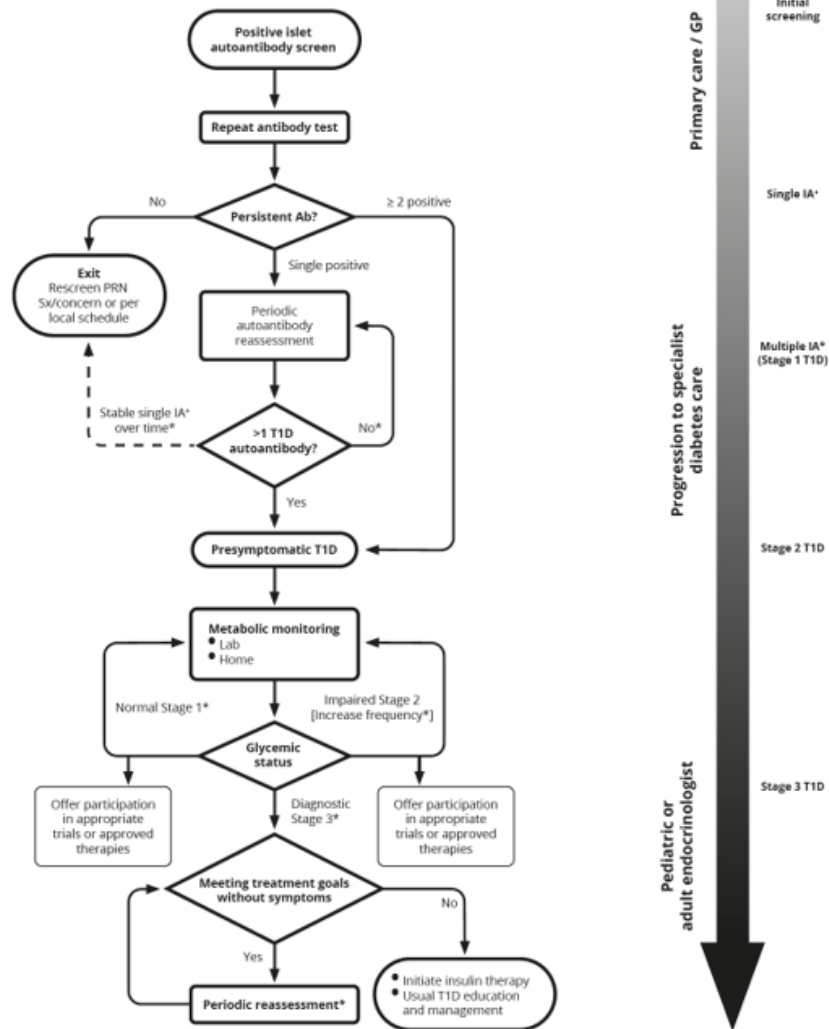


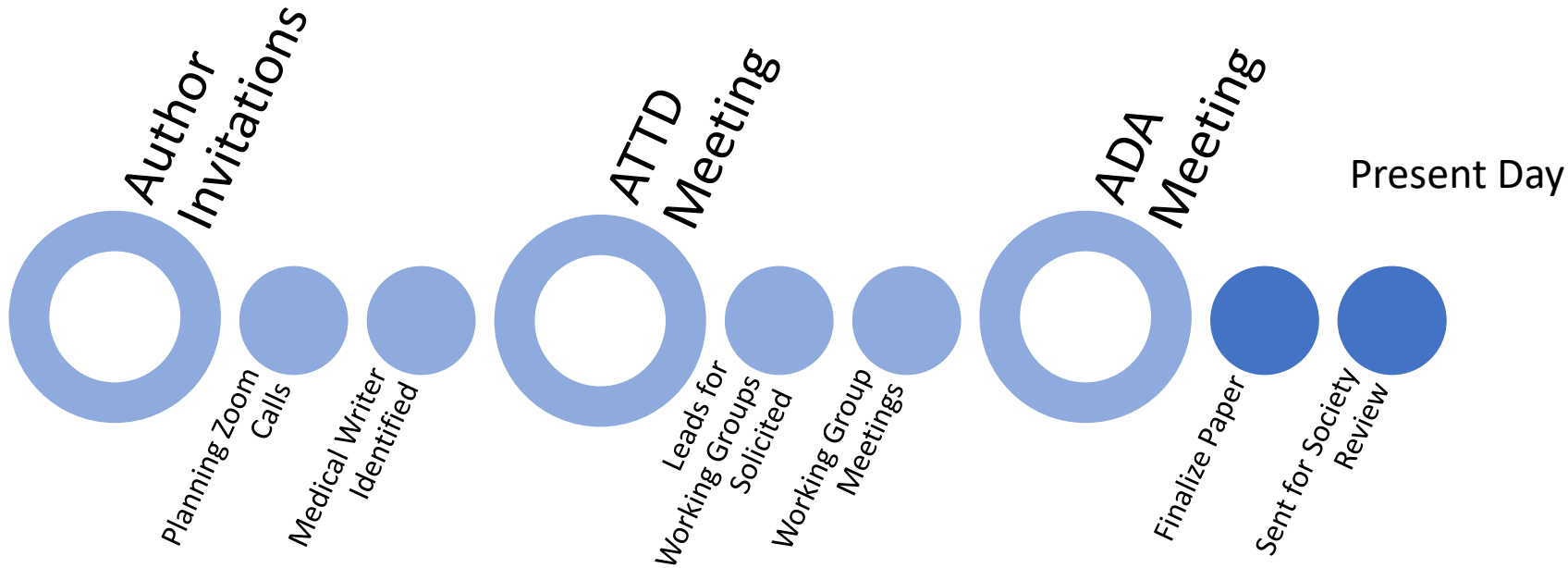
June 2023



22nd June 2023, ADA-San Diego USA









European Association
for the Study of Diabetes



THE LEONA M. AND HARRY B.
HELMSLEY
CHARITABLE TRUST

Sept 2023: Italian Population T1D Screening Initiative

Mulè (FI): “The law on pediatric screening for diabetes and celiac disease is an example of good policy”



"Italy, thanks to all the parliamentarians who have decided to support my bill, is today the first country in the world to have equipped itself with such an innovative tool to protect the health, and in many cases the lives, of our children "

Rome, 13 September 2023 © Agenzia Nova - Reproduction reserved



Symposium
Grote Zaal / Session Hall 1
Saturday, October 21, 12:15 - 13:45

Joint Symposium ISPAD - ATTD

Chair: Sze May Ng (United Kingdom)
Chair: Ananta Addala (United States)

What do we do with persons with Antibody-Positive Pre-Stage 3 Type 1 Diabetes?

Speaker: Moshe Phillip (Israel)

Real-world data on decision support system

Speaker: Mark Clements (United States)

Treatment of obesity in children

Speaker: Erica van den Akker (Netherlands)

Q&A

12:15 - 12:40
25 min

12:40 - 13:05
25 min

13:05 - 13:30
25 min

13:30 - 13:45
15 min

*Preliminary – endorsed by
working group and undergoing
society review prior to
submitting for peer
review/publication*

 **ISPAD 2023**
ROTTERDAM, THE NETHERLANDS
49th Annual Conference | October 18 - 21, 2023



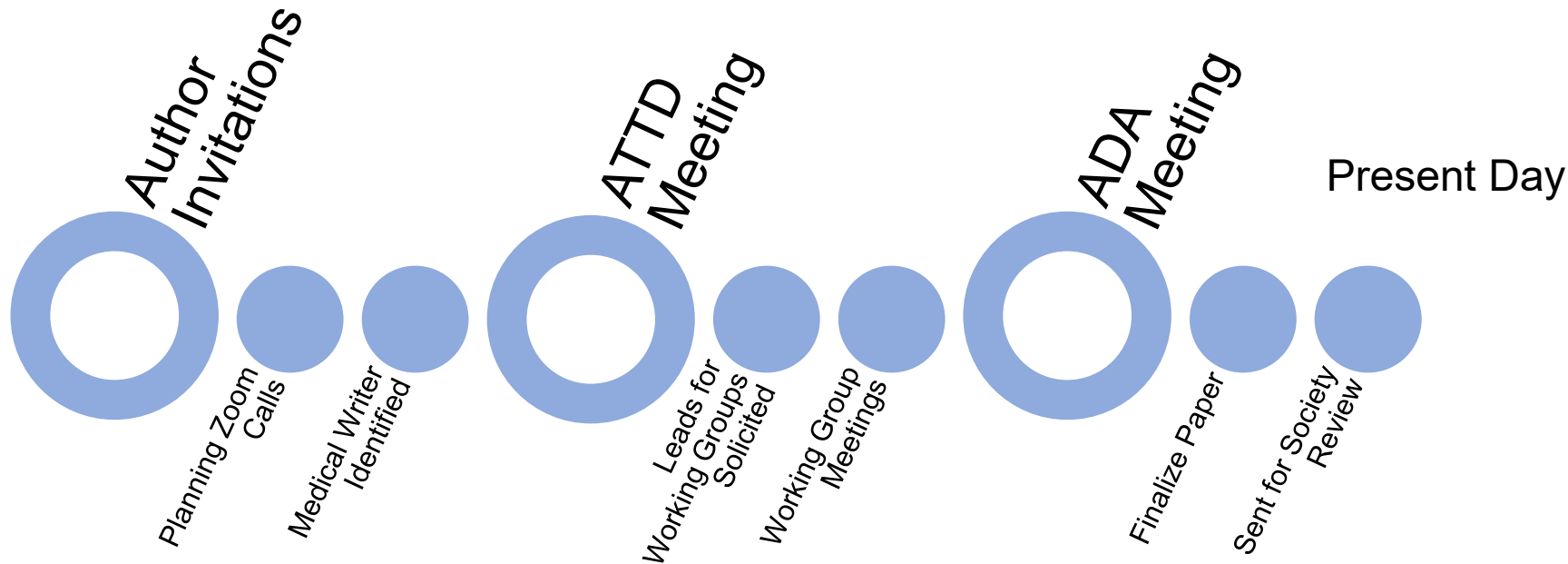
*Pediatric diabetes in a
rapidly changing world*



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Draft version 8.0



Next steps

1. Finalize feedback
2. Re-circulate to all authors
3. Submit to journal (!)
4. ATTD Presentation 2024



ATTD
Advanced Technologies
& Treatments for Diabetes

6-9 MARCH 2024
FLORENCE & ONLINE



Questions?



@DoctorDiMeglio @T1DIndy

Thank you to:

- Collaborators
 - For this initiative:
 - Moshe, Anastasia, Sanjoy, Rob
 - IU Center for Diabetes and Metabolic Disease
 - Carmella Evans-Molina, Emily Sims, Heba Ismail, Jamie Felton, Alex Tuttle
 - External
 - David Maahs
 - Kellee Miller
 - IFHC
 - Type 1 Diabetes TrialNet
- Funding: NIDDK
- My research staff and our study participants



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