

# Patient Reported Preferences from the Pro Solo Novel Patch Pump Clinical Trial

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# Disclosures

- u Roche Global Advisory Board; Roche IDS Advisory Board; Sanofi Integrated Care Advisory Board; Ascensia Global Advisory Board
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# Accu-Chek Solo Micropump System

- u Inserter
- u Pump holder
- u Cannula (6 or 9mm)
- u Durable component
- u Reservoir
- u Controller



# Why Patch Pumps?

- u Greater flexibility in clothes choices
- u Discreet remote bolus functionality
- u Patient choice in insulin delivery technology
- u Simplicity delivered accuracy
- u Quality of life - reduced visibility of disease state
- u Psychosocial functioning

# Inherent Bias Can Impede Access

- u considerable variation in the delivery of diabetes care processes, structured education, uptake of diabetes technologies and achievement of diabetes-related targets
- u This variability extends across multiple factors, including geographic area, gender, racial/ethnic groups and level of social deprivation
- u HCPs sometimes hold prejudicial and erroneous views about the types of individual that would most benefit from using diabetes technologies
- u It's always worth asking 'why not'?

# Enabling (or Stifling) the Patient Voice

- u Healthcare systems are structurally biased environments where the power imbalance is stark
- u Physicians on average interrupt their patient approximately 11 seconds after they start describing the problem
- u 'On demand' articulation of facilitators and barriers to self-management is exceptionally difficult
- u Gently probing questions can aid understanding

# PRO Solo Study

*Investigate effect on increased treatment satisfaction with the Accu-Chek® Solo micropump system in real life use of the vs. MDI and the Omnipod® 2 system*

## Intervention:

Accu-Chek Solo vs. MDI and vs. OmniPod 2 in adults

## Design:

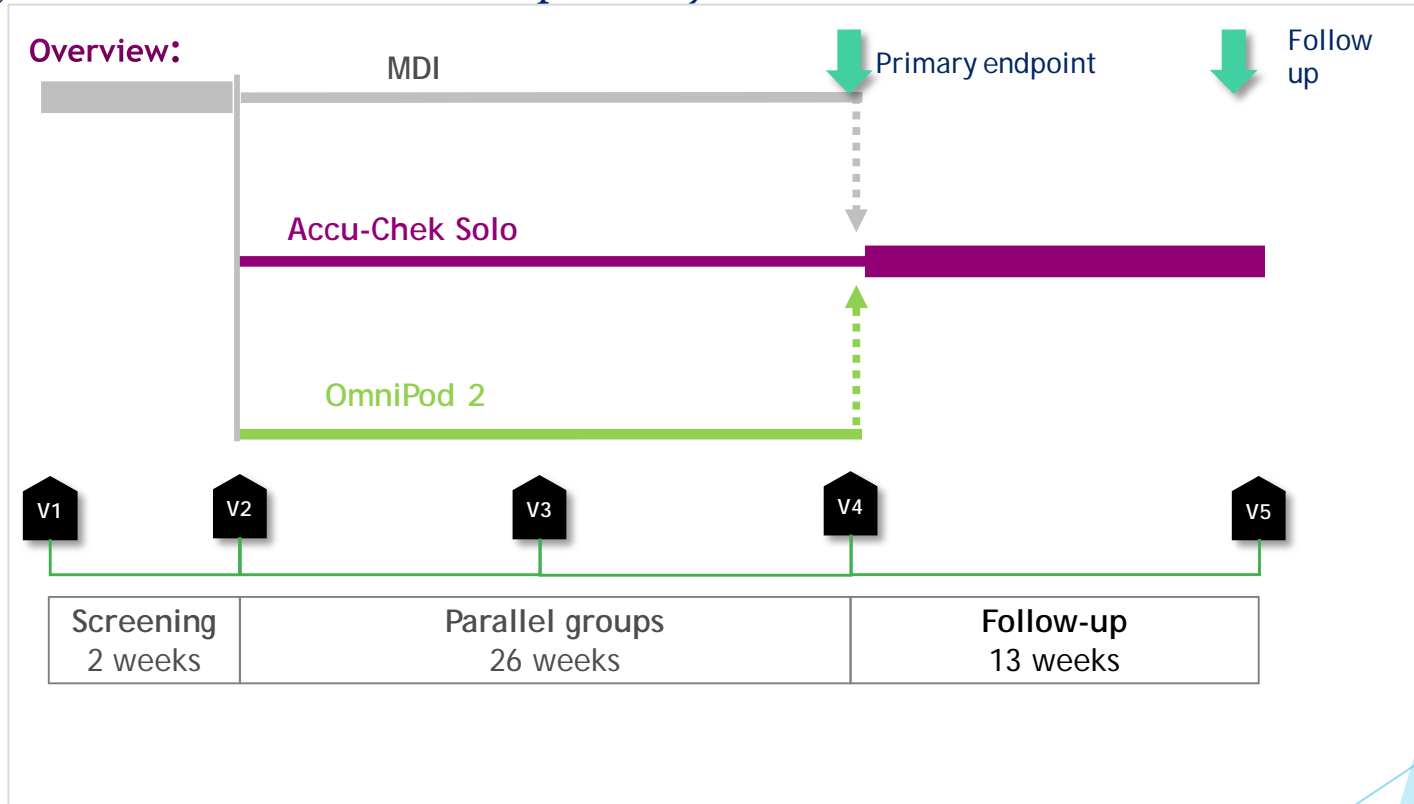
39+ weeks, 3-arm RCT, open, prospective, multicenter (21), multinational (A, D, PL, UK)

## Participants:

181 PwT1D, MDI  $\geq 6$  months  $\geq 18$ y

## Endpoints:

Treatment satisfaction (DTQ)  
Device satisfaction  
Device performance  
Severe hypoglycemia  
HbA<sub>1c</sub>



Status finished

# PRO Solo *Demographics*

Baseline Demographics (mean ± standard deviation)	All Subjects (N=181)	Arm A PRO Solo (N=62)	Arm B MDI (N=61)	Arm C OmniPod (N=58)
Female	79 (43.6%)	29 (46.8%)	29 (47.5%)	21 (36.2%)
Age (yrs)	39.0 ± 11.9	38.0 ± 11.8	38.6 ± 10.8	40.6 ± 13.1
Height (cm)	174.2 ± 9.5	174.2 ± 9.3	173.0 ± 10.7	175.4 ± 8.4
Weight (kg)	80.7 ± 16.8	77.2 ± 14.1	81.7 ± 17.7	83.4 ± 18.1
BMI	26.5 ± 4.6	25.3 ± 3.5	27.1 ± 4.7	27.0 ± 5.2
Years since diagnosis of diabetes	15.0 ± 10.8	14.0 ± 10.8	15.1 ± 10.8	16.0 ± 10.9
Ethnicity				
Asian	3 (1.7%)	1 (1.6%)	1 (1.6%)	1 (1.7%)
Other	3 (1.7%)	2 (3.2%)	0 (0.0%)	1 (1.7%)
White	175 (96.7%)	59 (95.2%)	60 (98.4%)	56 (96.6%)



# PRO Questionnaire Data

## DTQ - Diabetes Technology Questionnaire:

- Mean DTQ scores at 6 months:

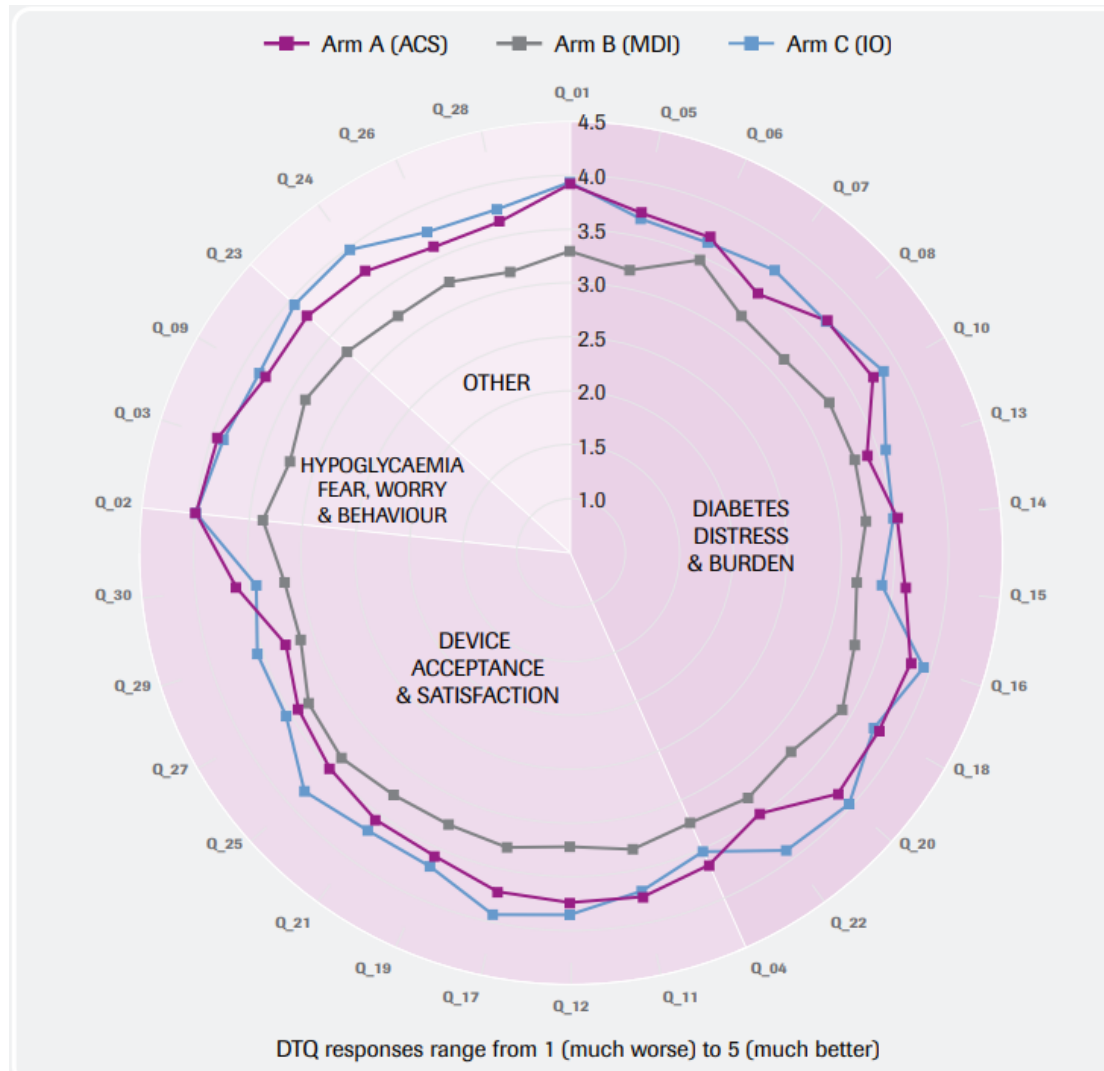
	Accu-Chek Solo	MDI	p-value
LSM ± SE	105.9 ± 2.66	94.8 ± 2.63	0.001

## PAID - Problem Areas in Diabetes:

- Reported problem areas in diabetes decreased with insulin pump use:

	Accu-Chek Solo	MDI	p-value
LSM ± SE	6.32 ± 0.43	7.62 ± 0.42	0.010

# DTQ Mapped to Psych Constructs



Mader, J. K., et al. "First results from PRO Solo: patient reported outcomes from a clinical trial comparing a new patch pump with MDI and an established patch pump." *Diabetologia* 2020; 63: Suppl 1.

# Biomedical and PRO Questionnaire Data

- u DTQ items each mapped to key psychosocial constructs: burden and distress, hypoglycaemia (worry, fear, confidence), tech acceptance and attitudes towards device
- u Significant improvement on all constructs for Solo users vs MDI users
- u Confidence was high around getting the right amount of insulin during exercise, on sick days or if meals are skipped/delayed
- u Visibility of disease state and sleep were improved
- u Interference in daily life was reduced

# Results – Thematic Analyses

## Most Cited Benefits

Benefit	<i>n</i>
Wireless (tubeless)	37
Quick bolus	32
No injections	28
Bolus calculator	22
Ease of use	22
Discreet	22

## Most Useful Attributes

Attribute	<i>n</i>
Bolus calculator	64
Flexible basal / bolus rates	42
Quick bolus	41

$n=181$  participants, providing  $n=226$  individual coded responses\*.

\*Some participants provided more than one response

# Results – Thematic Analyses Downsides

Feature	<i>n</i>
Not smartphone app	57
Not waterproof	39
Would like greater compatibility with other systems eg CGM/BG meter	26

# Participant Quotes - Benefits

## Fewer or no more injections

- "You don't need to give injections several times a day"
- "That I don't have to inject myself several times but the pump takes over some of the delivery."
- "The not forgetting to take my injections when rushing in the mornings and not worrying about losing my pen or misplacing it"

## Ease of use and convenience

- "The system makes my everyday life easier. It improves my everyday situation and I don't have to waste so much time thinking about my diabetes."
- "User-friendly layout. The pump system was very easy to use and the bolus calculator worked well."
- "Once the pod is in place you don't have to do anything for three days, really easy"

# Participant Quotes - Benefits

## Wireless

- “That the pump doesn't have a tube.”
- “Wireless operation - no connection between the remote and the pump.”

## Size/Appearance

- “It is small, compact and can be attached to the body as a whole system.”
- “Small micropump size”

## Discreet

- “a small, discreet pump, without additional cables, a manager similar to a phone, the pump can be concealed almost anywhere”
- “discreet bolus delivery in meetings and at restaurants”
- “Inconspicuous compared to the pen”

# What Participants Said They Would Change

## Alerts

- “It should be possible to switch off warning tones - vibrations would suffice”
- “the sounds it makes to remind you the pump needs changing can be disruptive in some situations”

## Remote operation

- “It would be good if the pump could also be controlled via mobile phone”
- “Please make an app so that everything can be managed via a cell phone”

## Greater Compatability

- “Make it possible for the device to communicate with a CGM”
- “The ability to connect the pump with the Libre type system, without the need to constantly collect blood drops. I work in the “public” sector, so I am unable to look for a secluded place every time.”



# Why It Matters

- u Parity of esteem is crucial - valuing mental health equally with physical health
- u Diabetes can be a very challenging condition - relentless, unforgiving, physically unpleasant, socially aversive
- u Devices that minimise burden, including visibility of disease state, are essential
- u Insulin pump therapy has well-proven glycaemic control benefits - providing choice of tubeless versus tubed pump is important personal preference
- u It is not a test of endurance and HCPs are not the gatekeepers of wellbeing; they are facilitators!

# Conclusions

- u Results show reduced burden of diabetes self-management
- u Frees the user of the 2<sup>nd</sup> thought associated with tethered pump eg pockets, using the bathroom, visibility, getting snagged
- u Greater compatibility / integration with other devices would be useful

# Thank you for listening

Any questions?

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