

Supplementary Material

Supplementary Table S1. Eligibility for HFS

Recruitment screener: full criteria by participant population	
RA patients:	<ul style="list-style-type: none"> • Age ≥ 18 years • Confirmed diagnosis of moderate to severe active RA • Symptoms involving the fingers, hands, or wrists for ≥ 3 months • Morning joint stiffness for ≥ 10 minutes • Currently using RA medications
CD patients:	<ul style="list-style-type: none"> • Age ≥ 18 years • Confirmed diagnosis of moderate to severe active CD for ≥ 3 months • >1 flare-up in the last 12 months • Currently using CD medications
AS patients:	<ul style="list-style-type: none"> • Age ≥ 18 years • Confirmed diagnosis of active AS for ≥ 3 months • Currently using AS medications
PsA patients:	<ul style="list-style-type: none"> • Aged ≥ 18 years • Confirmed diagnosis of active PsA for ≥ 6 months • Currently using PsA medications
CGs:	<ul style="list-style-type: none"> • CGs who administer subcutaneous injections for a patient with RA, AS, PsA, or CD
HCPs:	<ul style="list-style-type: none"> • HCPs currently in practice, for ≥ 2 years • Treat ≥ 1 RA, CD, AS, and/or PsA patient • Administering ≥ 4 injections per month
Healthy volunteers:	<ul style="list-style-type: none"> • Age ≥ 18 years

AS: ankylosing spondylitis; CD: Crohn's disease; CG: caregiver; HCP: healthcare professional; HFS: human factors studies; PsA: psoriatic arthritis; RA: rheumatoid arthritis.

Supplementary Table S2. Critical tasks evaluated in EU and US validation studies

Task number	Critical Task
CT01	Store DDCs in refrigerator
CT02	Configure e-Device for medication dose: 1) LD then MD1 2) LD then MD2 3) MD1 4) MD2
CT03	Distinguish between the training cartridge and medication DDC
CT04	Remove DDC(s) from refrigerator and allow drug product to warm
CT05	Prepare 1 or 2 DDCs
CT06	Inspect DDC window to view syringe and contents for visible defects
CT07	Choose injection site
CT08	Clean injection site
CT09	Power up e-Device
CT10	Insert DDC and wait for DDC to be drawn into e-Device
CT11	Remove needle cap
CT12	Position e-Device
CT13	Observe injection progress
CT14	Interrupt injection (if necessary)
CT15	Resume injection (following pause or interrupted injection)
CT16	Remove e-Device from injection site following a completed injection
CT17	Re-cap DDC
CT18	Pull DDC from e-Device
CT19	Observe date of next injection
CT20	Dispose of used DDC(s) in sharps bin
CT21	Clean e-Device
CT22	Respond to high and medium priority alarms appropriately

Critical task outcomes were reported as 'successes' (completed the task without mistakes), 'successes with difficulties' (completed the task within 3 attempts), or 'failures' (did not succeed within 3 attempts). DDC: dose-dispenser cartridge; LD: loading dose; MD1: maintenance dose 1 (200 mg every other week); MD2: maintenance dose 2 (400 mg every 4 weeks).

Supplementary Table S3. Study participants - formative (early prototype)

Study	1	2	3			4	
Participant	RA	RA	Vol	HCP	CG	Vol	HCP
N	14	14	7	4	1	10	1
Age, years, mean	41.8	39.7	36.7	41.5	59.0	36.6	42.0
Min	18	18	26	33	59	23	42
Max	61	57	53	54	59	62	42
Sex, F, n (%)	11 (78.6)	13 (92.9)	3 (42.9)	3 (75.0)	0	7 (70.0)	0
Ethnicity	NR	NR	NR	NR	NR	NR	NR
Years since diagnosis, mean	14.0	16.1	NA	NA	NA	NA	NA
Min-Max	5-31	1-47					
Disease severity^a							
Moderate	9	9	NA	NA	NA	NA	NA
Moderate to severe	0	0					
Severe	5	5					
Handedness							
Left	NR	NR	1	0	0	10	0
Right			6	4	1	0	1
Both			0	0	0	0	0
Prior injection experience, n							
Pre-filled pen	NR	NR	2	2	1	0	0
Pre-filled syringe			2	3	1	0	0
Standard syringe			2	4	1	0	1

^aLevels of disease severity were self-reported by patients. CG: caregiver; HCP: healthcare professional; NA: not applicable; NR: not reported; RA: rheumatoid arthritis; Vol: healthy volunteer.

Supplementary Table S4. Study participants - formative (fully functioning e-Device)

Study	5		6	7						8	9	10		12					
	RA	HCP	RA	CG	HCP	RA	AS	CD	PsA	Vol	Vol	RA	HCP	RA	CD	AS	PsA	CG	HCP
N	8	3	10	5	8	8	6	6	7	9	9	8	8	1	2	1	1	6	6
Age, years, mean	65.1	44.0	52.5	38.6	51.0	52.5	41.0	44.8	58.0	51.9	37.7	52.0	47.0	46.8				56.5	47.2
Min	48	35	38	25	33	34	20	25	37	28	29	23	32	29				45	35
Max	78	49	67	57	65	66	58	57	64	69	56	69	59	57				62	65
Sex, F, n (%)	3 (38)	2 (67)	7 (70)	3 (60)	3 (39)	7 (88)	1 (17)	4 (67)	1 (14)	4 (44)	4 (44)	5 (63)	5 (63)	1 (100)	2 (100)	1 (100)	1 (100)	4 (67)	4 (67)
Ethnicity																			
White ^a	8	2	10	1	4	2	3	5	5	NR	NR	6	6	4				2	2
Other ^b	0	1	0	4	4	6	3	1	2			2	2	1				4	4
Years since diagnosis, mean	18.3	NA	NR	NA	NA	12.6	17.8	17.2	6.4	NR	NR	NR	NA	1	8.5	4	1	NA	NA
Min-Max	1-32					1-46	1-42	0-34	2-12						7-10				
Disease severity^c																			
Moderate/active	4	NA	0	NA	NA	0	0	0	0	NA	NA	7	NA	0	0	1	1	NA	NA
Moderate to severe	3		10			8	6	6	7			1		1	2	0	0		
Severe	1		0			0	0	0	0			0		0	0	0	0		
Handedness																			
Left	2	0	1	1	1	2	0	0	2	1	1	0	2	0	0	0	0	1	0
Right	6	3	9	4	7	6	6	6	5	8	8	8	6	1	2	1	1	5	6
Both	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Prior injection experience, n^d																			
Pre-filled pen	0	NR	NR	NR	6	1	1	1	1	NR	NR	1	8	1	1	0	0	2	6
Pre-filled syringe	3				7	5	2	2	6			5	8	0	1	0	0	1	6
Syringe and needle/vial	1				0	0	0	0	0			0	8	0	0	0	0	3	6

^a“White” is composed of “White”, “White other”, “White British”, and “White American”; ^b“Other” is composed of “African American”, Southeast Asian / Middle East”, “India / Pakistan / Middle East”, “Mexican / Hispanic / Latino”, “Black / African / Caribbean”, “Other (not stated)”, “Black”, and “Asian”. ^cLevels of disease severity were self-reported by patients, with the exception of study 5, where specialists verified disease status; ^dInjection responses are not mutually exclusive. AS: ankylosing spondylitis; CD: Crohn’s disease; CG: caregiver; HCP: healthcare professional; NA: not applicable; NR: not reported; PsA: psoriatic arthritis; RA: rheumatoid arthritis; Vol: healthy volunteer.