

Mobilise-D Clinical Validation Study: Basic results summary REPORT

Acronyms:

- BMI: Body Mass Index.
- CAT: COPD Assessment Test;
- COPD Chronic Obstructive Pulmonary Disease
- C-PPAC: Clinical Visit-PROactive Physical Activity Tool
- DMA: Digital Mobility Assessment
- DMO: Digital Mobility Outcome
- FACIT: Functional Assessment of Chronic Illness Therapy
- FES-I: Falls Efficacy Scale International
- FVC: Forced Vital Capacity
- H&Y: Hoehn & Yahr Staging of Parkinson's disease
- EDSS: Expanded Disability Status Scale
- LEDD: Levodopa Equivalent Daily Dose
- LLFDI: Late Life Functional Disability Index
- Mini-BESTest = Balance Evaluation System Test
- MoCA =Montreal Cognitive Assessment
- mMRC: Modified Medical Research Council Dyspnoea Score
- MS: Multiple Sclerosis
- PIGD = Postural Instability and Gait Difficulties
- PD: Parkinson's disease
- PDDS: Patient Determined Disease Steps
- PFF: Proximal Femoral Fracture (Hip Fracture)
- SPPB: Short Physical Performance Battery
- TUG = Timed –Up and Go test
- 6MWD = 6-minute walking distance test

Study visits

- T0: screening visit
- T1: baseline visit (max 2 weeks after screening)
- T2: 6 months after the baseline visit ($\pm$ 4 weeks)
- T3: 12 months after the baseline visit ($\pm$ 4 weeks)
- T4: 18 months after the baseline visit ($\pm$ 4 weeks)
- T5: 24 months after the baseline visit ($\pm$ 8 weeks)

Datasets

- CVS_C: Clinical analysis set (participants with valid clinical data)
- CVS_D: DMO analysis set (participants with valid clinical data and available DMO data)

- CVS_V: Validation analysis set (participants with valid clinical and valid DMO data)

Contents

A) Participant Flow:

Figure 1: Flowchart T0-T1: Determination of the CVS dataset from initial candidates to baseline assessment. Total study and disease cohort figures reported. n = number of participants.

Figure 2: Flowchart T1-T5. Participants and DMO data availability across study visits (T1–T5). Total study and disease cohort figures reported. n = number of participants.

B) Baseline Characteristics:

Figure 3: Table to show Parkinson's Disease (PD) cohort characteristics by H&Y stage

Figure 4: Table to show Multiple Sclerosis (MS) cohort characteristics by disease type

Figure 5: Table to show Chronic Obstructive Pulmonary Disease (COPD) cohort characteristics by GOLD classification.

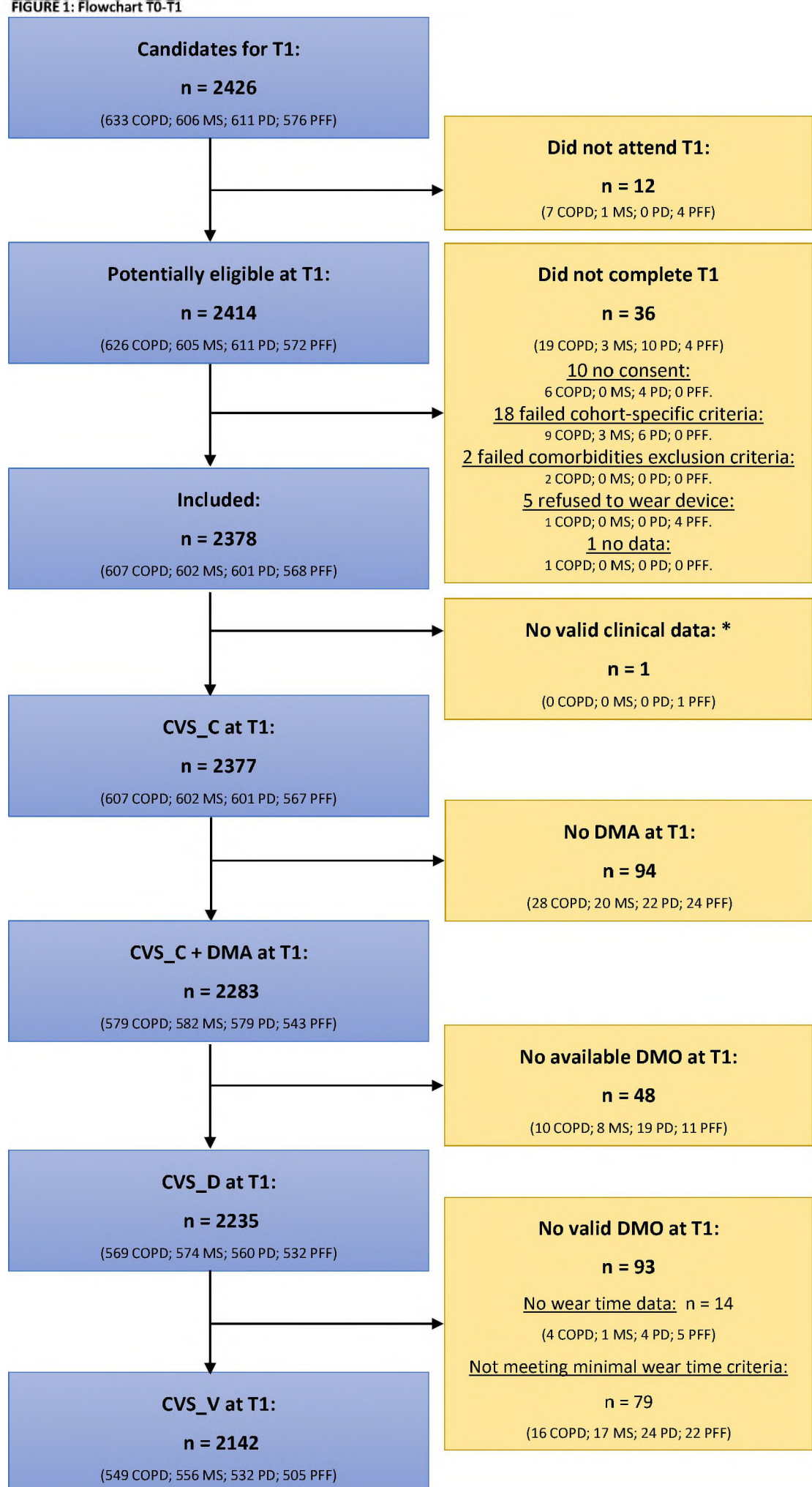
Figure 6: Table to show Hip fracture cohort characteristics by fracture type

C) Outcome Measures:

Figure 7: Table of study outcome measures for each disease cohort.

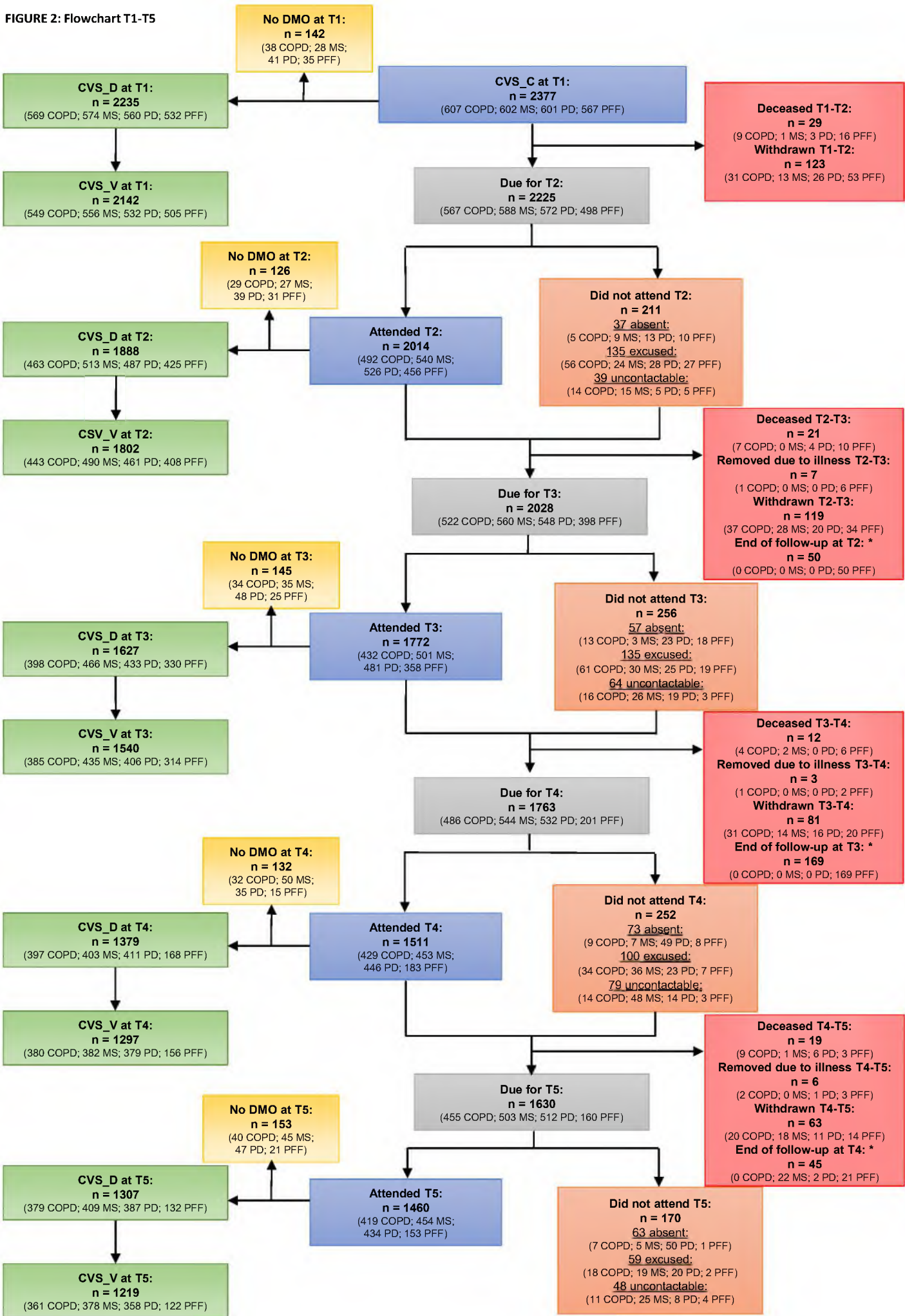
There was no adverse event reporting for this study as it is a non-interventional observational study.

FIGURE 1: Flowchart T0-T1



* Missing one of the following variables: age, gender, height or weight.

FIGURE 2: Flowchart T1-T5



* Participants whose recruitment started late, and end of study deadline was reached before all visits took place.

B) Participant Characteristics by cohort

Figure 3: Table to show Parkinson's Disease (PD) cohort characteristics by H&Y stage

Domain	Variable	Total, n= 531	Hoehn & Yahr I, n= 91	Hoehn & Yahr II, n= 356	Hoehn & Yahr III, n= 84
Socio-demographic Variables	Age, M(SD)	65.7(9.6)	63.8 (9.6)	65.0 (9.5)	70.9 (8.3)
	Gender, female, n (%)	189 (35)	42 (46.2)	114 (32.0)	33 (40.7)
	Marital status, married, n (%)	419 (79.4)	75 (14.2)	284 (53.8)	58 (11.0)
	Education, n (%)				
	College Degree or higher	286 (54.2)	58 (63.7)	194 (54.5)	31 (38.3)
	High school	62 (11.7)	10 (11.0)	49 (13.8)	9 (11.1)
	Less than high school (≤ 10 yrs)	38 (7.2)	2 (2.2)	31 (8.7)	6 (7.4)
	Others	145 (27.5)	21 (23.1)	105 (29.5)	35 (43.2)
	Site, n (%)				
	Kiel	170 (32.2)	27 (29.7)	120 (33.7)	23 (28.4)
Clinical Variables	Erlangen	111 (21.0)	11 (12.1)	80 (22.5)	20 (24.7)
	Leuven	48 (9.1)	9 (9.9)	30 (8.4)	9 (11.1)
	Newcastle	60 (11.4)	0 (0)	53 (14.9)	7 (8.6)
	Tel Aviv	142 (26.9)	44 (48.4)	73 (20.5)	22 (27.2)
	6MWD (m)	439 (96.3)	476 (83.2)	447 (92.2)	366 (93.3)
	TUG (s)	9.7 (3.0)	8.9 (2.2)	9.4 (2.3)	11.9 (4.7)
	Mini-BESTest	23.5 (3.7)	25.6 (2.0)	23.9 (3.3)	19.7 (4.1)
	4m gait speed (m/s)	1.11 (0.3)	1.16 (0.29)	1.13 (0.28)	1.0 (0.27)
	Scaled LLFDI-FC	63.4 (11.8)	69.4 (11.6)	63.9 (11.6)	55.5 (8.5)
	PIGD total	2.5 (2.4)	1.3 (1.22)	2.1 (1.8)	5.9 (3.0)
	LEDD (mg)	464 (322)	357 (288)	464 (302)	558 (373)
	MDS UPDRS part III	26.3 (12.3)	16.3 (8.8)	26.8 (11.1)	35.3 (12.6)
	MDS UPDRS Total	49.0 (18.4)	35.6 (14.4)	48.2 (18.0)	66.1 (22.7)
	MoCA	27 (4)	27 (4)	27 (4)	27 (4)

Figure 4: Table to show Multiple Sclerosis (MS) cohort characteristics by disease type

	Total, N= 556	Primary progressive N = 57	Secondary progressive, N=190	Relapsing- remitting, N= 304
Sociodemographic Variables				
Age, yrs, M(SD)	52.3 (10.7)	55.1 (11.7)	56.4 (8.7)	49.3 (10.7)
Gender, female, n (%)	360 (64.8)	17 (29.8)	123 (64.7)	218 (71.7)
Marital status, married, n (%)	375 (67.4)	36 (63.1)	138 (72.6)	197 (64.8)
Education, n (%)				
College Degree or higher	100 (18.0)	8 (14.0)	33 (17.4)	58 (19.0)
High school	152 (27.3)	11 (19.3)	50 (26.3)	89 (29.3)
Less than high school (≤10 yrs)/ others	302 (54.6)	38 (66.6)	107 (56.4)	134 (42.1)
Recruitment Site, n (%)				
Kiel	44 (7.9)	10 (17.5)	6 (3.1)	28 (9.2)
Erlangen	14 (2.5)	1 (1.8)	10 (5.3)	3 (1.0)
Sheffield	280 (50.4)	25 (43.9)	58 (30.5)	195 (64.1)
Milan	218 (39.2)	21 (36.8)	116 (61.0)	78 (25.7)
Clinical Variables				
EDSS, median (IQR)	5.0 (2)	6.0 (2)	6.0 (2)	4.5 (2)
MSWS-12, median (IQR)	38.5 (14.4)	42.3 (14.0)	44.6 (12.2)	34.1 (14.3)
T25-FW, s, median (IQR)	8.0 (5.8)	5.6 (1.5)	7.7 (2.7)	11.9 (8.27)
PDDS, median (IQR)	3.5 (3)	4 (2)	5 (3)	3 (3)
Systolic blood pressure, mmHg, M (SD)	130 (18.3)	133 (18.4)	133 (19.7)	129 (17.2)
Sub-group analysis				
Walking Aids, frequency used per setting n (%)				
Indoor	136 (24.5)	17 (29.8)	82 (43.2)	36 (11.8)
Outdoor	325 (58.5)	40 (71.9)	150 (78.9)	131 (43.1)
Falls in previous 12 months [median]				
0 fall	244	125	53	66
1 fall	71	27	14	30
≥2 falls	259	52	56	151

Figure 5: Table to show Chronic Obstructive Pulmonary Disease (COPD) cohort characteristics by GOLD classification.

	All n = 549	GOLD 1 n = 62 (11%)	GOLD 2 n = 235 (43%)	GOLD 3 n = 178 (33%)	GOLD 4 n = 74 (13%)
Age, median (Q1-Q3)	68 (62-73)	68 (62-73)	68 (63-74)	68 (63-74)	66 (60-71)
Sex, female n(%)	202 (37%)	28 (45%)	84 (36%)	60 (34%)	30 (41%)
Recruitment site, n(%)					
<i>Athens</i>	48 (9%)	2 (3%)	20 (9%)	15 (8%)	11 (15%)
<i>Barcelona</i>	148 (27%)	20 (32%)	60 (26%)	49 (28%)	19 (26%)
<i>Grosshansdorf</i>	132 (24%)	18 (29%)	65 (28%)	38 (21%)	11 (15%)
<i>Leuven</i>	109 (20%)	5 (8%)	53 (23%)	37 (21%)	14 (19%)
<i>London</i>	24 (4%)	3 (5%)	9 (4%)	8 (4%)	4 (5%)
<i>Newcastle</i>	47 (9%)	5 (8%)	15 (6%)	22 (12%)	5 (7%)
<i>Zurich</i>	41 (7%)	9 (15%)	13 (6%)	9 (5%)	10 (14%)
BMI (kg/m ²), mean (SD)*	28 (5)	27 (4)	29 (5)	27 (5)	26 (6)
Employment Status, (retired) n(%)	379 (69%)	46 (74%)	172 (73%)	114 (64%)	47 (64%)
Living Alone, (yes) n(%)	156 (0%)	23 (0%)	60 (0%)	50 (0%)	23 (0%)
Packs -years, mean (SD)	53 (29)	49 (29)	52 (26)	55 (30)	55 (31)
Dyspnoea (mMRC grade 0-4), median (Q1 - Q3)*	2 (1 - 2)	1 (1 - 1)	1 (1 - 2)	2 (1 - 3)	2 (2 - 3)
CAT Score (0-40), median (Q1-Q3)*	14 (9 - 19)	10 (6 - 17)	13 (8 - 18)	16 (11 - 20)	16 (12 - 23)
Isometric quadriceps muscle torque (N·m), mean (SD)*	121 (55)	135 (63)	126 (54)	115 (55)	108 (45)
6-min walk distance (m), mean (SD)*	416 (119)	483 (103)	444 (100)	395 (124)	320 (108)
FEV1 (% pred), mean (SD)	54 (20)	90 (9)	64 (8)	40 (5)	25 (4)
FVC (% pred), mean (SD)	85 (20)	111 (11)	91 (14)	77 (14)	60 (15)
GOLD ABE*					
<i>Group A - Low symptom severity, low exacerbation risk</i>	109 (20%)	25 (40%)	61 (26%)	20 (11%)	3 (4%)
<i>Group B - High symptom severity, low exacerbation risk</i>	322 (59%)	31 (50%)	138 (59%)	111 (62%)	42 (57%)
<i>Group E - High exacerbation risk</i>	107 (19%)	6 (10%)	28 (12%)	45 (25%)	28 (38%)
Self-reported diagnosis of comorbidities, n(%)					
<i>Arthritis</i>	169 (31%)	28 (45%)	71 (30%)	53 (30%)	17 (23%)
<i>Osteoporosis</i>	78 (14%)	11 (18%)	28 (12%)	25 (14%)	14 (19%)
<i>Chronic heart failure</i>	72 (13%)	8 (13%)	29 (12%)	28 (16%)	7 (9%)
<i>Neurological diseases</i>	9 (2%)	5 (8%)	0 (0%)	3 (2%)	1 (1%)
<i>Diabetes</i>	83 (15%)	12 (19%)	42 (18%)	21 (12%)	8 (11%)
<i>Depression</i>	131 (24%)	21 (34%)	59 (25%)	30 (17%)	21 (28%)
<i>Anxiety</i>	95 (17%)	14 (23%)	30 (13%)	32 (18%)	19 (26%)
<i>Visual Impairment</i>	197 (36%)	25 (40%)	82 (35%)	64 (36%)	26 (35%)
<i>Hearing Impairment</i>	87 (16%)	12 (19%)	46 (20%)	25 (14%)	4 (5%)
<i>Obesity</i>	165 (30%)	14 (23%)	78 (33%)	58 (33%)	15 (20%)
Inhaled corticosteroids (ICS) monotherapy, n (%)	5 (1%)	1 (≈0%)	4 (≈1%)	0 (0%)	0 (0%)
Long-acting bronchodilator (LAMA and/or LABA) alone, n (%)	82 (15%)	11 (13%)	46 (56%)	23 (28%)	2 (2%)

Long-acting bronchodilator (LAMA and/or LABA) and ICS, n (%)	312 (57%)	23 (7%)	111 (36%)	112 (39%)	56 (18%)
Short-acting bronchodilator (SAMA and SABA), n (%)	296 (54%)	22 (7%)	115 (39%)	109 (37%)	50 (17%)
Wearable device used, n(%)					
<i>Dynaport MoveMonitor</i>	452 (82%)	41 (66%)	201 (86%)	146 (82%)	64 (86%)
<i>Axivity AX6</i>	97 (18%)	21 (34%)	34 (14%)	32 (18%)	10 (14%)
Walking aids (yes), n(%)	44 (8%)	1 (2%)	12 (5%)	17 (10%)	14 (19%)
Long-term oxygen supplementation (yes), n(%)	42 (8%)	1 (2%)	6 (3%)	12 (7%)	23 (31%)
Physical Activity Experience (C-PPAC Scores, 0-100), mean (SD)*					
<i>Amount</i>	64 (19)	73 (17)	69 (17)	61 (19)	49 (19)
<i>Difficulty</i>	72 (16)	81 (13)	76 (14)	68 (15)	60 (14)
<i>Total Score</i>	68 (15)	77 (12)	73 (13)	64 (15)	55 (14)
Diastolic blood pressure (mm Hg), mean (SD)	80 (13)	83 (10)	80 (12)	80 (14)	79 (12)
Occurrence of moderate to severe exacerbations 12 month prior to study inclusion, n (%)	178 (32%)	11 (6%)	52 (29%)	71 (40%)	44 (25%)

*Some constructs had missing values: 6 in 6-min walk distance; 15 in CAT; 25 in mMRC; 34 in Isometric quadriceps muscle torque; 7 in CPPAC; 13 in GOLD ABE; 2 in Diastolic blood pressure; 7 in BMI

Figure 6: Table to show Hip fracture cohort characteristics by fracture type

	Total n = 505	Acute n = 100 (20%)	Post Acute n = 117 (23%)	Extended Recovery n = 201 (40%)	Long Term Recovery n = 87 (17%)
Age, m (SD)	77.5 (9.4)	78.5 (8.5)	79.4 (9.3)	75.6 (9.7)	78 (9.5)
Gender, female, n (%)	329 (65%)	73 (73%)	73 (62%)	126 (63%)	58 (67%)
Marital status, married, n (%)	245 (49%)	48 (48%)	53 (46%)	105 (52%)	40 (45%)
Education, n (%)					
<i>College Degree or higher</i>	119 (24%)	19 (19%)	31 (27%)	51 (25%)	18 (21%)
<i>High school</i>	66 (13%)	21 (21%)	11 (9%)	25 (12%)	9 (10%)
<i>Less than high school (<10 yrs) / others, n (%)</i>	319 (63%)	60 (60%)	74 (64%)	125 (62%)	60 (69%)
Recruitment site, n (%)					
<i>Montpellier</i>	39 (8%)	3 (3%)	1 (1%)	21 (10%)	14 (16%)
<i>Trondheim / Oslo</i>	238 (47%)	92 (92%)	31 (27%)	83 (41%)	32 (37%)
<i>Stuttgart / Heidelberg</i>	227 (45%)	5 (5%)	85 (72%)	97 (48%)	41 (47%)
Fracture Type, n (%)					
<i>Femoral neck fracture</i>	347 (69%)	85 (85%)	74 (64%)	130 (65%)	58 (67%)
<i>Extracapsular fracture</i>	155 (31%)	15 (15%)	41 (35%)	70 (35%)	29 (33%)
Days since surgery, med (P25 – P75)	60 (23 - 140)	3 (3 - 5)	28 (23 - 35)	98 (65 - 128)	325 (234 - 352)
Functional Comorbidity Index [0-18], mean (SD)	3.3 (2.1)	3.2 (2.1)	3.2 (2.1)	3.3 (2)	3.5 (2.3)
Hearing Impairment [2-8], mean (sd)	2.9 (1.2)	3.1 (1.2)	2.8 (1.1)	2.9 (1.2)	3.1 (1.2)
Arterial hypertension [>140 mm Hg systolic BP], n (%)	184 (37%)	34 (34%)	38 (33%)	75 (37%)	37 (43%)
Walking Aids, n (%)					
<i>Indoor</i>	277 (55%)	25 (25%)	107 (91%)	115 (57%)	31 (36%)
<i>Outdoor</i>	342 (68%)	42 (42%)	109 (94%)	143 (71%)	48 (55%)
TUG in s, m (SD)	19.8 (12.3)	-	25.5 (15.7)	17.5 (9)	17.4 (11.6)
SPPB					
<i>Total score [0-12], m (SD)¹</i>	6.2 (3.1)	3.5 (2)	5.5 (2.6)	7.3 (2.8)	7.6 (3.3)
<i>Gait speed (m/s), m (SD)</i>	0.7 (0.4)	0.4 (0.2)	0.6 (0.2)	0.8 (0.3)	0.9 (0.4)
6MinWT Distance (m), mean (SD) ²	283 (125.8)	-	317.5 (131.3)	225.8 (104.5)	301.6 (124.4)
LLFDI Function, med (Q1-Q3) ²	49 (42 - 59)	-	56 (46 - 65)	43 (40 - 49)	51 (45 - 58)
Short FES-I [7-28], med (Q1-Q3)	10 (7 - 14)	10 (7 - 15)	9 (7 - 12)	11 (8 - 15)	9 (7 - 13)
FACIT-F [0-52], med (Q1-Q3)	40 (31 - 45)	36 (29 - 42)	39 (30 - 44)	41 (34 - 46)	42 (33 - 46)

C) Outcome Measures:

Figure 7: Table of study outcome measures for each disease cohort.

Cohort	Convergent Validity		Divergent Validity		Known groups	
	PROM	#DMOs meeting or exceeding a priori established correlation threshold	Clinical Measure	#DMOs under a priori established correlation threshold	Clinical Measure	#DMOs under a priori established correlation threshold
PD	LLFDI	18/24	Severity & Consistency of Tremor	24/24	H&Y Stages	14/24
Hip Fracture	LLFDI	17/24	Hearing Impairment & Arterial Hypertension	24/24	Recovery phase (Acute, post acute, extended recovery and long term recovery)	21/24
COPD	LLFDI	17/24	Diastolic BP	24/24	Gold I-V, GOLD ABE and mMRC	22/24
MS	EDSS	22/24	Systolic BP	24/24	EDSS	23/24