

Data Collection Worksheet

Please Note: The Data Collection Worksheet (DCW) is a tool to aid integration of a PhenX protocol into a study. The PhenX DCW is not designed to be a data collection instrument. Investigators will need to decide the best way to collect data for the PhenX protocol in their study. Variables captured in the DCW, along with variable names and unique PhenX variable identifiers, are included in the PhenX Data Dictionary (DD) files.

Extrapyramidal Symptom Rating Scale (ESRS)

Summary of the ESRS examination procedure

1. Patient is asked to remove their shoes (omitted if judged clinically inappropriate or when patient hesitates, or delayed after patient has walked (after # 7). The patient is asked to remove anything from their mouth (except dentures). The patient is asked to sit facing the examiner on a chair with no armrests.
2. Observe facial expressiveness, speech, and dyskinesia while completing the questionnaire and while completing items 4, 5, and 6 below.
3. Patient is asked to extend both arms forward, with palms down and eyes closed.
4. The patient is asked to carry out pronation and supination of both hands as fast as possible, and to perform rapid alternate movements of both wrists. Repeat as necessary.
5. While the patient sits facing the examiner on a chair with no armrests about 1 foot (approx. 30 cm) from a table with his upper body turned, the patient is asked to copy a spiral with each hand and to write the name of his town, province/state and country.
6. Patient is asked to walk a distance of 12-15 feet (4-5 m) away from, and then back towards the examiner. Repeat as necessary.
7. Patient is asked to stand erect with eyes open with feet slightly apart (1-2 cm). The examiner pushes the patient on each shoulder, the back and pushes the chest or pulls from the back while asking the patient to keep his balance.
8. Carry out the examination of the muscular tonus of the four limbs.

In case of doubt score the lesser severity.

I. QUESTIONNAIRE: Parkinsonism, Akathisia, Dystonia and Dyskinesia. *In this*

questionnaire, take into account the verbal report of the patient on the following: 1) the duration of the symptom during the day; 2) the number of days where the symptom was present during the last week; and, 3) the evaluation of the intensity of the symptom by the patient.

Enquire into the status of each symptom and rate accordingly

	Absent	Mild	Moderate	Severe	
1. Impression of slowness or weakness, difficulty in carrying out routine tasks	0	1	2	3	__
2. Difficulty walking or with balance	0	1	2	3	__
3. Stiffness, stiff posture	0	1	2	3	__
4. Restless, nervous, unable to keep still	0	1	2	3	__
5. Tremors, shaking	0	1	2	3	__
6. Oculogyric crisis, abnormal sustained posture	0	1	2	3	__
7. Abnormal involuntary movements (dyskinesia) of tongue, jaw, lips, face, extremities or trunk	0	1	2	3	__

II. EXAMINATION: PARKINSONISM AND AKATHISIA

Items based on physical examinations for Parkinsonism

	Occasional	Frequent	Constant or Almost So
1. Tremor			
None:	0		Right upper __

				limb	
Borderline:	1			Left upper limb	__
Small amplitude:	2	3	4	Right lower limb	__
Moderate amplitude:	3	4	5	Left lower limb	__
Large amplitude:	4	5	6	Head	__
				Jaw/chin	__
				Tongue	__
				Lips	__

2. Bradykinesia 0

normal

1

global impression of slowness in movements

2

definite slowness in movements

3

very mild difficulty in initiating movements

|__|

4

mild to moderate difficulty in initiating movements

5

difficulty in starting or stopping any movement, or freezing on initiating voluntary act

	6	rare voluntary movement, almost completely immobile	
3. Gait & posture	0	normal	
	1	mild decrease of pendular arm movement	
	2	moderate decrease of pendular arm movement, normal steps	
	3	no pendular arm movement, head flexed, steps more or less normal	_
	4	stiff posture (neck, back) small step (shuffling gait)	
	5	more marked, festination or freezing on turning	
	6	triple flexion, barely able to walk	
4. Postural Stability	0	normal	
	1	hesitation when pushed but no retropulsion	

2	retropulsion but recovers unaided	
3	exaggerated retropulsion without falling	__
4	absence of postural response would fall if not caught by examiner	
5	unstable while standing, even without pushing	
6	unable to stand without assistance	

5. Rigidity

0	normal muscle tone	Right upper limb	__
1	very mild, barely perceptible	Left lower limb	__
2	mild (some resistance to passive movements)	Right lower limb	__
3	moderate (definite difficulty to move the limb)	Left lower limb	__
4	moderately severe (moderate resistance but still easy to move limb)		

- 5 severe (marked resistance with definite difficulty to move the limb)
- 6 extremely severe (limb nearly frozen)

Items based on overall observation during examination for Parkinsonism

6. Expressive automatic movements (Facial mask/speech)	0	normal	
	1	very mild decrease in facial expressiveness	
	2	mild decrease in facial expressiveness	
	3	rare spontaneous smile, decrease blinking, voice slightly monotonous	_
	4	no spontaneous smile, staring gaze, low monotonous speech, mumbling	
	5	marked facial mask, unable to frown, slurred speech	

	6	extremely severe facial mask with unintelligible speech	
7. Akathisia	0	absent	
	1	looks restless, nervous, impatient, uncomfortable	
	2	needs to move at least one extremity	
	3	often needs to move one extremity or to change position	__
	4	moves one extremity almost constantly if sitting, or stamps feet while standing	
	5	unable to sit down for more than a short period of time	
	6	moves or walks constantly	

III. Examination: DYSTONIA

Based on examination and observation

Acute torsion,
and non-acute
or chronic or
tardive dystonia

0	absent	Right upper limb	__
1	very mild	Left upper limb	__
2	mild	Right lower limb	__
3	moderate	Left lower limb	__
4	moderately severe	Head __	Jaw/chin __
5	severe	Tongue __	Lips __
6	extremely severe	Eyes __	Trunk __

IV. EXAMINATION: DYSKINETIC MOVEMENT

Based on examination and observation

	Occasional*	Frequent**	Constant or Almost So
1. Lingual movements (slow lateral or torsion movement of tongue)			
none:	0		
borderline:	1		
clearly present, within oral cavity:	2	3	4

with occasional partial protrusion: 3 4 5

with complete protrusion: 4 5 6 |__|

2. Jaw movements (lateral movement, chewing, biting, clenching)

none: 0

borderline: 1

clearly present, small amplitude: 2 3 4

moderate amplitude: 3 4 5

but without mouth opening:

large amplitude: 4 5 6 |__|

with mouth opening:

3. Bucco-labial movements (puckering, pouting,

smacking, etc.)

none: 0

borderline: 1

clearly present, 3 3 4
small amplitude:

moderate 4 4 5
amplitude,
forward
movement of lips:

large amplitude; 5 5 6 |__|
marked, noisy
smacking of lips:

4. Truncal
movements
(involuntary
rocking, twisting,
pelvic gyrations)

none: 0

borderline: 1

clearly present, 2 3 4
small amplitude:

moderate 3 4 5
amplitude:

greater 4 5 6 |__|
amplitude:

5. Upper extremities
(choreoathetoid movements only:
arms, wrists,
hands, fingers)

0

none: 0

borderline: 1

clearly present, 2 3 4
small amplitude,
movement of one
limb:

moderate 3 4 5
amplitude,
movement of one
limb or
movement of
small amplitude
involving two
limbs:

greater 4 5 6 |__|
amplitude,
movement
involving two
limbs:

6. Lower extremities
(choreoathetoid movements only:
legs, knees,
ankles, toes):

none: 0

borderline: 1

clearly present, 2 3 4
small amplitude,
movement of one
limb:

moderate 3 4 5
amplitude,
movement of one
limb or
movement of
small amplitude
involving two
limbs:

greater 4 5 6 |__|
amplitude,
movement
involving two
limbs:

7. Other
involuntary
movements
(swallowing,
irregular
respiration,
frowning,
blinking,
grimacing,
sighing, etc.)

none: 0

borderline: 1

0: absent	3: mild	6: marked
1: borderline	4: moderate	7: severe
2: very mild	5: moderately severe	8: extremely severe

VIII. CLINICAL GLOBAL IMPRESSION OF SEVERITY OF AKATHISIA

Considering your clinical experience, how severe is the akathisia at this time?

0: absent	3: mild	6: marked
1: borderline	4: moderate	7: severe
2: very mild	5: moderately severe	8: extremely severe

Scoring:

Questionnaire for Parkinsonism, akathisia, dystonia and dyskinesia:

- Each item is rated on a four point scale (0 = absent; 3 = severe). For subjective extra-pyramidal symptoms, severity is assessed over the last seven days and persistent symptoms are rated for the most typical day over the last seven.

Examination for Parkinsonism and akathisia (subscale II):

- Tremors and rigidity are scored on a seven-point scale (0 = none; 6 = severe) for each body part. Ratings for tremors account for amplitude and number of times the movement occurs during the interview.
- Total scores range from 0-102.
- A score of 3 or greater on any of the items is required to establish Parkinsonism for initiation of anti-Parkinsonism treatment.
- A score of 2 on 2 items or a score of 3 or greater on one item is required to establish the presence of Parkinsonism.
- Hypokinesia subscale scores (ranging from 0-42) are calculated from gait and posture, rigidity, expressive automatic movements, and bradykinesia.
- Hyperkinesia subscale scores (ranging from 0-54) are calculated from tremor and akathisia items.

Examination for dystonia:

- Acute and chronic movements are scored on a seven point scale (0 = none; 6 = most severe). Each body part is rated separately.
- Dystonia scores range from 0-60 and includes both acute and chronic dystonia.
- A score of three or greater on at least one item or a score of 2 on 2 items is required for presence of dystonia.

Examination for dyskinesia:

- Movements are scored on a seven-point scale (0 = none; 6 = severe) for each body part. Ratings account for amplitude and number of times the movement occurs during the interview.
- Dyskinesia scores range from 0-42 and is the total of all seven items.
- A score of three or greater on at least one item or a score of 2 on 2 items is required for presence of dyskinesia.
- Tardive dyskinesia subscale scores for each item separately
- Buccal-lingual-masticatory subscale is the total (0-18) from items 1, 2, 3 and an extremities score (0-12) from items 5 and 6.

Total Score:

- A total DMID score can be derived by adding together all 41 items.

Clinical global impressions of severity of Parkinsonism, akathisia, dystonia, and tardive dyskinesia:

- Results are rated according to results of the subjective questionnaire, examination subscales, and the evaluator's clinical experience by applying an 8-point rating (0: absent; 1: borderline; 2: very mild; 3: mild; 4: moderate; 5: moderately severe; 6: marked; 7: severe; 8: extremely severe).
- The 4 clinical global impressions of severity subscales are analyzed as separate items.

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Protocol source: <https://www.phenxtoolkit.org/protocols/view/661601>