Quality control questionnaire for limited use of psychedelics

Psychedelic-assisted therapy (PAT) is possible in Switzerland with an authorization of the Federal Office of Public Health (FOPH). PAT is not a standard treatment and controlled substances are used. Therefore, documentation of efficacy and tolerability is needed. A minimal data set should be collected for each patient. The FOPH requests a report at the end of each treatment period. Additionally, the present quality control survey is conducted by the University Hospital Basel in collaboration with the Swiss Medical Association for Psycholytic Therapy (SÄPT).

Kindly complete the questionnaire **once for every patient at the end of each FOPH authorization after a maximum of one year**. **Please complete one report for each substance.**

Please send the completed questionnaire (**one per patient and substance/authorization**) as Word or PDF or scan via mail or e-mail to Prof. Dr. med. Matthias Liechti (Matthias.liechti@usb.ch), Klinische Pharmakologie, Universitätsspital Basel, Schanzenstrasse 55, 4056 Basel.

Date:

Name of treating physician: _____

☐ First authorization/first treatment

☐ Extension of existing authorization/treatment

A. PATIENT CHARACTERISTICS:

Year of birth: _____

Biological sex: male ☐ female ☐

Diagnosis (treatment reason):
_____

Secondary Diagnoses (max. 3):
_____
_____
_____

Current psychopharmacological medication:

_____ paused before session: No ☐ Yes ☐

_____ paused before session: No ☐ Yes ☐

_____ paused before session: No ☐ Yes ☐

_____ paused before session: No ☐ Yes ☐

B. SUBSTANCE AND ACUTE EFFECTS:

Substance (choose only one):

☐ MDMA: Dose (min-max) _____ - _____ mg

☐ Psilocybin: Dose (min-max) _____ - _____ mg

☐ LSD: Dose (min-max) _____ - _____ µg

Number of sessions (during the approved treatment period of max. 12 months): _____

Session as single patient: No ☐ Yes ☐

Mostly single-patient sessions: No ☐ Yes ☐

Group sessions: No ☐ Yes ☐

Mostly group sessions: No ☐ Yes ☐

Duration of treatment (during the <u>current</u> approved treatment period of max. 12 months): _____ months

Total duration of treatment (all authorizations/extensions): _____ months

Acute effects of substance (<u>average</u> of all sessions):

Any acute effect, on scale of 0-10 (0 = no effect, 10 = maximal effect): _____

Acute effect was good/positive, on scale of 0-10 (0 = not at all, 10 = maximal): _____

Acute effect was bad/negative, on scale of 0-10 (0 = not at all, 10 = maximal): _____

C. CLINICAL GLOBAL IMPRESSION (CGI) (<u>for all diagnoses overall)</u>

1. Severity of illness (prior to PAT) Considering your total clinical experience with this particular population, **how (mentally) ill was the patient before the start of the current treatment (max. 12 months)?**	**2. Global Improvement (change after PAT)** How has the patient's condition **overall** changed (i.e., not just as result of the substance treatment). **Please compare the patient's current condition with that at the start of the treatment under the current authorization (max. 12 months)** and indicate the extent to which the patient's condition has changed during this period.
☐ cannot be determined	☐ cannot be determined
☐ normal, not at all ill	☐ very much improved
☐ borderline (mentally) ill	☐ much improved
☐ mildly ill	☐ minimally improved
☐ moderately ill	☐ no change
☐ markedly ill	☐ minimally worse
☐ severely ill	☐ much worse
☐ among the most extremely ill patients	☐ very much worse

3. Efficacy Index

Assess the therapeutic effect of the treatment (substance effect) and associated side effects **during the current treatment period of max. 12 months.**

3.1. Therapeutic Effect	**3.2. Side effects**
☐ cannot be determined	☐ cannot be determined
☐ marked - vast improvement. Complete or near complete remission of all symptoms.	☐ none
☐ moderate - decided improvement. Partial remission of symptoms.	☐ do not significantly interfere with patient's functioning
☐ minimal - slight improvement which does not alter status of care of patient.	☐ significantly interfere with patient's functioning
☐ unchanged or worse	☐ outweigh therapeutic effect

D. SPECIFIC SIDE EFFECTS (during the current treatment period of max. 12 months).

			Severity (1-3)
Headache (on treatment day):	No ☐	Yes ☐	_____
Nausea (on treatment day):	No ☐	Yes ☐	_____
Heart palpitations/chest pain (on treatment day):	No ☐	Yes ☐	_____
Sleep problems (on treatment day or day after):	No ☐	Yes ☐	_____
Anxiety/panic (on treatment day):	No ☐	Yes ☐	_____
Psychologically Destabilized* (within 1 month of session):	No ☐	Yes ☐	_____
Suicidal thoughts (within 1 month of session):	No ☐	Yes ☐	_____
Suicidality (elaborate planning/attempts; anytime):	No ☐	Yes ☐	_____
Flashbacks** (anytime)	No ☐	Yes ☐	_____

(* increased anxiety, irritability, depression, etc; ** short (seconds-minutes) recurrences of positive or negative elements of the substance experience)

Any other side effects? If yes, please indicate:

_____
_____
_____
_____
_____
_____