



**Belgian Association
of Phase 1 units**

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BAPU Survey: Payment of Patients in Phase 1?

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Would you as an **investigator** consider a patient fee/financial compensation for following trials ?

	Fully agree	Rather agree	Neutral	Rather disagree	Completely disagree	Not applicable
1. FIH, first in class for patients in general	4	0	0	0	0	1
2. FIH, first in class for oncology patients in particular	2	0	0	0	0	3
3. FIH, non-first in class for patients in general	4	0	0	0	0	1
4. FIH, non-first in class for oncology patients in particular	2	0	0	0	0	3

Would you as an **investigator** consider a patient fee/financial compensation for following trials ?

5. Expansion phase after phase I dose escalation (same protocol), FIH first in class for patients in general	3	1	0	0	0	1
6. Expansion phase after phase I dose escalation (same protocol), FIH first in class for <u>oncology</u> patients in particular	1	1	0	0	0	3
7. Expansion phase after phase I dose escalation (same protocol), FIH non-first in class for patients in general	2	1	1	0	0	1
8. Expansion phase after phase I dose escalation (same protocol), FIH non-first in class for <u>oncology</u> patients in particular	1	0	1	0	0	3
9. FIH of new combination of known IMPs already on the market; drugs known and reimbursed for the indication tested in	1	1	1	0	0	1

Would your **ethics committee** consider a patient fee/financial compensation for following trials ?

	Fully agree	Rather agree	Neutral	Rather disagree	Completely disagree	Not applicable
1. FIH, first in class for patients in general	2	1	1	0	0	1
2. FIH, first in class for oncology patients in particular	1	1	0	0	0	3
3. FIH, non-first in class for patients in general	2	1	1	0	0	1
4. FIH, non-first in class for oncology patients in particular	1	1	0	0	0	3

Would your **ethics committee** consider a patient fee/financial compensation for following trials ?

5. Expansion phase after phase I dose escalation (same protocol), FIH first in class for patients in general	2	1	1	0	0	1
6. Expansion phase after phase I dose escalation (same protocol), FIH first in class for <u>oncology</u> patients in particular	1	1	0	0	0	3
7. Expansion phase after phase I dose escalation (same protocol), FIH non-first in class for patients in general	2	1	1	0	0	1
8. Expansion phase after phase I dose escalation (same protocol), FIH non-first in class for <u>oncology</u> patients in particular	1	1	0	0	0	3
9. FIH of new combination of known IMPs already on the market; drugs known and reimbursed for the indication tested in	1	1	1	0	1	1

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What is a phase I clinical trial?

- **Phase I trial (Belgian Law):**

*“trial performed on **healthy volunteers** or on **certain types of patients without therapeutic objectives** which covers one or more of the following aspects: estimation of initial safety and tolerability, pharmacokinetics, pharmacodynamics, early measurement of drug activity” (Art 2, 12°).*

Clinical trials of an IMP that do not benefit subjects - whether they be healthy subjects or patients - are called phase 1 or non-therapeutic trials.⁷

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Questions

- Why are patients in general rarely reimbursed in phase I / FIH trials?
- Why should a distinction be made between healthy volunteers and patients in general?
- Why should a distinction be made between patients in general and oncology patients?
- As efficacy is no primary endpoint in phase I/FIH trials: should reimbursement be considered ?
- If patients are reimbursed, do the same principles apply as for healthy subjects?
- ...