Ahus - Accounting and use of the health company's income from innovations and clinical commissioned studies

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The deadline for revision of this document has passed, but the document is still valid.

1.0 Purpose

The guideline aims to ensure predictable terms for handling revenues and costs related to commercial collaboration with industry in the areas of innovations and clinical commissioning studies. The previous arrangement of establishing transferable funds at Inven2 is no longer permitted.

2.0 Scope

The guideline applies to all new revenues in ongoing and new clinical commissioning studies and innovations from January 1, 2019. The special arrangement for the liquidation of previous research funds at Inven2 and the phasing in of fund funds to Ahus from January 1, 2019 is handled according to the rules described in the guideline Ahus - Accounting and use of funds from transferred Inven2 funds (EQS ID 32440), and is not covered by this guideline 1.

3.1 Job description/ Action

3.2 Clinical assignment studies

Before starting a study, there should be a budget for the entire study period. For clinical commissioning studies, Inven2 will prepare a budget template that is sent to the project manager with coordinators for clinical studies, in the research support department, Research and Innovation Division (FID) in copy. The budget for the study is prepared in collaboration with coordinators for clinical studies, who assist the project manager with cost estimation and filling in the budget template for the study.

The following costs should be incorporated into the budget:

1. All costs in the performing department including salary costs for everyone involved. For clinical commissioning studies, the budget template will estimate the time spent by study physician(s) and study nurse(s) and other study personnel based on established hourly rates from Inven2. The visit costs based on the time spent by study personnel are set up per patient per visit and depend on the follow-up the study patient should have at the various visits.
2. Procedure costs and other counting costs that are not included in the visit prices or may occur outside of planned visits, e.g. follow-up of Serious Adverse Events, unplanned visits, etc.
3. Costs for assistance from other units in the hospital (e.g. imaging diagnostics, pathology, lab).
4. Studies should normally be budgeted at 0 or with a positive result 1.

Handling of revenues and load of costs:

1. The departments have a separate research cost center where revenues from clinical contract studies are accounted for.
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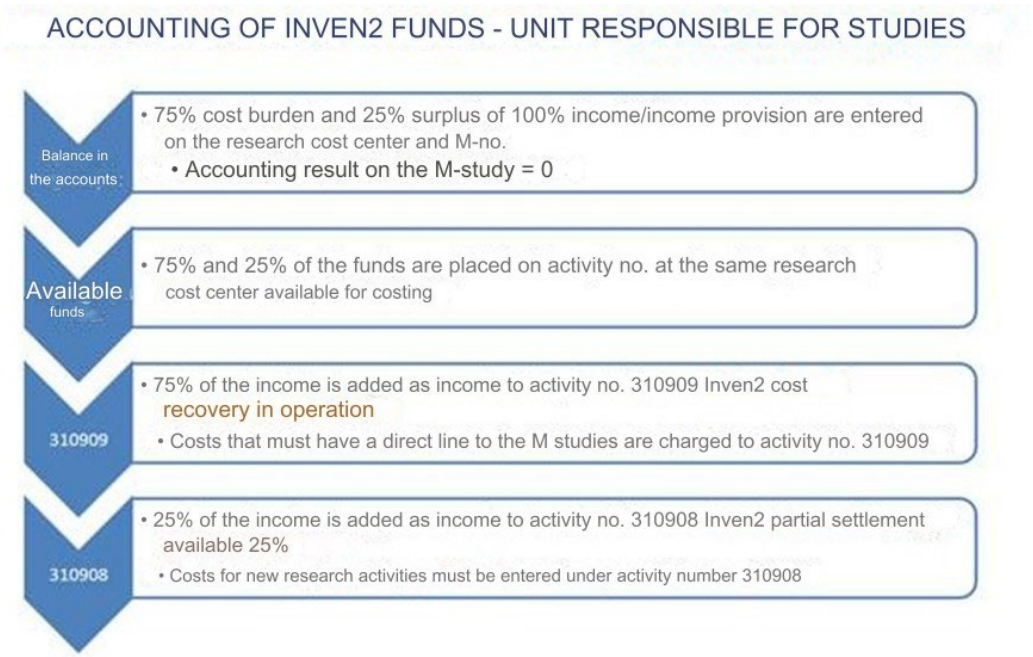
3. Both the Finance Department and the Research Support Department will be able to extract the financial status of the study's project number. It is also possible to check the balance in QlikLis by searching for the study's M-number. Accounting overviews for M-project numbers are available at K:\Ahus alle\Felles lagringsområde\Forskning\Økonomi kliniske studier\Regnskapsoversikter.
4. The project manager at Ahus submits a completed progress report to Inven2 twice a year, where Inven2 prepares an invoice basis for the industry/sponsor based on the performed study activity.
5. Inven2 invoices the industry/sponsor for the performed study activity from the hospital.
6. Twice a year, a settlement/partial settlement is made against Inven2. This happens at the beginning of January and the beginning of July each year. Then the income in the study is transferred from Inven2 to Ahus with a balance as of December 31 and June 30. In addition to the partial settlements, other months use VAT returns and portfolio reports as a basis for making provisions for income, 75% cost burden and 25% profit.

7. Coordinators for clinical studies quality assure payment to participating departments based on internal agreements entered into. The project manager must ensure that all reported activity done by the participating department is registered in the progress report. The Controller for FID ensures the transfer of funds to participating departmental cost centers.
8. When the partial settlement from Inven2 arrives, 100% of the income is booked to the unit responsible for the study at the research cost center. It has been found difficult to charge detailed actual costs on clinical studies, so it has been decided that costs on the study should always constitute 75% of the total income for each individual project number. Therefore, costs that amount to 75% cost burden and 25% profit are booked at the same time as the income is recorded at the same research cost center. The accounting result on the project number will thus be in balance. The controller for FID ensures that this cost burden is entered at the same time as the income is entered.
9. Simultaneously, guidance is provided in the accounts on the same research cost center, where 75% cost recovery and 25% profit are available as an income on activity no. **310909 Inven2 cost recovery in operation** and activity no. **310908 Inside2 partial settlement to disposition 25%.**
10. There is no occasion to lead costs directly on project number for M-study.
11. Research costs shall have one direct line to The M studies charged activity no. 310909 **same year as the income is carried**.
12. The remaining 25% of the income from Inside2 is considered as a profit on the study. Total annual surplus funds must be planned and used for new research purposes **within a reasonable time**. Costs for new research activity must be entered under activity number 310908.
13. The department manager disposes, plans, and approves the use of the funds. The controller unit will monitor the level of surplus and contribute to making plans for the disposal of the funds.Participating units receive their income based on the activity per patient in each individual study as reported by the project manager in connection with progress reporting to Inven2. Participating units receive 100% revenue recognition at their respective research cost center and project number 000000. There is no 75% cost burden and 25% profit of the income recorded for participating units. It is possible to record the income from clinical studies on a separate cost center to assess whether the income exceeds actual costs and use any difference for research-related activities. Participating units have the option to use activity number 310909 to record such research-related costs to more easily distinguish costs.

Figure as illustrates accounting of Inside2 funds:



3.3 Innovation revenue

Ahus has a framework agreement with Inven2, which is a Technology Transfer Office (TTO) for securing intellectual property rights and commercializing/developing inventions. The framework agreement stipulates that Inven2 has the right to 1/3 of all net income from commercialization. The framework agreement does not specify the distribution of income beyond the share to Inven2. The Employee Inventions Act states that the inventor shall receive reasonable compensation for the employer's acquisition of rights to the invention, and Inven2 applies the "3-part principle": 1/3 to TTO, 1/3 to inventors, and 1/3 to the employer. This is the basis for internal distribution of income from innovation processes.

Innovation gains are recognized as usual and cannot be placed in a fund that is transferred to another year. Ahus will distribute its one-third share of total innovation gains according to the following principles:

- In cases where the annual third to Ahus is ≤10 million NOK: 50/50 sharing between the central unit (FID) and the department(s) that produced the invention.
- In cases where the annual third to Ahus >10 million NOK: The hospital management administers funds over 10 mill/year, but with follow-up responsibility for Finance, which should involve FID and the department(s) that produced the invention to strengthen research and innovation at Ahus.

It is assumed that when establishing an innovation policy at Ahus, a closer look will be taken at the distribution of employer's innovation income (1/3).

4.0 Related documents

ID 32440 A house - Accounting and use of funds from transferred Inside2 fund.

6.2 Definitions

By Ahus' innovation revenue, the hospital's share of net profit from innovations that the enterprise should dispose of is meant.

By clinical commissioning studies, assignments from commercial partners, usually the pharmaceutical industry, where the industry owns the protocol for the study, takes care of the sponsorship responsibility, retains the rights to the results of the study, and simultaneously finances the study. If commercial partners provide financial contributions (i.e. co-financing) for the implementation of studies, the income is handled according to this guideline when the contribution is negotiated by Inven2, with the adjustments that follow from the budgeting of these studies.