CTU price examples for services delivered in a clinical trial as per 27. Mar. 2023

The costs of monitoring services are based on a national fixed hourly rate, agreed by the clinical research support units at Haukeland University Hospital, St Olav's Hospital / NTNU, University Hospital of North Norway and Oslo University Hospital.

The national prices can be found at NorCRIN's web pages.

The examples are indicative and have been established on the basis of our growing experience. In the early phase of a budget process, we recommend that some uncertainties be taken into account, e.g. extended inclusion time, need for protocol changes, expansion of number of sites, etc.

Example I – CTU makes the eCRF

Simple study, up to 10 PROM instruments, assuming **12 centers and a duration of 2 years**. ViedocMe used for patients self-reporting. Number of patients < 1000, and unlimited number of study site personnel entering data.

Viedoc set-up with automatic checking of the data and notifications to study participants and site personnel.

The study team takes care of data validation, coding, data export and site support.

Service	Includes	Budget total (NOK)	Budget per year (NOK)
Datahåndtering	Viedoc license	Viedoc license 48.000	Viedoc: 24.000 per year
	Set-up of eCRF/PROMs Approx. 20 hours	17.600	17.600 – First year
Sum		65.600	

Example II – CTU makes the eCRF

Simple study, up to 10 PROM instruments, and up to 10 other forms for collecting clinical data. Assuming **4 centers and a duration of 6 years**. ViedocMe used for patients self-reporting. Number of patients < 1000, and unlimited number of study site personnel entering data.

Viedoc set-up with automatic checking of the data and notifications to study participants and site personnel.

The study team takes care of data validation, coding, data export and site support.

Service	Includes	Budget total (NOK)	Budget per year (NOK)
Datahåndtering	Viedoc license	Viedoc license 36.000	Viedoc: 6.000 per year
	Set-up of eCRF/PROMs Approx. 40 hours	35.200	35.200 – First year
Sum		71.200	

Example III

Simple study with one site, 40 patients, 2 years duration

Service	Details	Budget in total (NOK)	Budget per year (NOK)
Monitoring	Initiation, 3 monitoring visits and some travel expenses	120 000	60 000
Data management	Viedoc license, eCRF programming, data collection and validation and delivery of a complete data set	Viedoc license 25 000 240 000	Viedoc license 12 500 120 000
Statistics	Sample size calculation, statistical analysis plan, analyses, programming and publication	340 000	170 000
In total		725 000	365 000

Example IV

Complex study with 4 sites, 80 patients, 6 years duration

Service	Details	Budget in total (NOK)	Budget per year (NOK)
Monitoring	Initiation and 6 monitoring visits at each site, no travel expenses because local monitor is monitoring at each site	750 000	125 000
Data management	eCRF programming, data collection and validation, Data Monitoring Committee and delivery of a complete data set	Viedoc license 66 000 600 000	Viedoc license 11 000 100 000
Statistics	Sample size calculation, statistical analysis plan, analyses, programming and publication, no DMC	340 000	170 000 First and last year of the project
In total		1 760 000	293 000 (average)

Example V

Simple study with 12 sites, 120 patients, 4 years duration

Service	Details	Budget in total (NOK)	Budget per year (NOK)
Monitoring	Initiation, 3 monitoring visits at each site and some travel expenses	1 110 000	275 000
Data management	eCRF programming, data collection, data monitoring committee and validation and delivery of a complete data set	Viedoc license 95 000 520 000	Viedoc license 24 000 130 000
Statistics	Sample size calculation, statistical analysis plan, analyses, programming and publication DMC included	380 000 Incl. DMC: 40 000 NOK	190 000 First and last year of the project (incl. DMC)
In total		2 100 000 (Incl. DMC)	525 000 (average, incl DMC)

What drives the costs?

The table below gives an indication of the major cost drivers when budgeting different services from the CTU.

Factor	Monitoring	Data management	Statistics
# sites	X	X	
# patients		X	
# monitoring visits per site	X		
Travel expenses	X		
Year of duration	X	X	
Complexity		X	X
Number of endpoints		X	X