

b UNIVERSITÄT BERN

# Annual Report 2021 CTU Bern





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Foreword

### July 2022

CTU Bern's main aim is to improve the quality of clinical research with a focus on academic projects. We are considered a Core Facility of the University and as such a publicly funded research infrastructure. Among research infrastructures, it is now uncontroversial that a systematic performance monitoring should be in place. This not only allows for an assessment how well the infrastructure achieves its objective but also helps to continuously improve.

Key Performance Indicators (KPIs) are an important aspect to achieve this goal. The process of analyzing and interpreting CTU Bern's KPIs is formalized in what is called annual Quality Management Review (QMR). CTU Bern's indicators aim to measure quality related to processes and allow deriving actions and adequate measures of improvement as needed. This Annual Report summarizes our effort and makes it transparent to the public. It also provides an overview of CTU Bern's last year activities.

Sven Trelle

### Introduction

CTU Bern's performance evaluation aims to measure quality related to processes and allows deriving actions and measures of improvement as needed. The evaluation is based on CTU Bern's internal Key Performance/Process Indicators (KPIs). CTU's KPIs are defined in a designated SOP "Quality Management Review" and its Appendix "Key Performance Indicators CTU Bern".

The indicators cover a variety of topics. For some, quantitative goals are defined and certain thresholds pre-specified that indicate whether actions are needed. For others, a qualitative assessment is deemed more appropriate. The following three main areas are evaluated:

- Continuous Development
- Process Performance and Conformity of Products and Services
- Institute Performance and Visibility

Each area has multiple indicators that allow evaluating the performance over the year as well as compared to previous years.

The displayed results cover the period of January – December 2021.

#### **KPI Evaluation**

Each KPI is evaluated using a quantitative or qualitative assessment and measured against a threshold defined for each KPI.

To exhibit the KPIs evaluation results, a color-coding system is used, displaying the KPI status compared to its threshold. The following color codes apply.

≥80% (green) or qualitative evaluation <80% (yellow) or qualitative evaluation ≤50% (red) or qualitative evaluation



### CTU Performance – KPI Summary 2021

## KPI 2021 **Continuous Develop Quality Objectives** Significant Changes Adequacy of resources (finances, overtime, si **Process Performance** Nonconformities, Erro Internal Audit Compli Risks and Opportunitie Customer satisfaction Institute Performance Institute Performance Teaching / GCP Course Scientific Output and External Audit Compli

ly working.

(CAPA) are raised.

**CTU Bern** 

	Status					
oment of CTU Bern						
s and working environment ck leave, resignations)						
e and Conformity of Services						
ors & CAPA						
ance						
es						
(Consulting and Services)						
ce and Visibility						
(Consulting and Projects)						
es						
Grants						
iance						

### 2021 KPI results demonstrate that the CTU QMS is adequate-

#### Actions and measures for improvement

Any improvement measures based on the KPI evaluation are identified during the annual quality management review. Measures are defined as action items and appropriate Corrective Actions and Preventive Actions



## **KPI Evaluation**

Continuous Development CTU

Process Performance and Conformity of Products and Services

Institute Performance and Visibility

### Continuous Development CTU

To measure and facilitate CTUs continuous development, the achievement of quality objectives, the management of internal and external changes impacting the CTU and the adequacy of available resources (financial and staffing) and work environment are evaluated.



### **Quality Objectives**

CTU Quality Objectives are defined once per year for the next 12 months and define specific actions to further develop CTU Bern's Quality Management System. The indicator measures the capacity of CTU Bern to determine and implement quality objectives, which allow continuous development and improvement of CTU Bern.

The 2021 Quality Objectives focused on the CTU Bern QMS restructuring in regards to the new Department of Clinical Research (DCR) and on the data protection evaluation on Data Management and Statistic processes in alignment with standards defined by the European Clinical Research Infrastructure Network (ECRIN).

#### KPI achievement

Out of the two identified Quality Objectives for 2021, one has been closed with 100% completion and the second one, related to the development of a CTU data protection policy, continued in a CAPA.

#### **CTU Quality Objectives 2021**



### Significant Changes Impacting CTU

This KPI is defined to create awareness and facilitate a proactive management of internal and external changes and their impact on CTU quality management system. Furthermore, it is used to illustrate trends regarding internal and external changes, allowing adequate actions to be implemented.

In 2021, six internal and two external changes were identified, which had a direct impact on CTU structures and its processes:

Month	Source of change	Торіс		
February	CTU Process (internal)	Replacement of paper task delegation log (TDL) with electronic system		
May	Regulations (external)	EU MDR in force, Switzerland adapting its legislation		
May	Guidelines (external)	Publication of new Code of Conduct for Scientific Integrity by the Swiss Academies for Arts and Sciences		
July	CTU Structure (internal)	Leaving of Deputy Director CTU		
August	CTU Process (internal)	Implementation of a new Document and Trainingsmanagement Software (ORCA)		
September	CTU Service (internal)	Potential REDCap terms and conditions issue		
November	CTU Structure (internal)	Leadership and responsibility changes in divisions Clinical Study Management and Monitoring		
December	CTU Structure (internal)	Structural and managerial changes related to DCR, CTU and CIU		



### Actions Database for TDL created; creation of corresponding SOPs, WIs Staff training, amendment of CTU controlled documents Amendment of respective CTU controlled documents Operational deputation in place via CTU Heads; Organigram and Homepage update Amend document and training management, adapt SOPs, train staff Clarifications with University legal department and Vanderbilt University, Adaptation of REDCap light service Updated organigram to illustrate functions and shared responsibilities for Regulatory Affairs processes and consulting; controlled document ownership and codes updated Alignment and implementation of quality documents reflecting the structure and procedures of the new department DCR and units CTU and CIU



Compared to 2020 more internal changes were identified and implemented. All changes were managed in accordance with the CTU internal processes and respective measures defined and executed to ensure timely and adequate implementation of the change. Two relevant external changes impacting on CTU Bern are worth mentioning: 1) the Medical Device Regulation entered into force in the European Union and, 2) the Swiss Academies of Arts and Sciences published a new Code of Conduct for Scientific Integrity. The first mainly impacts on future trials and will impact on Swiss regulation of device trials, the second mainly affects internal training.

#### CTU internal and external significant changes



### **Resources & Working Environment**

Financial aspects, overtime, sick leave and resignation reasons are evaluated as proxies to assess the adequacy of available resources in regard to the working environment.

#### **KPI Result – Finances**

CTU Bern aims for financial independence beyond the core funding that it receives from the University and Inselspital Bern. A small financial reserve is required to achieve this. All accounts of CTU Bern have a positive balance but project income was not sufficient to build the (internally) pre-defined financial reserve.

#### **KPI Result – Overtime**

The assessment of CTU overtime is used as indicator to measure sufficient staffing and stress and any negative relation to the working environment at CTU. The benchmark for 2021 relates to the UniBe regulation, allowing a max. of +/-100 hours overtime and the internal CTU regulation for vacations to be carried over to the next year. As a consequence, the 2021 threshold was set at 141.2 hours overtime at the end of the year i.e. none of the staff members should accumulate overtime above this threshold.

#### **Overtime**



32% of all CTU staff accumulated more than 141.2 hours of overtime at the end of 2021. It is to be noted, that in previous years the benchmark was set remarkable higher to 182.4 hours (100 overhours + 82.4h vacation), thus the noticeable raise in employees above the benchmark in 2021. To further monitor and reduce accumulated overtime, specific measures such as reduction planning and aiming to evenly spread workload amongst staff members have been agreed for 2022 and will be monitored throughout the year.

#### **KPI Result – Sick Leave**

The mean and median absence rate is benchmarked against the Federal Office of Statistics (FSO) annual figure of 2.4% (Swiss-wide absence rate in the applicable work sector).

In 2021, CTU is below this benchmark with a mean of 2.2%. The median absence rate of 0.6% indicates that the distribution of absence rate is not normally distributed: 9% of employees (N=5) accumulated an absence rates of  $\geq$  4.6%. Overall the KPI remains below target, with specific sick leaves being addressed on an individual basis.

### KPI Results – Resignation Reasons

Reasons for resignation are reviewed to ensure that resignations are not related to the working environment (stress, supervision, etc) to ensure that CTU Bern remains an attractive employer.

### **Reasons for resigning 2021**



The 2021 results showed a total of 9 resignations, of which two were further assessed. CTU Bern is continuing to monitor the resignation reasons throughout the coming review period.

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### Process Performance and Conformity of Services

CTU Bern assesses the adequacy of internal improvement measures. For this purpose, internal non-conformities, errors, corrective and preventive action due dates are evaluated. In addition, the conduct of the annual internal audits is verified according to a predefined audit plan.

The assessment of CTU risks and opportunities allows defining mitigation actions aiming at reducing the risk exposure, subsequent occurrence of errors and improvement of overall process performance and customer satisfaction.

94%

### Non-Conformities, Errors and CAPA

In order to evaluate any issues arising at CTU and to verify the effectiveness of corrective and preventive actions (CAPAs) taken, the figures and closure rate of any CAPAs are evaluated over the year.

#### **KPI Result – Errors**

A total of 14 Errors and 1 Near-Error have been raised in CTU Bern's internal error management system in 2021 in the below listed areas. Compared to 2020, 6 Errors and 1 Near-Error more had been raised, which is considered a significant increase. However, as CTU Bern promotes a positive error culture and encourages its staff to report any identified issues, an increase in errors per se is not considered problematic. Investigation of the errors indicated that low quality work was not the reason for the increase.

Main Areas	# of Errors / Near-Error
Datamanagement	7
Admin	2
Clinical Study Management	1
Monitoring	1
Management	1
Quality Management	1
IT	1

#### **KPI Result – CAPA**

The CTU goal of closing CAPA within their individually defined timeframe has been met. However, various open CAPA of the upcoming QMR period already indicate an overdue closure date. As such, respective measures to further minimize the overdue closure of upcoming CAPAs, have been taken.

#### CTU CAPA opened, closed, extended and overdue



### Internal Audit Compliance

This KPI measures CTU's capacity to determine and conduct internal audits in accordance with an annual audit plan. By assessing the results, this gives an indicator how well CTU ensures adherence to internal processes and facilitates continuous development and improvement.

#### **KPI Result**

A total of 3 internal audits in 3 different divisions were planned and executed in 2021, resulting in a 100% compliance to the 2020 plan. Each audit assessed the divisions compliance with internally regulated processes and defining CAPAs where deviations occurred.



The following observations have been identified during the internal audits:

Observations	Statistics (interim analysis)	CTU Project Coordination	Central Data Monitoring	Total
Recommendations	1	-	1	2
Minor Observations	1	1	1	3
Major Observations	1	3	1	5
Critical Observations	_	_	-	-
Resulting Corrective & Preventive Actions (CAPA)	2	3	2	7

### **Risks and Opportunities**

CTU Bern has a structured Risk Management System. Risks are documented in a Risk Register and reviewed to allow awareness and illustrate the proactive management of risks and opportunities and their impact on CTU Bern and its Quality Management System.

#### KPI Result

The CTU Risk Register is reviewed annually and the adequacy of the defined risks compared to identified errors or issues noted during internal audits. If necessary, risks are adapted, removed or new ones added. A slight increase of risks compared to 2020 was identified. New risks were raised for the Clinical Study Management (CSM) division and included in the Risk Register.

#### Number of risks per CTU division



### Customer Satisfaction

This KPI looks at the evaluation and if applicable improvement of customer satisfaction regarding CTU's consulting and service quality, availability/accessibility, response time and friendliness of CTU staff members, as well as the price/performance ratio.

#### KPI Result

Overall, customers are very satisfied with the consulting (90.2%) and project services (100%). A general area of concern remains the perceived high pricing of CTU services.

#### Feedback from consultings





#### **Project feedback**



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### Institute Performance and Visibility

CTU Bern's main aim is to improve clinical research activities of researchers at the University of Bern and Inselspital by providing respective support. To this end, KPIs look into quantitative aspects of provided services and whether these services are provided to the whole spectrum of the Faculty of Medicine.



### Institute Performance – Consultings

Consulting with researchers is a significant aim of CTU Bern. The KPI indicates if this objective is met and that CTU serves all internal institutions (and not only a selection). In 2021 CTU Bern had an increase in consultings of 9.6% as compared to the previous year.

#### CTU consultings conducted in 2021 with Inselspital clinics



### CTU consultings conducted in 2021



Development of consultings over time



#### **KPI Evaluation**

### +2.2%

### Institute Performance – Projects

Supporting clinical research projects is a main aim of CTU Bern and a main source of income. The KPIs indicate trends in the main service area and if sustainability and achievement of the main objective of CTU Bern are reached.

In 2021, CTU project support increased by 2.9%, considering there was a decrease of 11% in 2020.

#### CTU supported projects in 2021







#### Number of projects per institution

Kardiologie Neurologie Allgemeine Innere Medizin Hämatologie und Hämatologisches Zentrallabor Frauenheilkunde · Medizinische Onkologie Viszerale Chirurgie und Medizin -Endokrinologie, Diabetologie und Klinische Ernährung Nephrologie und Hypertonie Universitäres Zentrum für Palliative Care Augenheilkunde Geriatrische Universitätsklinik Intensivmedizin Kinderheilkunde · Neurochirurgie -Urologie Angiologie Dermatologie Diagnostische und Interventionelle Neuroradiologie Herz- und Gefässchirurgie Insel Data Science Center Nuklearmedizin · Orthopädische Chirurgie Plastische- und Handchirurgie Schädel-, Kiefer- und Gesichtschirurgie Thoraxchirurgie Institute of Social and Preventive Medicine (ISPM) Berner Institut für Hausarztmedizin (BIHAM) Institut für Infektionskrankheiten Institut für Komplementäre und Integrative Medizin Universitäre Psychiatrische Dienste -ARTORG Center for Biomedical Engineering Research -Department for BioMedical Research Institut für Psychologie Klinische Psychologie und Psychotherapie Theodor Kocher Institut (TKI) External non-profit External for-profit

#### **KPI Evaluation**



Focus CTU projects 2020 (IMP, MD, sample/data collection, further use or other)







### Teaching / GCP Courses – Participants & **Course Quality**

Further education is one way by which CTU Bern tries to improve quality of clinical research. Attendance to courses provided by CTU is an indicator of acceptance by local researchers and evaluation by participants is the main measure to quantify quality of the courses provided.

#### **KPI Results**

The KPI is measured by evaluating the attendance rate of the current year compared to the median of the previous three years. The below result shows a slight drop in attendance of the basic and advanced GCP courses (-11% and -4%). Attendance to the GCP Refresher course continues to increase (+48%) in 2021. This is positive confirmation for the re-established course in 2020, which continues to be offered twice a year as an online course.

### Number attendees in CTU GCP courses (Basic, Advanced and Refresher)





The overall quality of the presentation and adequacy of topics and content was comparable to previous years and remained stable at a quality score of 5.4 and 5.5 out of possible 6.





### Scientific Output and Grants

The number (N) of peer-reviewed publications is seen as indicator of CTU Bern contributing to projects that are completed and published. The Relative Citation Ratio is a measure of influence based on individual articles. CTU Bern also aims to increase the number of projects supported by independent, competitive grants.

#### **KPI Results**

The overall number of original publications (median over last 3 years compared to current year) increased significantly by 68% and a relative citation ratio of 1.16 was achieved (considering all original publications over the last five years including the current reporting period).

In addition, 17 grants were obtained with CTU contribution (by internal rules, CTU staff members cannot act as applicants).

CTU supported grant submissions and publications, including citation ratio



### **External Audit Compliance**

CTU compliance is evaluated in regard to external customer expectations and certification body requirements, by assessing external audit results and observations made.

#### **KPI Results**

In 2021 the following external audits were conducted at the CTU Bern:

→ Surveillance audit ISO 9001:2015 ; SQS Zürich With one minor observation identified, the ISO certification could successfully be maintained.









## Highlights

### **CTU Highlights**

### **OPFRAM**

#### Short summary

OPERAM was a cluster randomized controlled trial to examine the effect of optimizing drug treatment on drug-related hospital admissions in older adults with multimorbidity and polypharmacy ad- mitted to hospital.

### «CTU Bern provided

a great support for the initiation, the conduct, and the analysis of the OPERAM trial. The quality of the CTU's services was a key factor in the success of this study.» Prof. Rodondi: BIHAM

110 clinicians were randomized to usual care or a structured pharmacotherapy optimization intervention performed at the individual patient level (2,008 patients overall). Inappropriate prescribing was very common (in 789 participants (86%) in the intervention arm). In 491 of these (62%), at least one recommendation from the optimization intervention was successfully implemented at two months. In the intervention group, 211 participants (21.9%) experienced a first drug related hospital admission compared with 234 (22.4%) in the control group (hazard ratio of 0.95, 95% confidence interval 0.77 to 1.17). In conclusion, inappropriate prescribing was found to be common in this population and the intervention was able to reduce it but this did not translate into a reduction of drug-related hospital admissions. Additional efforts are needed to identify pharmacotherapy optimization interventions that reduce inappropriate prescribing and improve patient outcomes. (Reference: BMJ 2021; 374: n1585 [link: https://doi.org/10.1136/bmj. n1585]; NCT02986425

Link: https://clinicaltrials.gov/ct2/show/NCT02986425

#### The project in selected numbers

- 2,008 patients enrolled in 110 clusters at 4 European sites
- 13,951 completed visits or follow-up phone calls
- 1,457,464 data points in trial database
- 9,824 lines of code for data preparation and main statistical analysis

### MASTER DAPT

#### Short summary

MASTER DAPT was a global randomized-controlled trial to evaluate the appropriate duration of dual antiplatelet therapy in patients with coronary artery disease at high risk for bleeding.

«MASTER DAPT has been a very long but extremely successful journey which would have not been possible without the extraordinary passion, devotion and professionalism that CTU Bern dedicated to this trial. It was just a privilege to do this together.»

Marco Valgimigli; Istituto Cardiocentro Ticino

One month after they had undergone implantation of a stent for coronary heart disease, 4,579 patients at high bleeding risk were randomized to either discontinue dual antiplatelet therapy immediately (abbreviated therapy) or to continue it for at least two additional months (standard therapy). One month of dual antiplatelet therapy was non-inferior to the continuation of therapy for at least two additional months with regard to the occurrence of net adverse clinical events and major adverse cardiac or cerebral events; abbreviated therapy also resulted in a lower incidence of major or clinically relevant nonmajor bleeding. (Reference: N Engl J Med 2021; 385; 1643 [link: https://doi. org/10.1056/NEJMoa2108749]. NCT03023020

Link: https://clinicaltrials.gov/ct2/show/NCT03023020

#### The project in selected numbers

- 142 trial sites with 820 users
- Electronic Case Report Form: 1671 Variables à 78 forms à 7 visits; 3,780 rules, conditions, or automatic checks implemented
- 166,005 forms completed
- 54,048 gueries generated



## CTU Publications 2021

### CTU Publications 2021

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