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STUDY DESIGN

The 'Advancing Cardiovascular Risk Identification with Structured Clinical Documentation and Biosignal Derived Phenotypes Synthesis' project: conceptual design, project planning, and first implementation experiences

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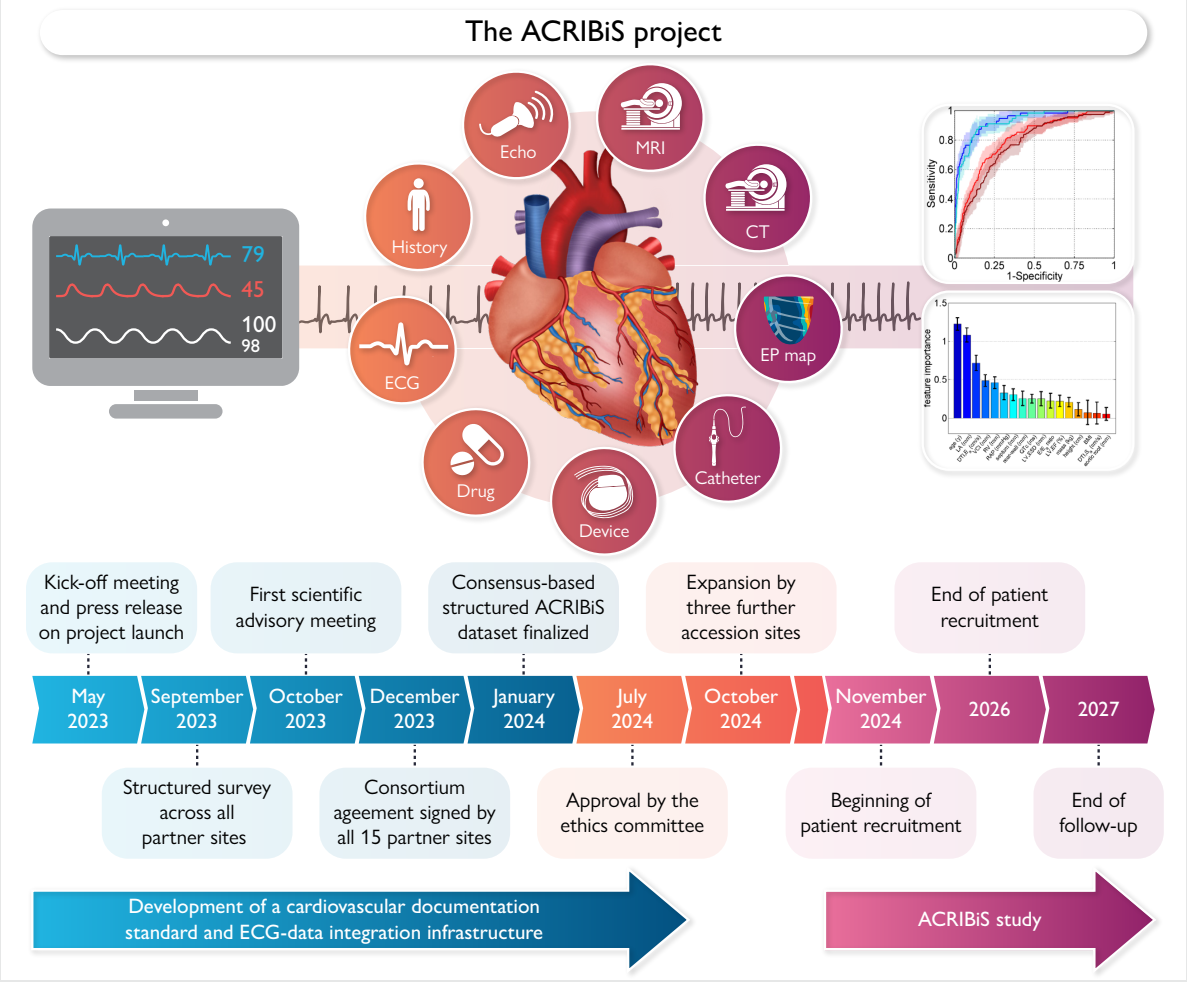
Aims Personalized risk assessment tools (PRTs) are recommended by cardiovascular guidelines to tailor prevention, diagnosis, and treatment. However, PRT implementation in clinical routine is poor. ACRIBiS (Advancing Cardiovascular Risk Identification with Structured Clinical Documentation and Biosignal Derived Phenotypes Synthesis) aims to establish interoperable infrastructures for standardized documentation of routine data and integration of high-resolution biosignals (HRBs) enabling data-based risk assessment.

Methods and results Established cardiovascular risk scores were selected by their predictive performance and served as basis for building a core cardiovascular dataset with risk-relevant clinical routine information. Data items not yet represented in the Medical Informatics Inititative (MII) Core Dataset (CDS) FHIR profiles will be added to an extension module 'Cardiology' allowing for maximum interoperability. HRB integration will be implemented at each site through a modular infrastructure for electrocardiography (ECG) processing. Predictive performance of PRTs and their dynamic recalibration through HRB integration will be evaluated within the ACRIBiS cohort consisting of 5250 prospectively recruited patients at 15 German academic cardiology departments with 12-month follow-up. The potential of visualising these risks to improve patient education will also be assessed and supported by the development of a self-assessment app.

Discussion The ACRIBiS project presents an innovative concept to harmonize clinical data documentation and integrate ECG data, ultimately facilitating personalized risk assessment to improve patient empowerment and prognosis. Importantly, the consensus-based documentation and interoperability specifications developed will support the standardisation of routine patient data collection at the national and international levels, while the ACRIBiS cohort dataset will be available for broad secondary use.

Trial registration The study is registered at the German study registry (DRKS): #DRKS00034792.

Graphical Abstract



Keywords ACRIBiS • Personalized risk prediction • Biosignals • Cardiovascular risk scores • Interoperability • Secondary use

Introduction

Cardiovascular guidelines recommend the use of personalized risk assessment tools (PRTs) with specific scores for different outcomes and patient groups to tailor prevention, diagnosis, and treatment.[1,2] However, implementation and uptake of PRTs has been slow in Germany due to unstructured clinical documentation. Technologies providing output via high-resolution biosignals (HRBs) carry great potential for enhancing predictive precision,[3,4] but standardized infrastructure for HRB integration and analysis is lacking, even though HRBs, like electrocardiograms (ECGs), are ubiquitously acquired and routinely used for clinical decision-making. Thus, HRBs represent a major underutilized resource. Novel concepts are needed to combine them with risk factor data to evaluate their added value in real-world medical situations. Combining innovations in digital infrastructure with structured clinical documentation in healthcare, harmonized across multiple institutions, may provide a sustainable solution to this need.

The successful implementation of such fundamental changes requires a robust infrastructural foundation. The Advancing Cardiovascular Risk Identification with Structured Clinical Documentation and Biosignal Derived Phenotypes Synthesis (ACRIBiS) project is a large-scale initiative funded by the German Federal Ministry of Education and Research (Bundesministerium für Bildung und Forschung, BMBF) and embedded in the Medical Informatics Initiative (MII), which has established a national level digital infrastructure for secondary use of healthcare data in German academic medical centres. Within the MII, Data Integration Centres (DICs)[5] have been established at all participating hospitals to facilitate advanced data usage scenarios. These DICs have recently received long-term funding under the auspices of the Network of University Medicine (NUM) funding scheme.[6] This was combined with significant investments in national interoperability specifications to represent clinically available data items in a harmonized way. However, these infrastructure efforts have not focused on improving standardized, structured clinical data acquisition at the source, nor have they enabled interoperable and transferable processing of biosignals, such as ECGs.

Accordingly, we designed the ACRIBiS project with the aim to provide near-term improvements in cardiovascular risk assessment and its interoperable representation, and to demonstrate that an integrated approach to clinical documentation evolution and quantitative analytics is both feasible and translational.

Here, we present the experiences and first results of the interdisciplinary conceptual development, project planning, and initial implementation phase of ACRIBiS. ACRIBiS aims to harmonize, standardize, and interoperably represent routine clinical documentation across 15 German cardiology departments, while also establishing an interoperable biosignal analytics infrastructure. The next phase will involve the development a predictive pipeline to improve risk assessment, derived from a cohort of patients treated at the participating sites, generating a large and standardized dataset that will also be made available for secondary use according to the FAIR (findability, accessibility, interoperability, and reusability) principles.

Methods

Project rationale in the national and international context

Cardiovascular disease (CVD) is the leading cause of morbidity and mortality in Germany and worldwide, affecting nearly one in three adults in their lifetime.[7–9] The enormous human cost and financial burden on healthcare systems in many countries calls for more intensive preventive and therapeutic measures based on a patient's individual risk.

The ACRIBiS initiative aims to enhance the utilisation of PRTs in routine clinical practice by defining a consensus-based, time-efficient routine documentation standard that is also described in a fully interoperable fashion by using and contributing to the extension the MII Core Dataset (CDS) through additional nationally standardized FHIR profiles.[10] In addition, ACRIBiS will establish an interoperable infrastructure to enable the integration of HRBs and data from structured clinical documentation for systematic analysis and dynamic recalibration of existing PRTs. Thereby, ACRIBiS contributes to the preparation of the common European Health Data Space, both by strengthening standardisation and harmonisation at the national level and by contributing interoperable specifications of domain specific clinical information for cardiovascular medicine. Simultaneously, the establishment of an interoperable infrastructure is a prerequisite for a learning health system aiming at continuous knowledge acquisition and model recalibration from routine clinical data. ACRIBIS will thus set a precedent for the capture and storage of clinical data from routine cardiology practice in other healthcare systems worldwide, representing a substantial advancement in the global effort to combat CVD.

Relevant prior work in the field

Structured clinical documentation

At present, data obtained from a patient's history and physical examination are generally collected and stored in an unstructured manner within hospital records. There are several interacting and interdependent factors that contribute to this: (i) A lack of user-friendly technical tools that allow for structured data entry along the patient journey, while respecting and optimally adapted to clinical needs.[11,12] (ii) Overreliance on referral letters, discharge notes, and manually generated prose documents to transfer information between hospital physicians and general practitioners in the German healthcare system.[11,13] (iii) Preference of free text entry over more time-consuming structured data entry by hospital physicians.[11]

We hypothesize that factor (i) is a major driving factor for (ii) and (iii). Past efforts to share clinical data for secondary use have yielded only modest results in Germany. Routine documentation was found to be too unstructured and heterogeneous between different hospital sites to allow for reliable extraction of clinical information.[11,13] Also, frequent use of free text entries by hospital physicians required additional language processing to extract specific clinical information and subsequent manual re-entry by study nurses into electronical medical records (EMR) and databases for research.

In the light of these discouraging experiences, future efforts to standardize clinical documentation should place greater emphasis on creating user-friendly interfaces and interoperable information systems for seamless integration into clinical routines.

Biosignal integration and processing

Besides structured clinical data, cardiovascular risk can be assessed by analysis of HRB data. The most common modality for cardiac assessment is the ECG, which is used for different purposes: (i) for rapid diagnosis in emergency care; (ii) for detection of paroxysmal arrhythmias, such as atrial fibrillation (AF); (iii) as a screening tool as part of routine care, or (iv) for long-term patient monitoring in intensive care. In use cases (i) to (iii), most devices rely on file storage, either on the device itself or within the clinical network. However, device vendors often provide only proprietary file formats for export, such as custom XML formats. In use case (iv), continuous ECG data are often made available via network streams. ECG device vendors increasingly offer file exports in Digital Imaging and Communications in Medicine (DICOM) format, which enables integration into a standard DICOM-enabled Picture Archiving and Communication Systems. A broad spectrum of methods is available for standardized analysis of biosignals, including linear time and frequency domain methods, as well as non-linear time series and mechanistic model-based approaches.[3,14,15] Nevertheless, integration of HRBs in clinical information systems has been slow. Additionally, semantic and syntactic mappings between DICOM-based HRB representations and the International Organization for Standardization (ISO) 11073 domain relevant for medical device communication,[16] as well as Health Level Seven International Fast Healthcare Interoperability Resources (FHIR®),[17] which form the interoperable backbone for data sharing in the MII, remains to be addressed.

The development of the open-source solution AcuWave at the University Hospital Bonn (UHB) has resulted in the creation of a modular infrastructure that enables close-to-real-time biosignal processing from patient monitoring systems.[18] This infrastructure facilitates enrichment of HRB data streams

with low-dimensional clinical data in interoperable formats. Its generalisability and transferability have already been demonstrated.[19,20]

Integration of biosignals from mobile devices

Increased use of wearable technology, which continuously monitors patient health parameters, has precipitated an exponential proliferation of ECG data. As a result, at multiple ACRIBiS sites, data obtained from wearables were integrated into the local DIC within the Use Case Cardiology of the HiGHMed-MI-project.[11] Additionally, University Hospital Heidelberg developed a dashboard for clinicians that reports and analyses single-channel ECGs and heart rate variation measurements from Apple Watch devices that were used for research purposes only.[21] University Hospital Göttingen also gained experience by integrating data collected by wearables into a research data infrastructure, including implementation of FHIR mapping for the proprietary mobile data formats of Apple Health Kit and Google Fit. These achievements underscore the feasibility of wearable integration in real world hospital associated infrastructures.

Risk prediction in the cardiovascular context

The assessment of an individual's risk constitutes an integral component of the management of CVD. The importance of accurate risk prediction has grown significantly over the past decades, as the primary and secondary prevention of CVD has become the primary focus of researchers and clinicians in their efforts to improve the implementation of preventive and therapeutic strategies.[22] Concurrently, a paradigm shift within medicine has occurred towards increased personalisation of treatment with a view to reducing adverse side effects, minimising costs and optimising therapeutic efficiency. In this contemporary medical context, PRTs have acquired a predominant influence in the decision-making process for cardiology treatments. This approach is consistent with both national and international guidelines and may encompass a wide range of areas, from the initiation oral anticoagulation to the prevention of sudden cardiac death. The most commonly used PRTs are risk scores, which comprise variables that usually are easily accessible in clinical routine, e.g. age, sex, the presence of comorbidities, laboratory values etc., and have been calibrated on the basis of high-quality data from epidemiological studies.[22] However, their applicability to specific clinical scenarios is often far from clear. For example, cardiovascular risk estimation works well in middle-aged patients but can overestimate risk in the elderly and underestimate risk in younger patients.[22] Furthermore, advances in the diagnosis and treatment of CVD, e.g. in interventional cardiology, lipid-lowering medication and imaging, have led to changes in the demographics and the disease course of patients seeking cardiovascular care. This underscores the necessity for continuous recalibration of established PRTs. For instance, Rücker *et al.*[23] highlighted the need for recalibration of the Systematic Coronary Risk Evaluation (SCORE) score.[23]

Besides risk scores, analysis of biosignals has also been shown to be of value in the assessment of cardiovascular risk. For example, the presence of wide left bundle branch block (a readily discernible feature in a standard 12-lead ECG), is a surrogate marker of left ventricular dys-synchrony and thus a well-known predictor of cardiovascular mortality risk.[24] More advanced analyses of ECGs have yielded other, less well-established parameters, such as the deceleration capacity[15] and heart rate turbulence after premature ventricular contractions,[4,25] which also possess predictive value with regards to cardiovascular risk.[4,15,25] Moreover, the combination of different biosignals has led to the creation of biosignal-based risk scores, such as the Polyscore.[3] In addition, analysis of biosignals can be further improved by artificial intelligence (AI) and deep learning. For instance, recent studies have demonstrated the feasibility of employing deep learning for the diagnosis of occlusion myocardial infarction[26] and prediction of increased 90-day mortality risk in hospitalized patients.[27] Future studies will attempt to utilize deep learning algorithms to combine clinical and biosignal-derived parameters to improve the predictive power of PRTs.

The ACRIBiS workplan

To address the clinical need for PRT implementation and to foster harmonisation of documentation standards, ACRIBiS (German Clinical Trials Register ID: DRKS00034792) was developed as a cross-consortial clinical Use Case within the MII, co-ordinated by UHB, the Hannover Medical School, and the University of Würzburg. Six core sites (Bonn, Göttingen, Hannover, Heidelberg, München, Würzburg) will develop the ACRIBiS processes and technology, which will be rolled out to nine implementation partners, including university and non-university hospitals, to demonstrate transferability and generic applicability, while simultaneously increasing sample size for both the calibration and validation cohorts (cf. *Figure 1* and supplementary material online, *Table S1*). A multi-level organisational structure was developed to ensure coherent decision-making and integration of all sites, stakeholders, and patient representatives. The main objectives of ACRIBiS are presented in *Table 1*.

Establishing structured and standardized routine documentation in cardiovascular medicine

In cooperation with the relevant scientific and clinical organisations, including patient representatives and the German Cardiac Society (Deutsche Gesellschaft für Kardiologie, DGK), ACRIBiS aims to establish a consensus-based documentation standard that contains items relevant for risk prediction, while simultaneously being compatible with effective clinical workflows. A comprehensive review of existing risk scores, quality assurance measures, registries, and standards for scientific data sets, such as those from the German Centre for Cardiovascular Research (DZHK), screened for candidate data items, considering clinical practicability and relevance for secondary use. ACRIBiS has prompted the development of novel user interface concepts for implementing a documentation standard that facilitates site-specific integration into clinical workflows. This ensures that the appropriate data item is offered in the relevant clinical context, thereby minimising redundancy and inefficiency, as well as addressing patient safety concerns.

Infrastructure survey

A structured survey was conducted between 09/2023 and 10/2023 at all ACRIBiS partner sites about data integration, biosignal infrastructure and structured clinical data assessment. The results are displayed in Supplementary material online, *Table S1* and underscore the lack of standardized infrastructure concerning clinical routine data, biosignal integration, and low dissemination of the DICOM standard.

Selection of prediction models

One of the key aims of ACRIBiS is to establish a core data set of routine cardiovascular parameters that is structured, standardized and fully semantically and syntactically interoperable at all 15 partner sites, such that it could become the documentation standard for hospitals across Germany and internationally. The implementation of this initiative is expected to yield substantial advancements in the domains of risk stratification and prediction, attributable to the following three main reasons:

(1) Existing risk prediction models, which are often based on study cohorts from outside Germany, can be re-evaluated with respect to their predictive performance and their applicability to German patient cohorts.
(2) Existing risk prediction models could be re-calibrated and continuously improved in a dynamically learning healthcare environment.
(3) This will foster creation of novel PRTs, which can be validated in a national multi-centre study cohort. Moreover, the establishment of a consensus-based documentation standard will facilitate the comparison of these models with those used in other patient cohorts outside of Germany.

To test the utility of the proposed core data set of cardiovascular parameters with regards to improving risk stratification and prediction, a selection of established risk prediction models was chosen for performance evaluation and potential subsequent dynamic re-calibration in the ACRIBiS cohort. The risk prediction tools displayed in *Table 2* were selected by members of ACRIBiS based on their clinical relevance according to the guidelines, data availability in routine care at the partner sites, and predictive value. These prediction tools were then grouped according to the type of cardiovascular event they predict. In addition, the selected risk scores were prioritized to account for differences in data availability at the participating partner sites. The selection was approved by patient representatives and the international scientific advisory board. International experts in the field were selected as external advisors and assembled into an advisory board. These external advisors are available during regular

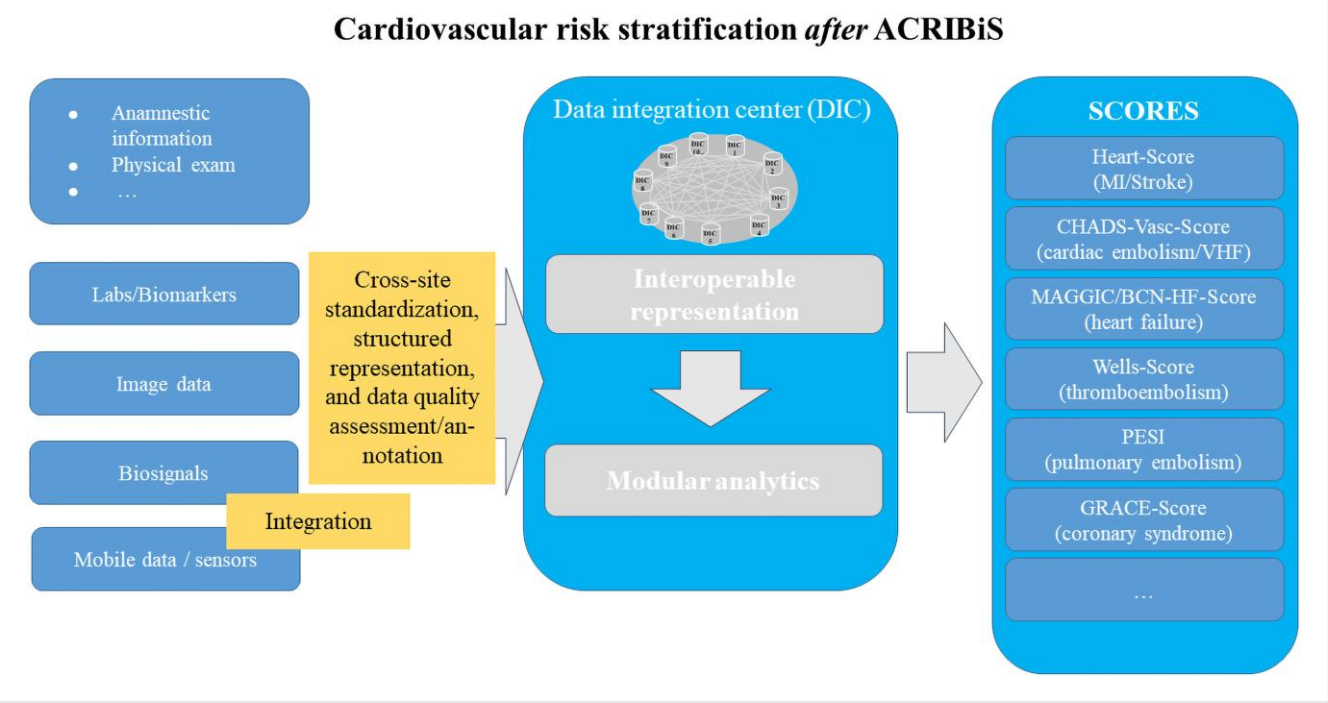


Figure 1 Cardiovascular risk stratification after ACRIBiS: the proposed flow of routine cardiovascular data ACRIBiS aims to establish, using the DICs as nodal points for integration, processing and quality assurance of healthcare data to enable optimized and personalized cardiovascular risk assessment.

Table 1 The ACRIBiS objectives

1	Establish a structured and standardized routine documentation of a core data set of relevant cardiovascular information and systematic follow-up
2	Establish a harmonized and interoperable infrastructure to analyse data sets with high-resolution ECG biosignals from various sources in clinical routines
3	Evaluate the predictive performance of existing risk quantification tools and demonstrate the feasibility of dynamic recalibration with structured clinical and biosignal data
4	Enhance risk awareness and foster self-empowerment by engaging patients in individualized risk identification through interactive risk visualisation and information
5	Prove the transferability and generalisability of thus generated improvements in clinical documentation and infrastructure at implementation partner sites and within the MII

ACRIBiS, Advancing Cardiovascular Risk Identification with Structured Clinical Documentation and Biosignal Derived Phenotypes Synthesis; ECG, electrocardiography; MII, Medical Informatics Initiative

meetings. During regular scientific advisory board meetings, risk scores of interest and item selection were presented and discussed. Patient representative selection was organized by the German Heart Foundation (Deutsche Herzstiftung e.V., https://herzstiftung.de/).

The ACRIBiS dataset and cohort

Within ACRIBiS, a core data set comprising cardiovascular parameters was defined for routine documentation in the participating cardiology departments, encompassing over 300 items in total (see Supplementary material online, *Table S2*). It is the explicit aim of ACRIBiS to make this data set fully semantically and syntactically interoperable, thereby facilitating its utilisation across hospitals nationwide. The MII infrastructure, supported by local DICs, will be used to achieve this objective. However, given the time constraints imposed by ACRIBiS, data availability at some partner sites may be impaired. Therefore, within ACRIBiS, reduced data sets containing the items required for calculating the established risk scores outlined in Section 6 (cf. *Table 2*) have also been defined.

The ACRIBiS study, which aims to test the feasibility of automated score calculation on standardized data obtained in the clinical routine and thereby prospectively re-evaluate the performance of established risk prediction models in routine clinical conditions, will be conducted at the 15 main partner sites (cf. *Figure 1*). For this purpose, 5250 patients receiving routine care in the participating cardiology departments will be included prospectively. Recruitment commenced in December 2024. The Ethics Committee of the University of Würzburg (82/24-sc) approved the study. The first goal of the study is to evaluate the performance of three established risk scores (one each for overall cardiovascular risk, for atrial fibrillation and for heart failure), comprising some 35 data items: the Barcelona-Bio-HF 3.0,[30] CHA_2DS_2VA[29] and SMART-Score,[28] which can be evaluated with respect to their performance for 1-year outcomes. For each of the three scores, we aim to recruit ~1750 patients. The SMART score cohort will consist of patients with overt atherosclerotic disease. The CHA_2DS_2VA cohort will comprise patients with documented atrial fibrillation, whilst the Barcelona-Bio-HF cohort will include patients who have been diagnosed with chronic heart failure. All patients included in the study will be required to give their written informed

Table 2 The selected personalized risk prediction tools

Cardiovascular risk	Atrial fibrillation/anticoagulation	Heart failure readmission + mortality	Biosignals: cardiovascular mortality
SMART[28]	**$CHA_2DS_2VA(Sc)$**[a][29]	**Barcelona-Bio-HF**[30]	Micro fragmentation
SMARTreach[31]	CHARGE-AF[32]	MAGGIC[33]	Polyscore[3]
	ABC-AF Stroke[34]		
	ABC-AF Death[35]		
	ABC-AF Bleeding[36]		
	HASBLED[37]		

[a]The most recent 2024 ESC guidelines on atrial fibrillation recommend the use of the CHA_2DS_2VA-score in lieu of the CHA_2DS_2VASc score to predict the risk of stroke in AF patients. At the time when the scores were selected, which was before the 2024 ESC guidelines were released, the CHA_2DS_2VASc was the recommended risk prediction tool. The three main risk scores of ACRIBiS are highlighted in bold.

ABC, Age, Biomarkers, Clinical History; AF, Atrial fibrillation; HF, heart failure; CHARGE, Cohorts for Heart and Aging Research in Genomic Epidemiology; $CHA_2DS_2VA(Sc)$, Congestive heart failure, hypertension, age, diabetes, stroke, vascular disease, age, sex category; ESC, European society of cardiology; HASBLED, Hypertension, Abnormal renal/liver function, Stroke, Bleeding history or predisposition, Labile international normalized ratio, Elderly (> 65 years), Drugs/alcohol concomitant; MAGGIC, Meta-Analysis Global Group in Chronic Heart Failure; SMART, Second manifestations of arterial disease.

consent, which is implemented as a standard-compliant modular extension of the MII Broad Consent.[38]

Follow-up of the ACRIBiS cohort and app-based patient empowerment

Patients in the ACRIBiS cohort will be followed up for 12 months. The follow-up visit can be conducted in one of three ways: (i) an in-person visit during a routine visit to the study site, (ii) by telephone or by mail, or (iii) online through an app/web-browser. The primary outcomes based on the chosen risk-scores will be collected: SMART (myocardial infarction, stroke, cardiovascular death), CHA2DS2VA(Sc) (stroke), BNC-HF (death, hospitalisation due to worsening of heart failure). During the follow-up visit, Patient Reported Outcome Measurements (PROMs) in the form of questionnaires [PROMIS-29[39] and EuroQol 5-Dimension 5-level (EQ-5D-5)[40]] will be complemented by data derived from modern smart devices. If a patient cannot be reached for follow-up, investigators will contact the patient's family practitioner to ask about his/her vital status. If the patient is deceased, investigators will ascertain whether the cause of death was due to CVD. In addition to the utilisation of digital tools to facilitate follow-up, ACRIBiS aspires to provide a personalized risk assessment app for patients, thereby promoting risk-aware personalized lifestyle choices. In accordance with the Medical Device Regulation, the CE marking (probably risk class IIa) of the application will be mandatory for introduction to the EU market. The requirement engineering for the development efforts for this app has begun, co-ordinated by the ISO 13485 certified UHB quality management and software development team, which is led by the ACRIBiS scientific co-ordinator. While patient input of structured clinical information will in all cases be reviewed by physicians before clinical use, sensor data acquisition, quality assurance, and utilisation from patient owned mobile devices, relevant only to the follow-up phase, will rely on existing technologies and processes.

Integration in the national infrastructure and organisations in cardiovascular medicine

ACRIBiS is integrated into the national MII and NUM infrastructure and is fully committed to using the national health data research portal (Forschungsdatenportal Gesundheit, FDPG, https://forschen-fuer-gesundheit.de/en/) processes for data usage governance and organisation, as well as the NUM Dashboard federated analysis infrastructure for close-to-realtime cross-site monitoring of cohort recruitment and predictive model performance.[10] This will also enhance the existing MII CDS FHIR modules with relevant cardiovascular information by contributing a 'Cardiology' extension module to the nationally standardized extensible and modular MII CDS FHIR profiles. Additionally, the German Cardiac Society has endorsed ACRIBiS and is in exchange with this project for further co-ordination and collaboration. Moreover, the scientific dataset of the German Centre for Cardiovascular Research (DZHK) was utilized during the screening phase to identify relevant data items for the ACRIBiS dataset.[41] Synergies with the society for telematics applications of the health card (gematik) were additionally explored, which recently released a position paper regarding a basic cardiology dataset.[42] ACRBiS aims to support gematik specification efforts in a similar approach to the contributions from ACRIBiS partners in the context of the interoperable description of data relevant to Intensive Care Unit (ICU) treatment, where significant parts of the MII CDS extension module ICU were contributed to and implemented in the ISIK 4 specification relevant to all German healthcare IT vendors servicing the inpatient sector. The German Heart Foundation and the German Stroke Foundation both support the project by providing patient representation on the Scientific Advisory Board.

Discussion

Standardized infrastructures for near real-time processing of clinical data and HRB are lacking. However, the establishment of such infrastructures is important to guide clinical decision-making in the real world, especially with the advent of digitalisation and deep learning that will help to leverage the growing amount of available healthcare data. Therefore, the ACRIBiS project was initiated. Here, we provide a comprehensive description of the principal concepts and rationale behind ACRIBiS. The survey data presented support the feasibility and translatability of this approach into a real-world setting involving 15 academic medical centres in Germany. Furthermore, we present the ACRIBiS core dataset, consisting of defined clinical routine variables of prognostic relevance, with the aim to harmonize clinical documentation between different hospital sites.

Feasibility and risks

Structured surveys at different German university hospitals revealed a marked variability in the assessment, processing, and storage of clinical and ECG data. This variation is attributable to different documentation types, EMR systems, and clinical routines. However, these surveys also revealed a paucity of interfaces for monitoring ECG data integration at a large number of sites, which displays a potential obstacle that the ACRIBiS project aims to overcome. Additionally, PRT relevant information is often not automatically derived for automated risk calculation. Currently, these factors impede the implementation of standardized data integration infrastructures.

Through the collective support of the ACRIBiS consortium that encompasses clinicians, medical informatics specialists, and patient representatives, a harmonized core dataset based on established cardiovascular risk scores was developed. Yet, the large-scale collection

of high-quality structured patient data remains challenging in clinical routine practice due to the absence of efficient, time-saving technical tools that support low-threshold, high-quality structured documentation. The practicality and user acceptance rely on usability and clinical relevance of these tools.[43] To address these challenges, ACRIBiS aims to implement a user-centered design, optimized user interfaces for seamless integration into daily workflows, and raise awareness regarding the benefits of structured documentation. In particular, the reduction of redundant data entries, the integration of patient-centred tablet applications, and automated discharge letter generation are the focus of secondary ACRIBiS project activities, which aim at improving clinician acceptance.

Another important aspect is the heterogeneity of software and IT infrastructure at different hospitals, which makes the establishment of standardized infrastructures for HRB challenging and resource intensive. To address this point, the open-source solution AcuWave of the UHB is distributed to participating hospitals. This modular infrastructure supports close-to-real-time biosignal data acquisition, processing, and visualisation from patient monitoring systems and provides a standardized interface and environment for the implementation and sharing of analysis algorithms.[18] By performing structured surveys, we demonstrated that this module can be applied in almost all centres, which is a prerequisite for automatic near real-time risk calculation. This indicates that our approach is feasible in a real-world setting comprising diverse healthcare facilities. However, these surveys also revealed that interfaces for monitoring ECG data integration are lacking at a large number of sites, which displays a potential obstacle, which is aimed to be overcome within the ACRIBiS project.

However, automatic extraction of HRBs and structured clinical data, which is essential for near real-time calculation and for merging and jointly analysing data efficiently, must comply with current data protection guidelines. This is only made feasible within the constraints of the ACRIBiS project by extending the generic MII regulatory, organisational, and technical framework, which in turn will benefit from the ACRIBiS functional extensions.

Implications of ACRIBiS for cardiovascular medicine and beyond

Large datasets derived from different sites are increasingly important for cardiovascular research to expand evidence on specific procedures and increase patient safety. With the distribution and application of the ACRIBiS core dataset, harmonized clinical assessments across hospitals can be achieved, thus allowing the efficient generation of large, multicentric datasets from routine care that are jointly usable.

In addition, the adoption of a modularly extended MII Broad Consent in ACRIBiS cohort recruitment ensures that the ACRIBiS dataset in its entirety will be available for secondary use in approved research projects via the national health data research portal (Forschungsdatenportal Gesundheit, FDPG; https://forschen-fuer-gesundheit.de/en/) following the FAIR principles.

The importance of HRBs in the context of cardiovascular risk prediction has grown in recent years. AI based prediction models that integrate both HRBs and clinical data have shown superior prediction accuracy compared with current risk scores.[44] Near real-time availability of HRBs and clinical data are prerequisites for the application of these prediction models in settings like Chest Pain Units, Intensive Care Units or outpatient departments, which is one of the primary objectives of ACRIBiS. Identifying high-risk patients, e.g. for in-hospital cardiac arrest, may enhance patient safety through extended diagnostic regimens, more aggressive lifestyle interventions, adapted and intensified monitoring of disease progression, and risk factor related pharmaceutical interventions.[1,45,46] Concurrently, the increased availability and utilitsation of risk calculation models carries the risk of 'alarm-fatigue'. This requires prioritisation of models to ensure their effective and efficient use. This, for instance, could entail the adaption of risk models to particular clinical settings (e.g. emergency room vs. outpatient department) and specific patient groups. Translational strategies contribute to a more personalized medicine, for which the harmonisation efforts of ACRIBiS regarding clinical documentation and its representation, biosignal acquisition and analysis, and the close-to-real-time model calibration and evaluation infrastructures can serve as relevant enablers.

Furthermore, individualized risk communication through interactive risk visualisation can be applied. Use of colours[47] or the type of risk estimates being presented can improve individual risk communication to the patient and may also improve patient education, self-empowerment, and therapy adherence.[47,48] The ACRIBiS project will contribute to the growing body of evidence regarding the potential benefits of these enhanced risk prediction and visualisation tools, as well as, through utilisation of a broad consent approach during recruitment, will create a sustainable long-term dataset to support translational cardiovascular research.

Beyond the discussed implications of ACRIBiS on cardiovascular medicine in Germany, this project could serve as a paradigmatic example in other use cases, other medical specialties or other healthcare systems in Europe and beyond. However, even though AI based risk models can be derived from HRBs and clinical data, clinical trials are needed to generate evidence regarding whether application of these risk models improves patient outcomes in real-world settings. Nevertheless, early clinical trials investigating AI based decision tools from ECG data have yielded encouraging results, for example, in diagnosing occlusion myocardial infarction[26] and identifying hospitalized patients at increased 90-day mortality risk.[27] Furthermore, considering constantly rising costs of healthcare, automated personal risk assessment infrastructures may also enhance the efficiency of patient care by concomitantly reducing costs and increasing patient safety.[49]

Contribution to the concept of a learning healthcare system

More broadly, ACRIBiS may serve as a small-scale pilot project and procedural template for a significant part of a strategic approach to implementing the dynamically learning healthcare system of the future. This is achieved by combining cross-site documentation standardisation, technical implementation of such standards in routine clinical IT systems, and making the resulting clinical data available for secondary use, including calibrating risk prediction models. Such secondary use of standardized clinical data can support the learning healthcare system both by facilitating routine data-driven vigilance mechanisms and enabling scientific exploration and hypothesis (and in some cases even evidence) generation. Furthermore, a model recalibration facility for selected PRTs using outcome surrogate-based approaches (PROM) and a systematic follow-up of ~5250 patients within the ACRIBiS cohort will be established. Calibrated risk models based on routine data can then serve to perform advanced risk adjustment based on patient properties to develop fair and meaningful inter-institutional quality comparisons.[50]

The ACRIBiS project presents a concept and implementation plan to harmonize clinical data documentation and integrate the resulting data with ECG data in a medical real-world setting to improve personalized risk assessment in cardiovascular medicine using an innovative, standardized, and interoperable infrastructure. First results support the feasibility of this project. After successful implementation, validation of its effects on provider performance and patient outcomes will be an essential next step.

Lead author biography

ACRIBiS PI Sven Zenker is a physician/scientist/administrator with German board certification in anesthesiology, emergency medicine, intensive care medicine, and medical informatics. He is founding Medical Director of the Staff Unit for Medical & Scientific Technology Development & Coordination (MWTek) at the University Hospital Bonn, while simultaneously leading research groups within the Institute for Medical Biometry, Informatics and Epidemiology (Applied Medical Informatics) and the Department of Anesthesiology & Intensive Care Medicine (Applied Mathematical Physiology). He is President of the Society for Complex Acute Illness (SCAI), and chair of the EXPAMED panel 'Respiratory system, anaesthesiology, intensive care' initiated by the European Commission.

Supplementary material

Supplementary material is available at *European Heart Journal – Digital Health*.

Consent

The study was approved by the Ethics Committee of the University of Würzburg (82/24-sc) and is registered at the German study registry (DRKS) under: DRKS00034792.

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Data availability

All data presented in this manuscript are made available by the corresponding author upon reasonable request.

Notes

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