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## **Davos BioSciences AG**

*We deliver precision in dermatology and allergy*

### **Description of the technology platform, products and services provided for drug and diagnostics development programs**

#### **Who are we?**

Davos BioSciences AG (DBS) was founded as a non-profit Biotech SME and spin-off of CK-CARE (Christine Kühne-Center for Allergy Research and Education) and the Kühne-Foundation, a non-profit foundation of the Kühne Family (Kühne and Nagel, Logistics). Davos BioSciences AG is a subsidiary of the Davos Allergy Campus and belongs to the non-profit Kühne-Foundation ([www.Kuehne-Stiftung.org](http://www.Kuehne-Stiftung.org)).

#### **What is our aim?**

Davos BioSciences AG provides a high-quality expertise in biobanking and laboratory services to help pharmaceutical companies in their effort to accelerate and optimize the discovery and development of new therapeutic agents and biomarkers as well as validation of markers and products to meet regulatory requirements. As of today, the main expertise is on atopic dermatitis as well as for other allergic diseases and for other disorders of the immune system. We focus our efforts particularly in the emerging field of precision medicine.

Davos Bioscience was primarily founded to manage and attend the business related aspects of the CK-CARE registry and biobank as well as data and biomaterial from other sources. CK-CARE (Christine Kühne-Center for Allergy Research and Education, an initiative of the Kühne Foundation) is one of Europe's largest private initiatives in the field of dermatology and allergology and unifies five European key players in the field.

The CK-CARE Registry and Biorepository provides an ideal scientific reference and knowledge background for the activities of Davos BioSciences AG which, in tight collaboration with all members of the CK-CARE consortium and especially with the world-renowned Swiss Institute for Allergy and Asthma Research (SIAF), can benefit from a state-of-the-art technology platform. This enables DBS to rapidly address critical questions in an agile way at any stage, in the preclinical and clinical drug development programs as well as in the development, validation and regulatory qualification of biomarker-based diagnostic tests.

### What are our unique selling points?

- i. Steadily growing reference **patient registry** (the CK-CARE data base) covering almost all relevant aspects of the epidemiologic and phenotypic complexity of atopic diseases and associated comorbidities as well as health controls. **The registry collects “regulatory grade” real world data.**
- ii. Strong **expertise in operating a specialized biorepository** for dermatology and allergy.
- iii. A state-of-the-art **technology platform** for the storage and analysis of the biomaterial from clinical trials and development programs for diagnostic tests.
- iv. A unique and steadily growing reference **biorepository** (the CK-CARE Biobank) collecting and storing annotated biomaterial samples (linked to the CK-CARE registry) from a large spectrum of representative patients with atopic dermatitis and associated comorbidities as well as healthy controls
- v. A world-renowned **team of experts in biomedical research** in the field of atopic diseases and allergic conditions

### What is our value proposition?

In a world of agile drug development, optimization of the preclinical and clinical programs will save costs and time in drug development programs. You have a unique drug or biomarker development program and need answers to specific questions? We provide customized and unique solutions based on long lasting strong scientific and clinical background and experience. With our help, you can reduce drug development time, reach lower rates of failures in P2 and P3 trials, facilitate go/no-go decisions, develop companion diagnostic programs. We can also provide services and help for post licensing evidence generation (PLEG). You need a deep dive into real-world data for your clinical development plan or for market access/HTA issues? Our registry provides sufficient information with high granularity for such purposes.

### What are our products and services?

In brief, the growing portfolio of Davos BioSciences includes following products and services (see summary on Figures 1 and 2) to satisfy any of your specific requests:

#### ① ***In silico* deep phenotyping-based research and patient stratification**

The CK-CARE registry collects a unique range of data from patients with atopic dermatitis (currently more than 1,500 patients included; age range: birth to 99 years) including, among others, following aspects: current severity (SCORAD and EASI), age of onset, detailed disease course and history, family background, associated diseases (including infections) and

comorbidities (asthma, rhinitis, other allergies) of patients and relatives, sociodemographic information, life style, past and current treatment regimens, intolerances, quality of life, routine lab data such as total and detailed sensitization profile of specific IgE (ISAC Chip), .... High quality photography is performed for each patient. The patients are seen once per year for up to 5 years, thus providing follow up data, of particular interest in the pediatric population. Overall, based on the detailed questionnaire and results from the clinical examination, more than 1,500 data points are generated per patient and per visit.

The registry also includes an increasing number of (i) patients who are in remission of their AD, (ii) patients with psoriasis, (iii) control patients who have other atopic disorders but no AD as well as (iv) normal non-atopic individuals.

The registry offers a unique opportunity for in depth *in silico* analysis to better understand the complex phenotype of atopic dermatitis and its comorbidities as a valuable help for strategic decisions in drug development programs.

#### ② **Contracted research projects for drug and biomarker discovery.**

Using the samples of the CK-CARE biorepository and the technology platform, we offer a unique opportunity to test your therapeutic approach and strategy, new molecules or diagnostic test procedures on high quality and clinically well characterized biomaterial from patients and control individuals (including normal and other inflammatory skin conditions for sensitivity and specificity purposes). The biomaterial from the CK-CARE biobank is also an ideal material for comparative studies with a well-defined population and for control purposes.

#### ③ **Storage of samples from preclinical and clinical trials (phases I-IV).**

Our extended experience in operating large biorepositories offers the best conditions for the labeling, short/long term storage and management of biospecimen collected during preclinical and clinical procedures/trials.

#### ④ **Immunohistochemistry**

Histology and immunohistochemical staining procedures belong to the well-established investigational tools in dermatology. For drug discovery and for biomarker programs in the context of clinical trials, we offer a large panel of staining procedures using specific antibodies directed against structural and cellular features in the skin to explore the *in situ* impact of new compounds on the inflammatory infiltrate and/or the epithelial and dermal compartments. A dedicated team of experienced histopathologists will provide the qualitative and quantitative analysis of the results. In case of need of reference biopsies and for sensitivity/specificity purposes, the CK-CARE biorepository can provide adequate



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material from well characterized patients and control individuals. We will also be able to scan the slides for further image analysis and A.I. approaches on the stained samples.

#### ⑤ **Analysis of soluble mediators in liquid samples**

Measurement of soluble mediators in liquid biospecimen such as serum, sputum, interstitial fluids or culture supernatants is a major pillar in biomarker programs flanking clinical drug development. Our platform offers a panel of different technologies including Luminex and the newest generation multiplex analysis using the state-of-the-art Olink technology (the mandatory internal bridging controls for these technologies are provided by samples from the CK-CARE biorepository). Any body fluids, including obtained those from skin biopsies, can be measured by our highly sensitive Olink-technology.

#### ⑥ **Cellular phenotyping**

Multicolor flow cytometric analysis of blood or skin samples provide a useful tool to analysis the behavior of the cells before, during and after the therapy with new compounds. Our platform is equipped with several modern multicolor flow cytometers such as FACS Aria and Galios (both 10 colors), as well as BD LSRFortessa (18 colors).

#### ⑦ **Transcriptome analysis**

We provide a state-of-the-art RNA isolation and processing for expression profiling from biosamples of any kind. Sequence and array-based technologies are used for a comprehensive coverage for RNA transcriptomic analysis of the samples from your program.

#### ⑧ **Biomarker discovery and development services**

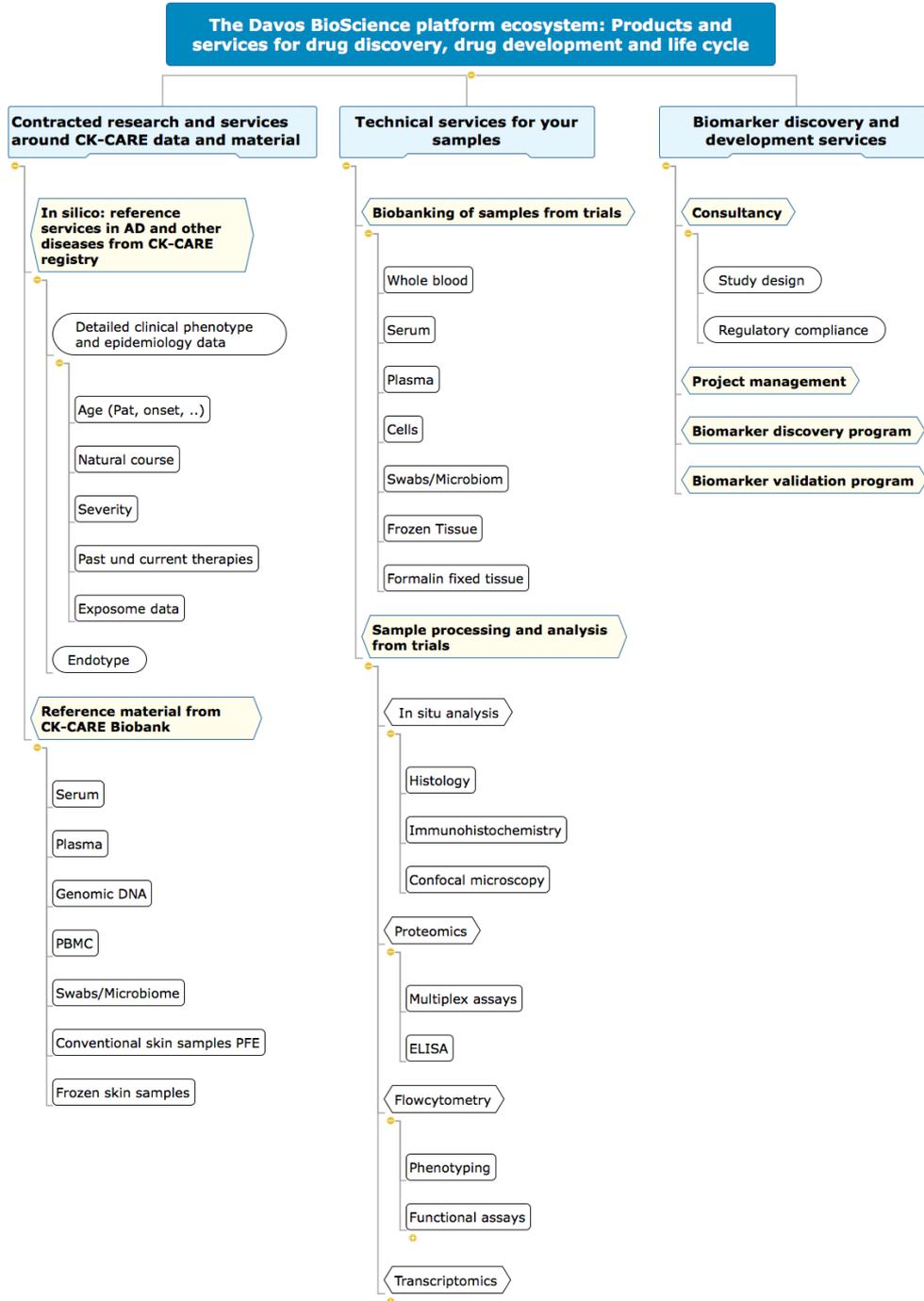
We provide a competent project management for all above-mentioned services and help in the design of trials aim to identify new biomarkers as potential companion diagnostics. Candidate biomarkers can be combined into panels of significant discriminatory power and thereby be used for diagnostic, prognostic or predictive purposes. Beyond discovery programs, our services can provide valuable help for validation steps (replication studies) as well as for regulatory qualification/fitness for use.

#### **For further information, please contact:**

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or

Prof. Dr. Dr. Prof. h.c. Thomas Bieber, MDRA (Founder and Chair of the board)  
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**Figure 1: The portfolio of services and technologies provided by Davos BioSciences**

## High quality expertise and services based on a modern technology platform The path for an agile classic or precision medicine approach in development programs for drugs and companion diagnostic tests

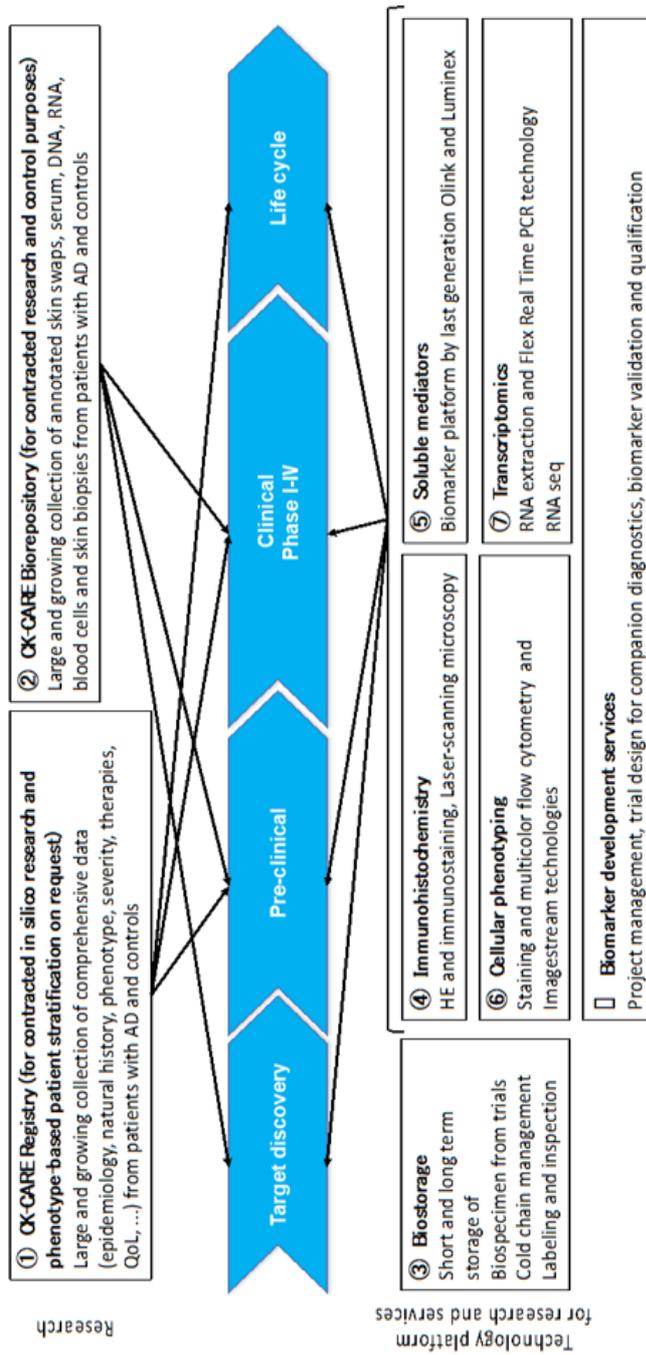


Figure 2: Davos BioSciences services along the drug development program and life cycle