Optimise your drug development cost and time; the patients are waiting.

KAN Consulting
Brochure 2017

Kamila A. Novak
Founded in 2010 by Kamila A. Novak, MSc, KAN Consulting collaborates with and provides expert solutions to biotechnology and pharmaceutical companies as well as start-ups and spin-offs to facilitate their medicinal product development, manage research projects, identify and manage risks, thus, meeting their targets on time with the desired quality and within budget.

Apart from biotech and pharma, our client portfolio includes other key players in the R&D field, namely, institutions, individual researchers – investigators, and CROs.

Our goal is to optimise drug development cost and time from discovery through Proof of Concept to the market, while maintaining the regulatory-required participants’ safety, data quality and integrity, so that patients may benefit from new therapies as soon as possible.
ADVANTAGES

We are lean, networking, standardised and risk-management oriented.

What does it mean to be **LEAN?**

The purpose of lean is to **deliver** value to clients.

Lean flexible structure

Scaling your project exactly as needed to keep overhead costs at the minimum.

Network of partners

Partnering with experts in the fields of e-solutions for clinical trials, data analytics and system modelling to optimise your projects.

ISO 21500:2012

Guidance on Project Management

Project management following ISO 21500

From initiating, through planning, implementing and controlling up to closing, we follow the ISO 21500 standard in executing your project.

Risk management

Risk Plan

In compliance with the FDA and EMA guidelines and regulations as well as TransCelerate Biopharma Inc. recommendations, we implement the FMEA technique in your study.
Having worked in different environment settings, we understand you well no matter if you are a drug developer, institution or contract research organisation.
MEET YOUR CONSULTANT

Kamila A. Novak, MSc.

Having graduated in Molecular Genetics from the Masaryk Memorial University, Brno, Czechoslovakia, Kamila had gained experience in various fields, including science, management, translation and interpretation as well as teaching and administration, before starting her career in clinical research.

In 1995 – 1997, she worked in a local pharmaceutical company as a translator and QA support. In 1997, she started her clinical research career as a Clinical Research Associate, gradually assuming responsibilities of a Regional and later a Global Clinical Team Lead, Country Manager, Associate Director and a special task force member for process streamlining at Quintiles. Since 1997 Kamila has been engaged in different roles in about 50 clinical trials world-wide.

She gained a wealth of experience in the Middle East having been working in the region since 2002 and living there for 7 years. In 2009 – 2010 she established a regional CRO in Jordan for a group of investors.

In 2010 she joined ANTAEA Medical Services Ltd. working as a Regional Manager of Clinical Operations in MENA and the company Training & QC Manager; in 2015 - 2016 she served in the role of the Group Operations Director.

Since 2007 Kamila has delivered dozens of training courses and workshops on Good Practices (Good Clinical Practice, Good Laboratory Practice, Good Documentation Practices), Clinical Data Management, Clinical Operations, Project Management, Risk Management, Protocol Development, Manuscript writing, International and Local Regulations governing clinical research, etc. to Investigators, clinical research staff, IRB and Regulatory Authority personnel; in addition, she developed and delivered business development, negotiation and presentation skills courses. Since 2013, she has been an Affiliate Member of the CPD Certification Service, UK, and a CPD Registered Presenter.

Over the past 8 years, Kamila has been involved in **medical writing**, including clinical study reports, manuscripts and medical Advisory Board Reports for local and global Pharmaceutical Companies, study Protocols, Patient Information sheets and Informed Consents.

Her **Quality Assurance and Quality Control** expertise includes both system- and project-related activities. Since 1995 Kamila has been involved in dozens of system and site audits in European and Middle East countries as well as one EMA inspection in Greece being responsible for audit preparations, observation analyses, CAPA plan design as well as their implementation oversight. She performed numerous quality control visits to study sites making recommendations for **process improvements**. She has been involved in evaluation of vendors including GXP vendors. Kamila is the author of Quality Manuals, Project Management Plan and Risk Management Plan templates as well as Standard Operating Procedures and Working Instructions in the areas of QA, HR, Regulatory Affairs, Clinical Operations, Project Management, Risk Management, Medical Writing, Company Administration, and Training. Fostering the vital need of continuing professional development, she authored internal certification and education programs for clinical research personnel in clients’ companies.

Her interest in rare diseases and orphan drug development directed her to become a member of the Rare Disease Foundation in Vancouver, Canada as well as other professional societies.
OUR JOB

Whether you are a small biotechnology or pharmaceutical company, a start-up or a spin-off, your project success is undoubtedly your top priority. You need to focus on science and save the time spent on seeking fitting technical solutions or operating models. As your own resources may be limited, working with KAN Consulting can be the missing piece in your puzzle.

Moreover, KAN Consulting collaborates with selected Partners - Consultants in different countries who provide expert solutions in the areas of

- Technology (EDC systems, IVRS/IWRS, registries),
- Medical devices,
- Clinical trial data analytics and forecasting, and
- Systemic modelling.

Should you wish so, these partners may come on board to support your project.
STRATEGIC CONSULTING

- A sound **Project Plan** is the key to your success. A fitting study design, selection of geographic areas, defined project baseline including timelines, resources and budget will help you to estimate your study funding and milestones.
- **Vendor selection** is a time-consuming activity as you need to pre-identify them, schedule product demos or interviews of key personnel, get quotations, develop your vendor scorecard, etc. in order to make informed decisions. KAN Consulting, having a database of vendors, may provide you with a shortlist and recommendations in the very start of your project.
- **Project oversight and coordination**, especially with multiple vendors located in different countries, may get quite challenging. You can delegate it to your consultant who acts as a member of your team protecting your interests.

QUALITY ASSURANCE AND QUALITY CONTROL

Acceptance of study results by the Regulatory Authorities is the prerequisite of your asset further development. Whether you plan to out-license your molecule or bring it to the market yourself, regulatory compliance is mandatory all along the way. A solid **Quality Management Plan** and quality control activities will help you to meet regulatory requirements.

We offer

- Vendor qualification and re-qualification audits,
- Quality oversight visits to study sites,
- Site staff training in GCP and study management for investigators,
- In-house and site preparation for inspection,
- Finding analysis,
- CAPA Plan development and implementation support.

SENIOR PROJECT MANAGEMENT ROLES ON DEMAND

If you need a contract project manager or director, we can offer you experienced candidates to manage your projects according to ISO 21500 standard and in compliance with applicable regulations.
YOUR BENEFITS

Everyone could do with a bit of extra time and money and KAN Consulting can help save you both. Whether you are a biotechnology or pharmaceutical company, an institution representative, an investigator, or a CRO, you may find something in our offer you can benefit from.

SMALL BIOTECH AND PHARMA, START-UPS AND SPIN-OFFS

We contribute to increase your asset value.

- Business Intelligence and forecasting as the first steps in your project will provide you with information needed in the initial project considerations.
- Fitting study design, right sample size and statistical plan will minimize the need of costly amendments, changes in scope, or adding new countries mid-way, thus, we save time and money in executing your project.
- Professional Project Control saves time and reduces cost while ensuring your selected vendors perform to expectations.
- Regulatory-required Quality, Project and Risk Management Plans will save you sleepless nights creating a no-surprise environment.
INSTITUTIONS

Institutions engaged in research, whether conducting its own or industry-sponsored projects, are more successful with functional research offices or centres taking care of organisational and technical aspects of studies. It relieves investigators and their teams from the administrative burden allowing them to focus on the science and patient care.

KAN Consulting supports institutions wishing to enhance their research potential with

- Establishment or optimisation of research office operations, e.g. gap analysis of existing SOPs, study budgeting solutions, benchmarking and forecasting;
- Clinical research training of personnel, including but not limited to research ethics, regulations, study management for investigational sites, GCP, contract negotiation, protocol development;
- Technical solutions, such as platforms for registries and registry management tools.

INVESTIGATORS

Whether you are just starting your research career or run your own studies routinely, a strong project plan including budget calculations will help you to present your research idea to the grant committee or find a sponsor in the industry. Pharmaceutical and biotechnology companies do offer funding, however, each investigator-driven project undergoes a thorough scrutiny in order to get selected for funding.

KAN Consulting offers support in project plan development as well as its presentation to increase your winning score.

In addition, we help the investigators in protocol development, study report and manuscript writing.

CROs

Our CRO clients are particularly interested in

- Specialised training courses and workshops on project management, risk management, negotiation skills, presentation skills and business development;
- Consulting on technology solution procurements;
- Support in implementing advanced project management and risk management approaches to keep pace in the rapidly changing drug development environment.
Thank you for reading out brochure. Hope you have found the information you sought. Thanks to technology, physical distances are less and less important. Please do not hesitate to contact us with inquiries, we will respond within 24 - 48 hours.

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Skype meetings will be scheduled upon request.