



Praktische Doings bei der Studienplanung und -durchführung

Webinar des SVDGV

Wie plane ich eine Evaluationsstudie zeitlich?

Wie binde ich eine Studienzentrums an?

Wie setze ich Verträge auf?

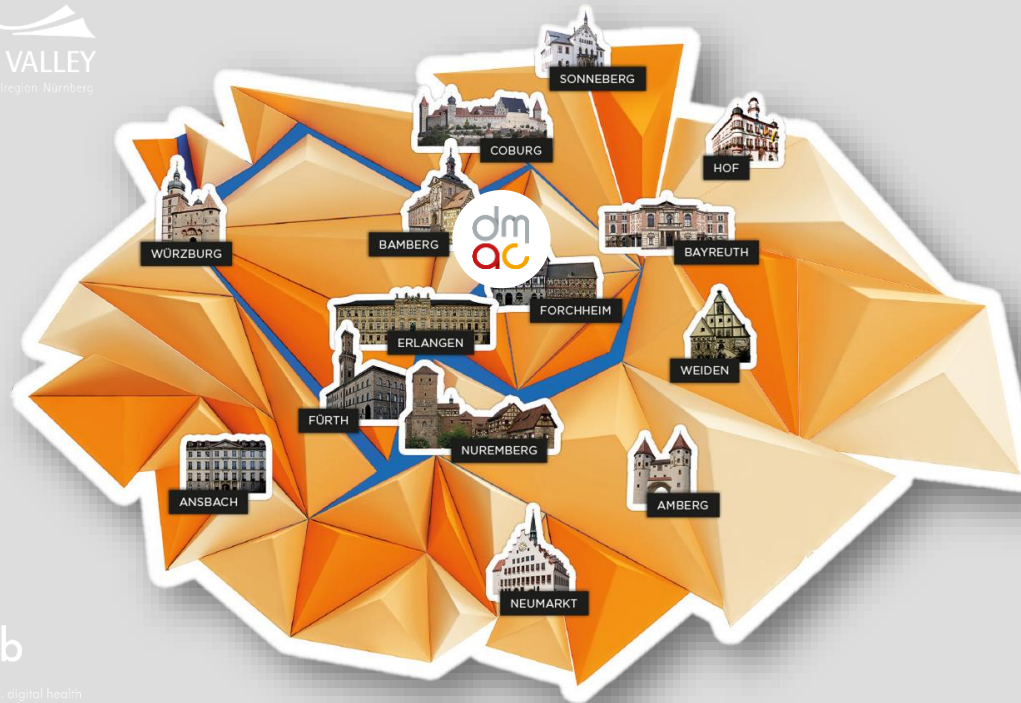
Was heißt es einen Ethikantrag zu stellen?

Wie vergüte ich eine Studie?

Wie kann eine Technologieintegration ins Studiendesigns aussehen?

dmac is the digital health think tank of an internationally leading healthcare ecosystem

Medical Valley European Metropolitan Region Nuremberg



de:hub
digital ecosystems
nürnberg erlangen digital health

500+
MedTech Companies

65+
Hospitals

80+
Universities

20+
Non-university Research Institutes

4
Medical Valley Centers



dmac is a joint venture of Medical Valley EMN and Fraunhofer IIS and builds on both partners' complementary strengths



Core Partners

Network

Internationally leading innovation ecosystem in the area of healthcare management.

Digital Health Expertise

Think tank and service provider for digital healthcare manufacturers.

Technology

Application-oriented research institute and a global leader in microelectronic and information technology system solutions and services.

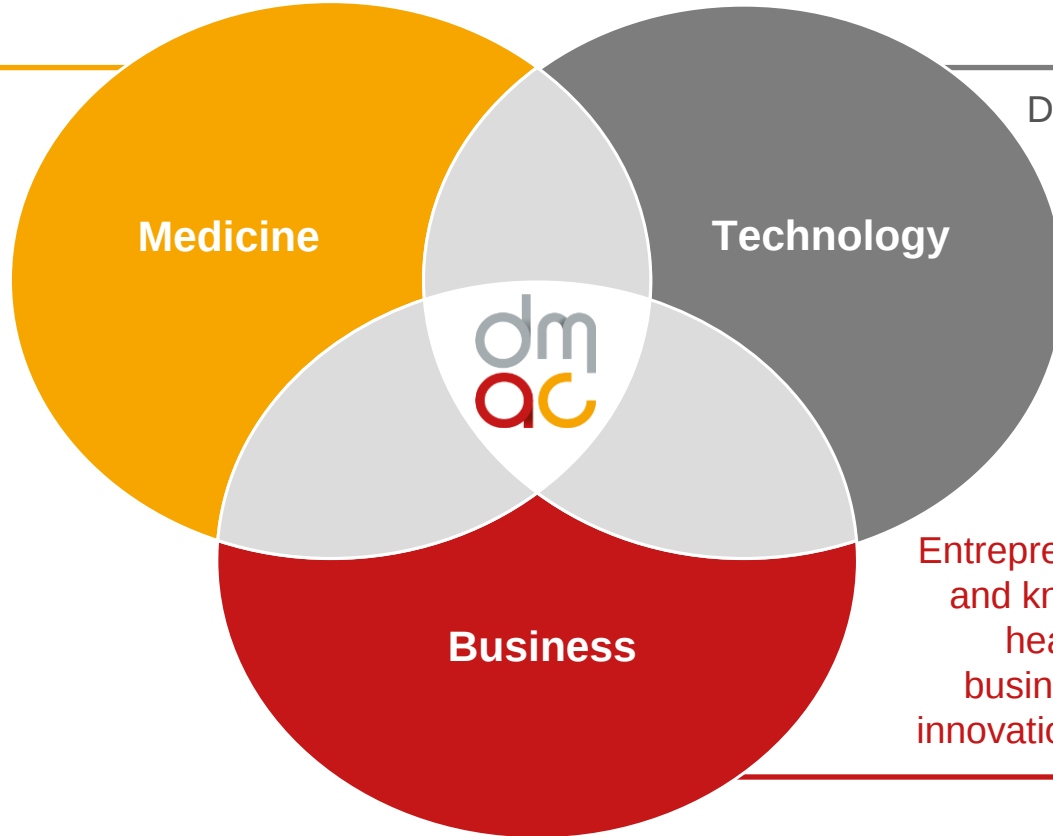


dmac combines expertise from medicine, business and technology for a holistic view on healthcare



Areas of Expertise

Focus on the well-being of the patient and experience in medical care and clinical research

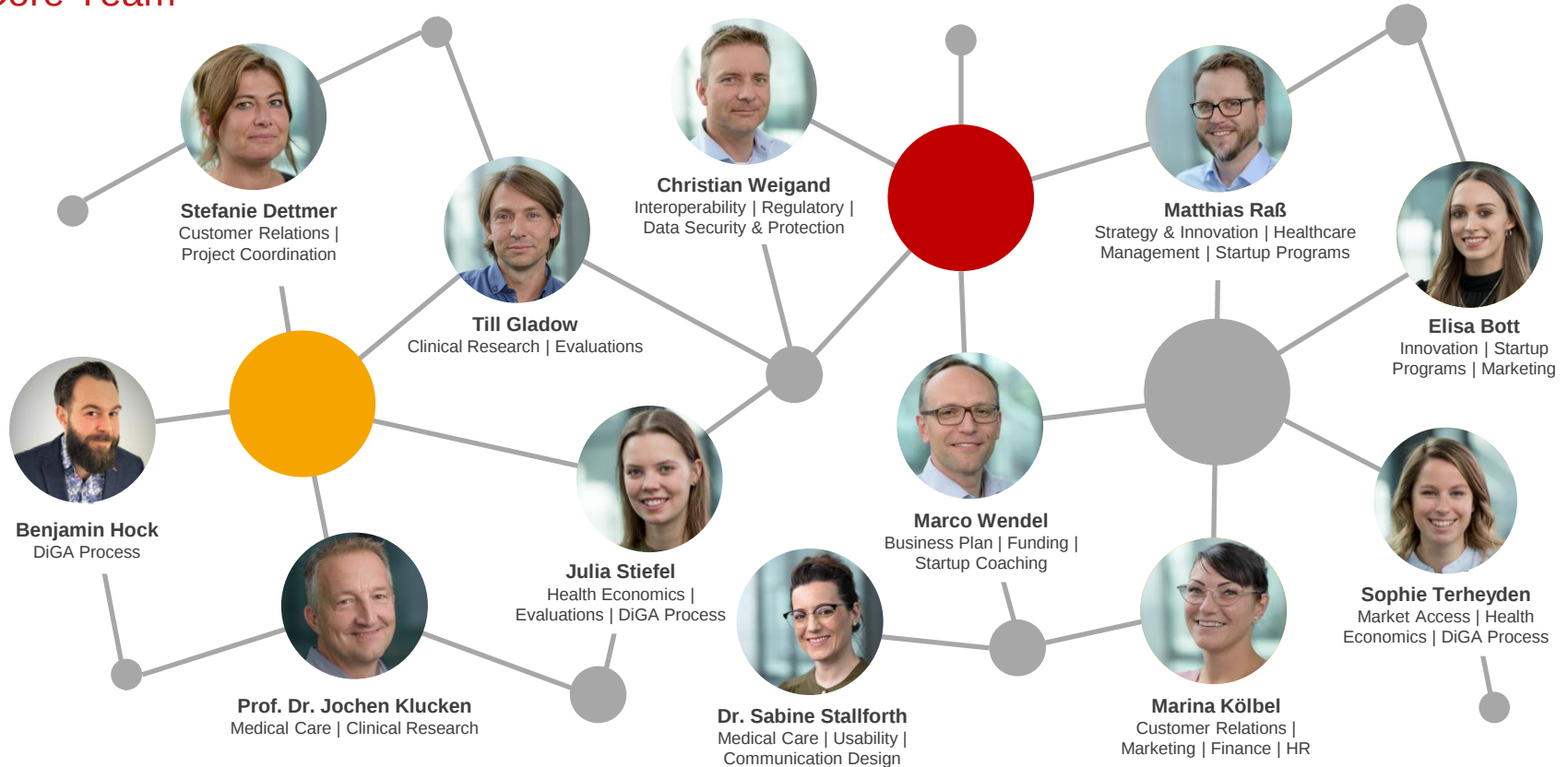


Deep understanding of digital technologies, required skills and transformation processes

Entrepreneurial mindset and knowledge on the healthcare market, business models and innovation management

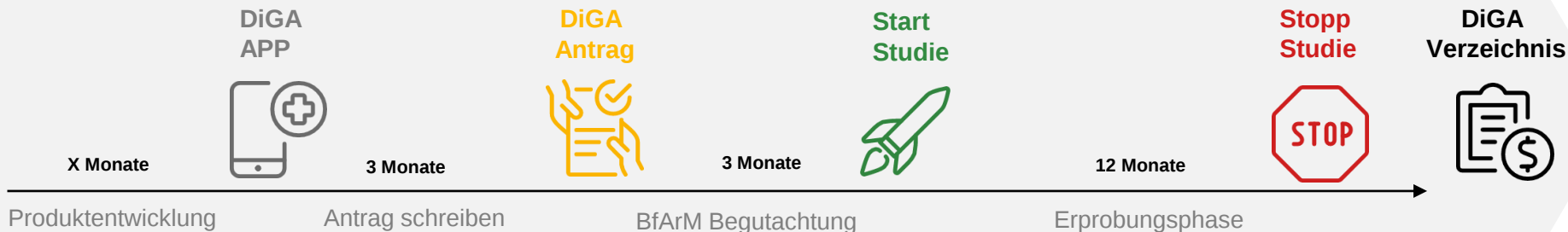
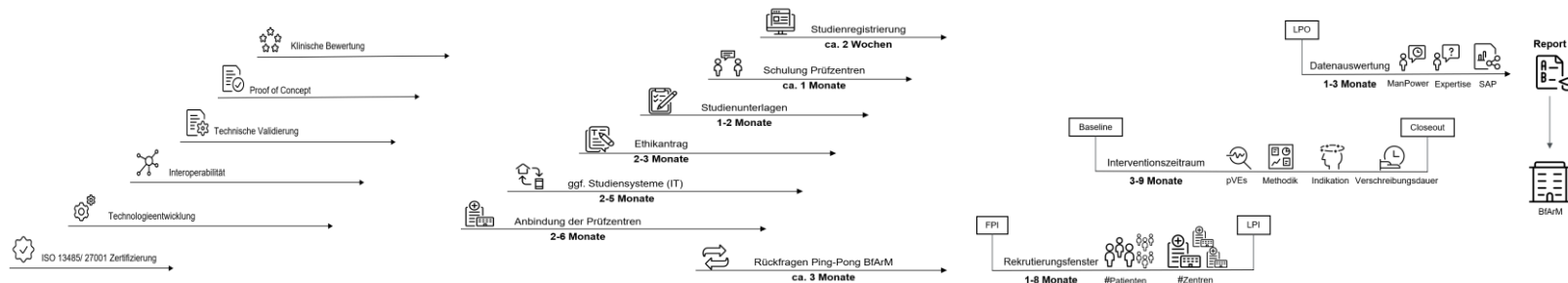
Our key asset is a multidisciplinary team of digital health enthusiasts with a proven track record in the industry

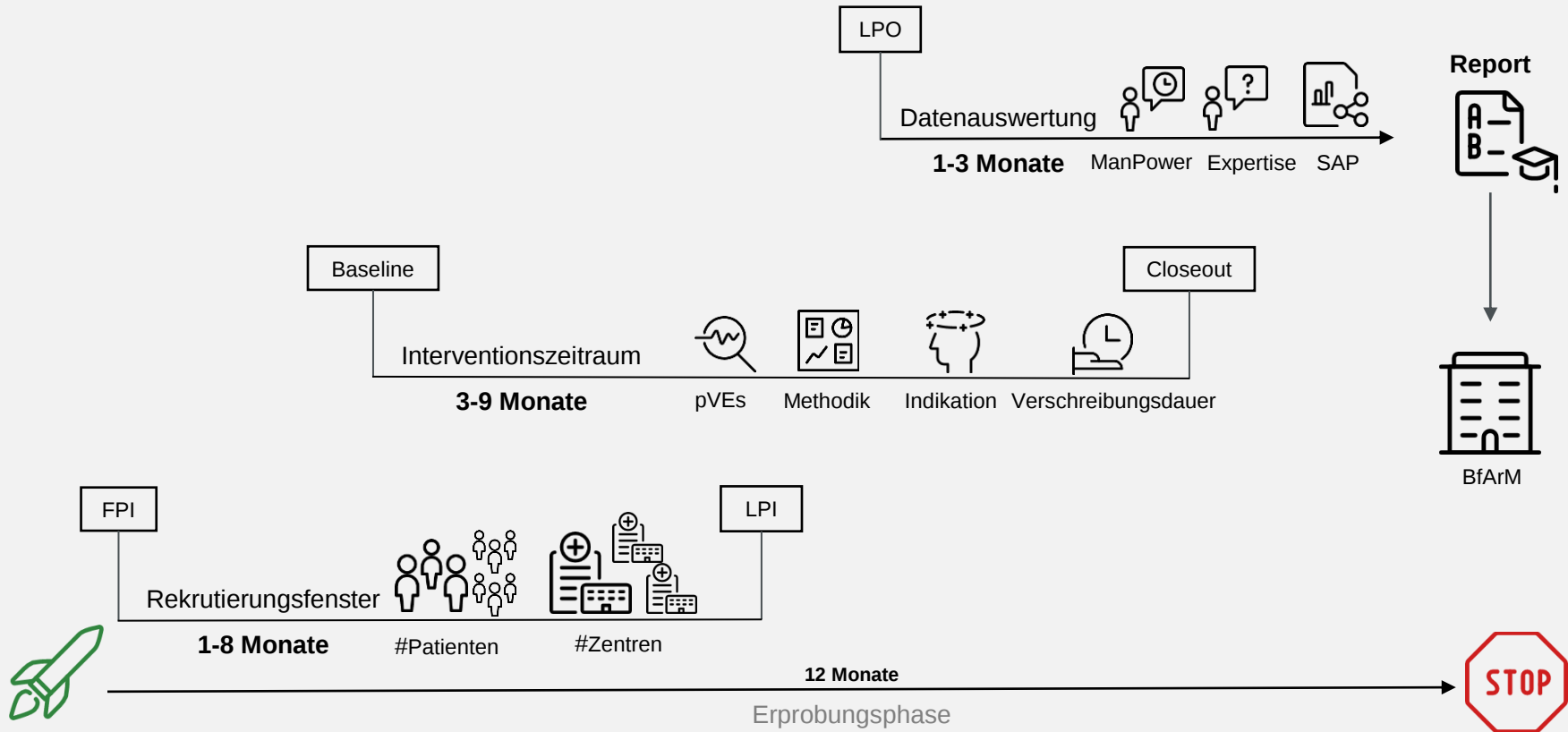
Core Team



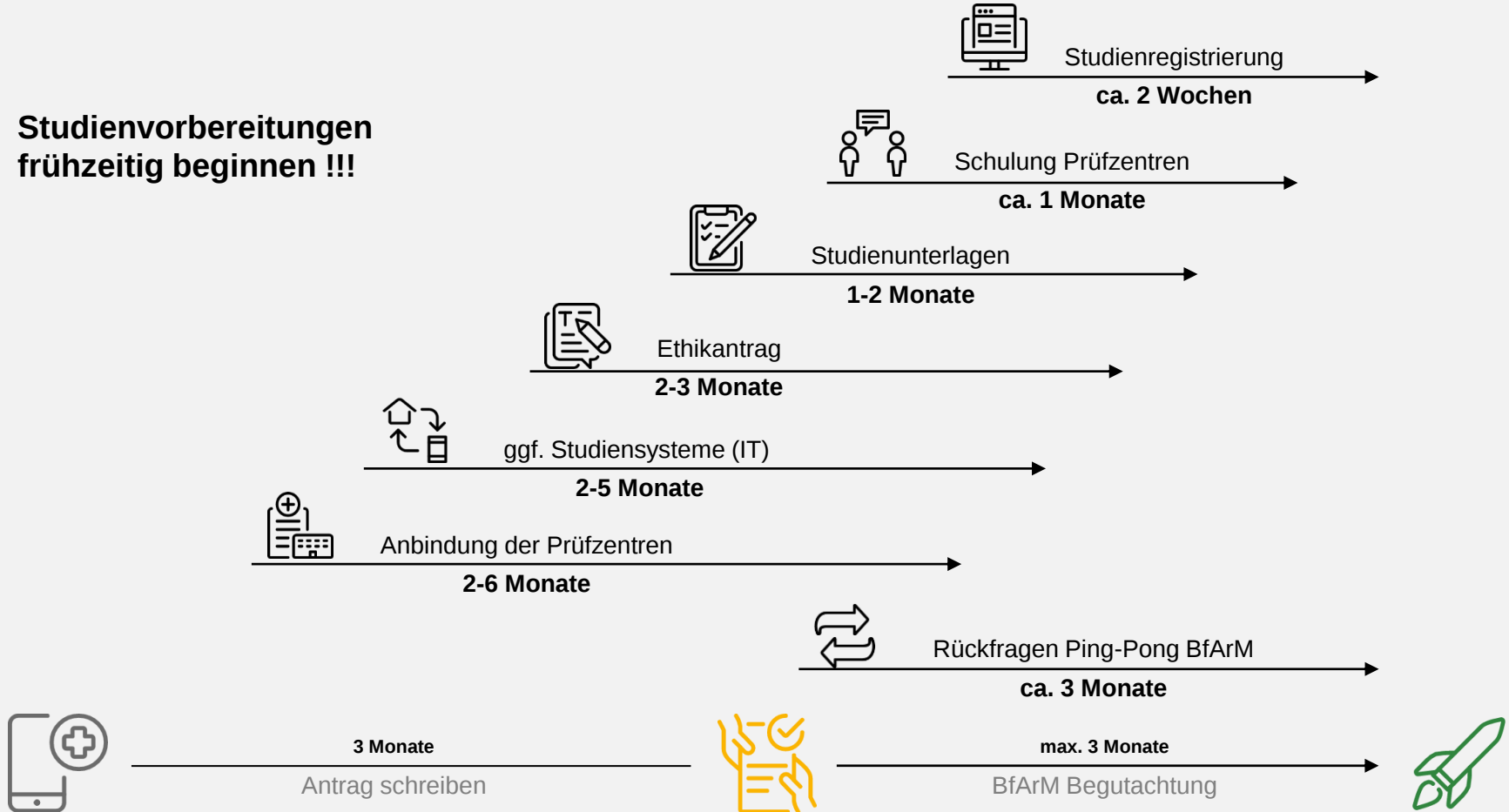
Meilensteine auf dem Weg in das DiGA-Verzeichnis

Studienplanung

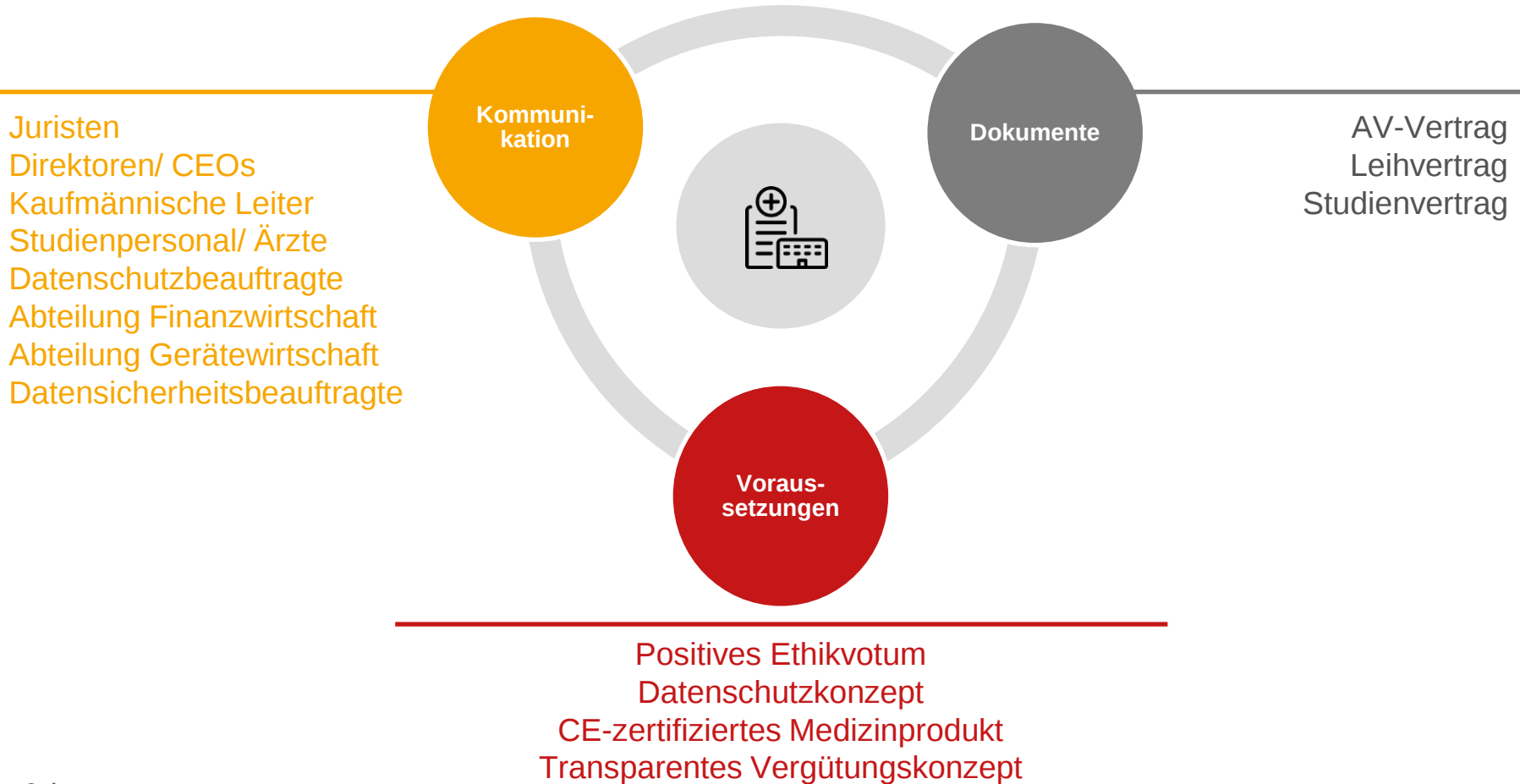




Studienvorbereitungen frühzeitig beginnen !!!



Anbindung von Prüfzentren

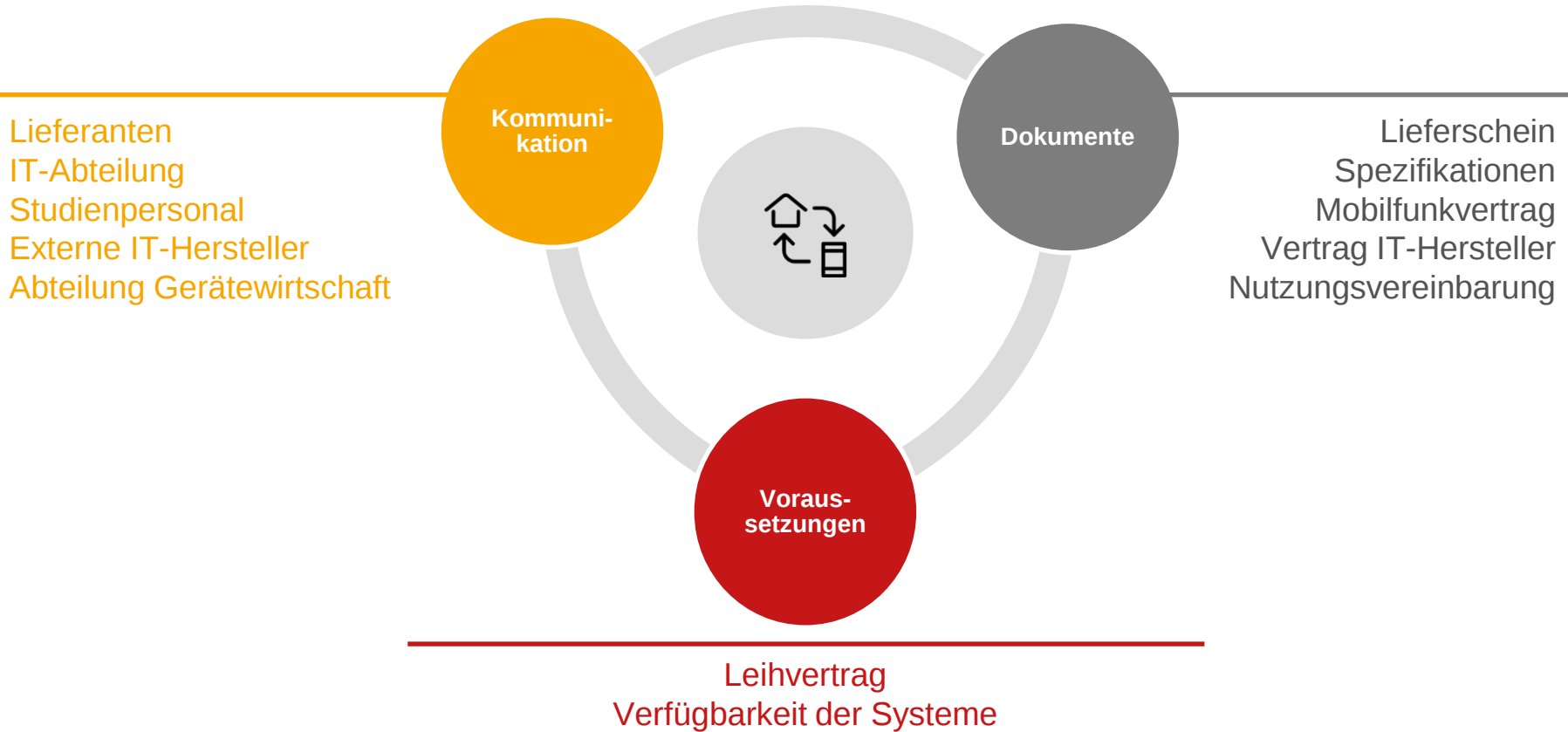


Studienvergütung – Was kostet eine Studie?

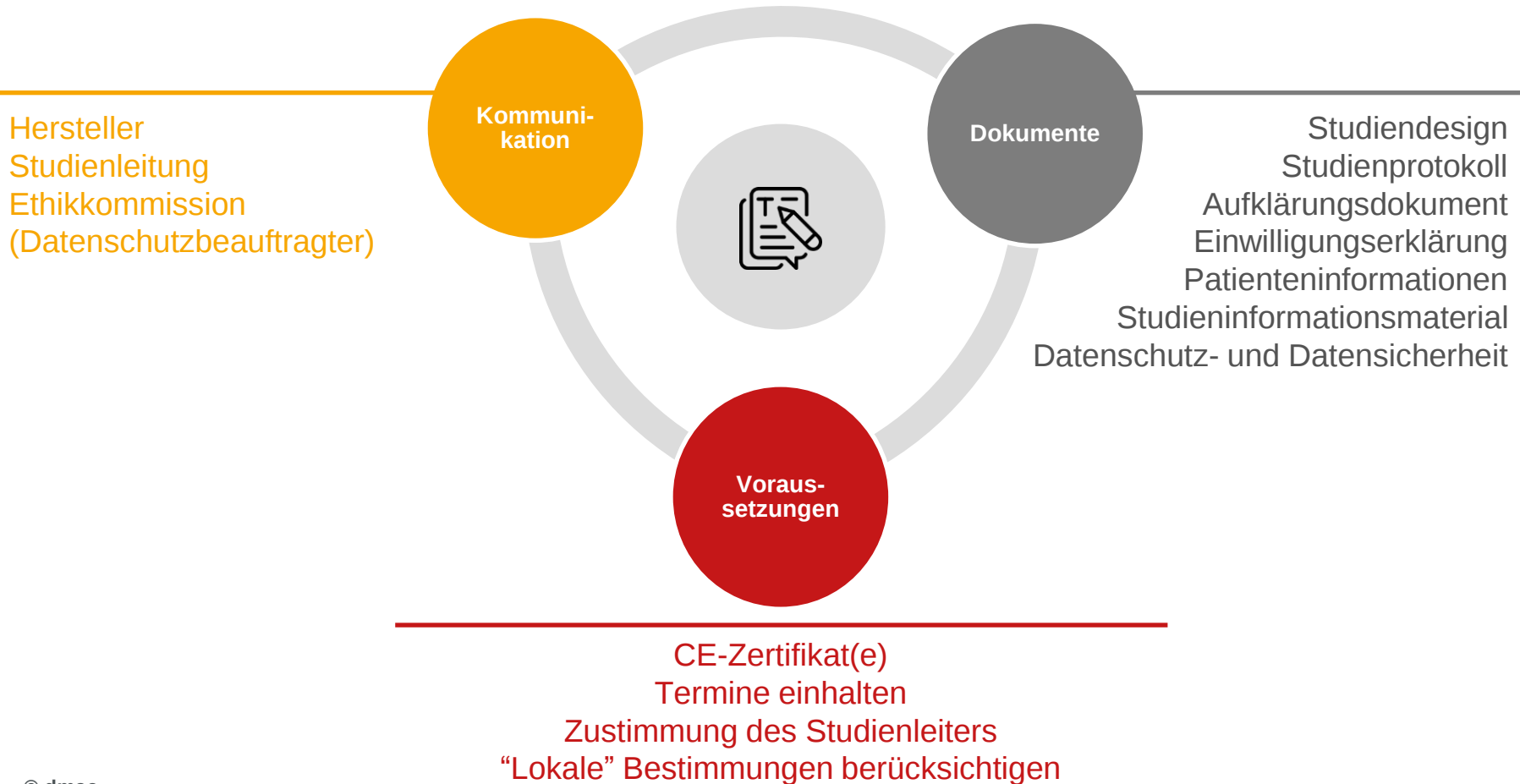
Variable Kosten pro Patient	Feste Kostenanteile
• Personalkosten • Patientenvergütung • Untersuchungskosten • eCRF • Materialkosten Hersteller	• Personalkosten Hersteller • Auftrag CRO • Lizenzen Fragebögen • Ethikkommission
Gesamtkosten der Studie	

⇒ Vergütung der Kliniken pro Patient (Pay for Service)

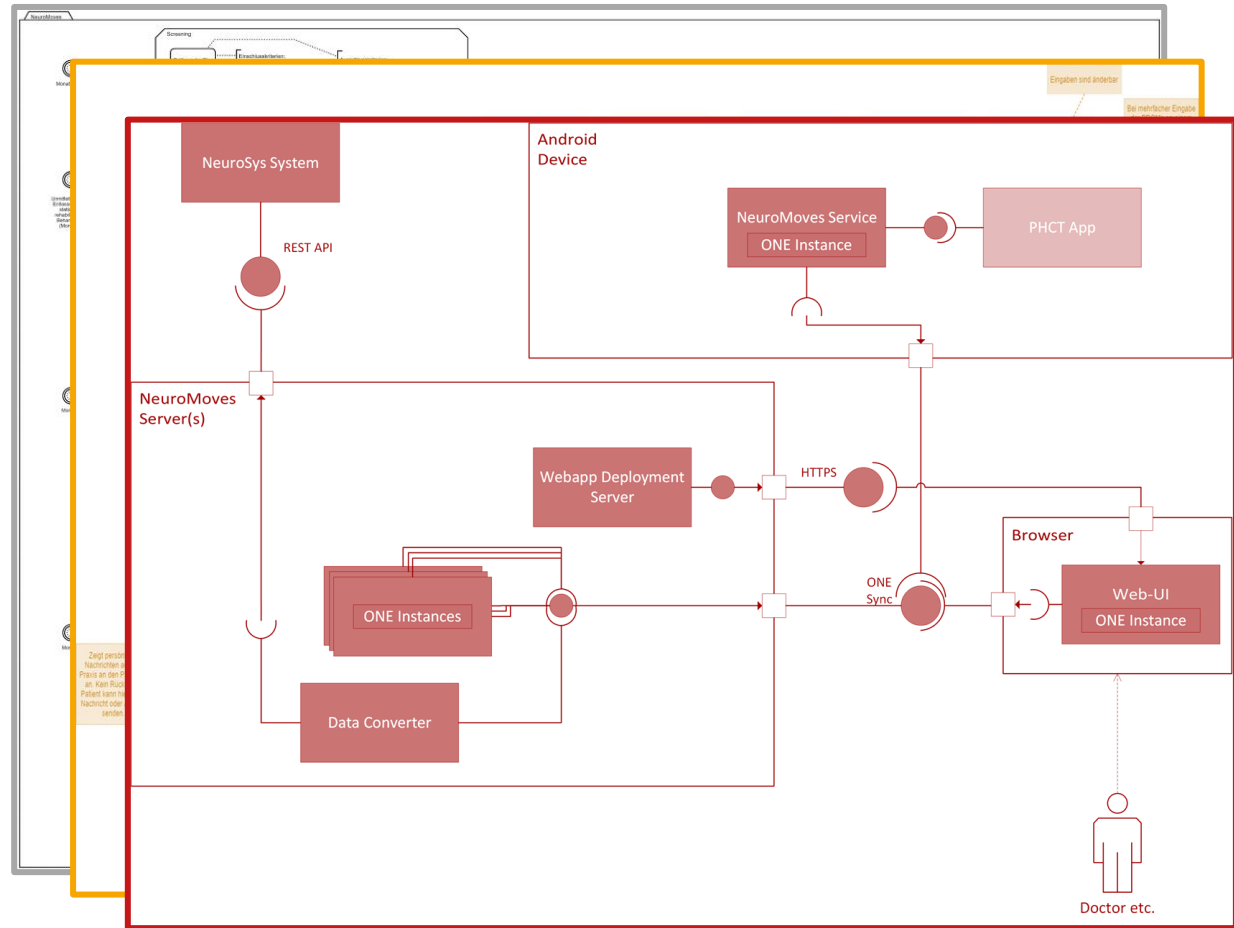
Bereitstellung von Studiensystemen



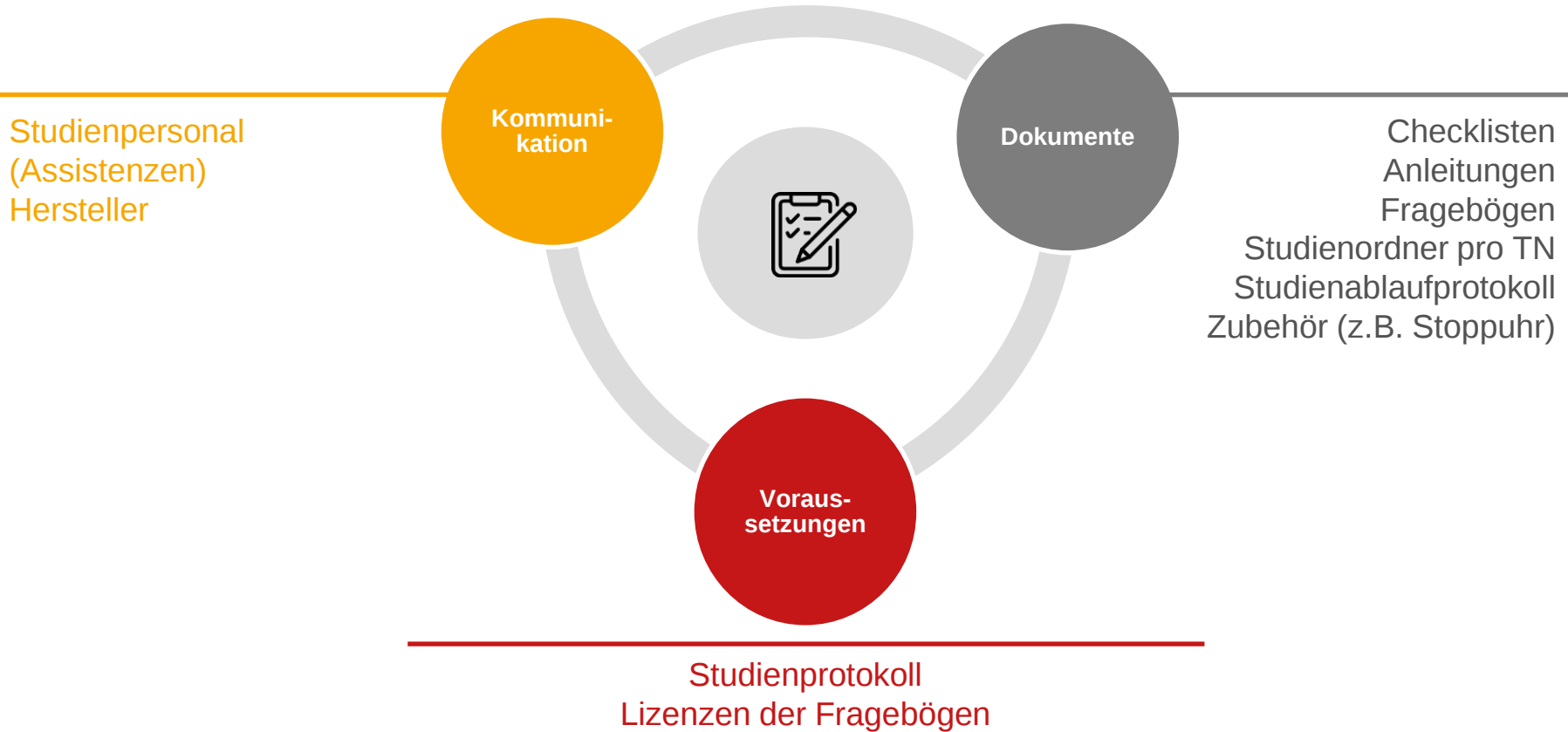
Ethikantrag



Studiendesign – Technologieintegration in medizinische Studienkonzepte

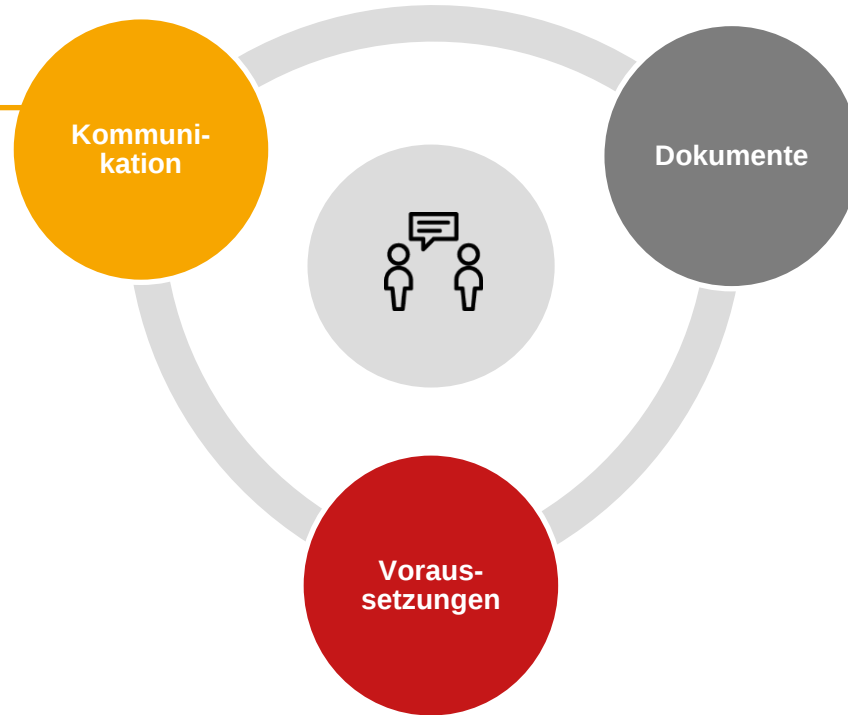


Bereitstellung von Studienunterlagen



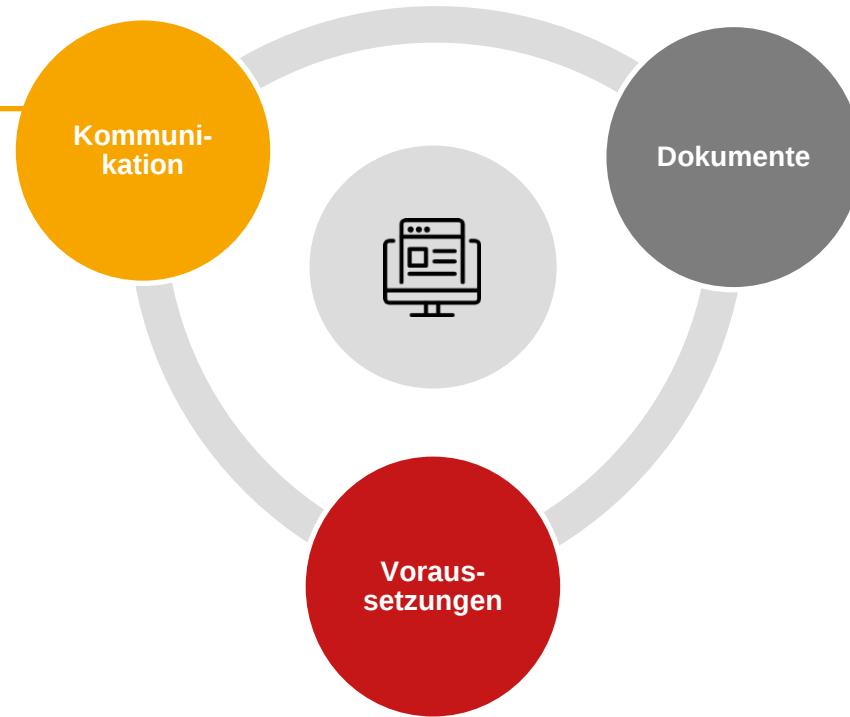
Schulungen der Prüfzentren

Hersteller
Studienärzte
Studien-Assistenzen



Schulungsunterlagen
Schulungsbestätigung
Bedienungsanleitungen

Frühzeitige Terminierung
Studiensysteme verfügbar und vor Ort
Vertragliche Anbindung abgeschlossen



www.clinicaltrials.gov
www.drks.de

Studienprotokoll
Positives Ethikvotum
Prüfzentren angebunden

Fragen, Erfahrungsaustausch, Diskussion, ...



Till Gladow

**Head
Clinical Research Services**

+49 951 96430032
till.gladow@mv-dmac.de



a joint venture of
Medical Valley &
Fraunhofer IIS



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