swissmedic
20 Jahre 2002 - 2022

Einführung
Session: Klinische Versuche und Bewilligungen

Alexander Mion, Leiter Abteilung Klinische Versuche

Klinische Versuche und Bewilligungen

Focus on innovation: Early phase clinical trials and DCTs	Alexander Mion
Digitalisierung: Chance, Herausforderung und Limits	Federico Cimini Georges Meseguer Christian Schärer
Remote approaches to GCP and GVP regulatory oversight	Simone Ferbitz
Anpassungen im Betäubungsmittelrecht zur medizinischen Verwendung von Cannabis	Monika Joos
Anschliessend (16:00-17:30): *Swissmedic Info-Markt inkl. Apéro*	*All welcome*

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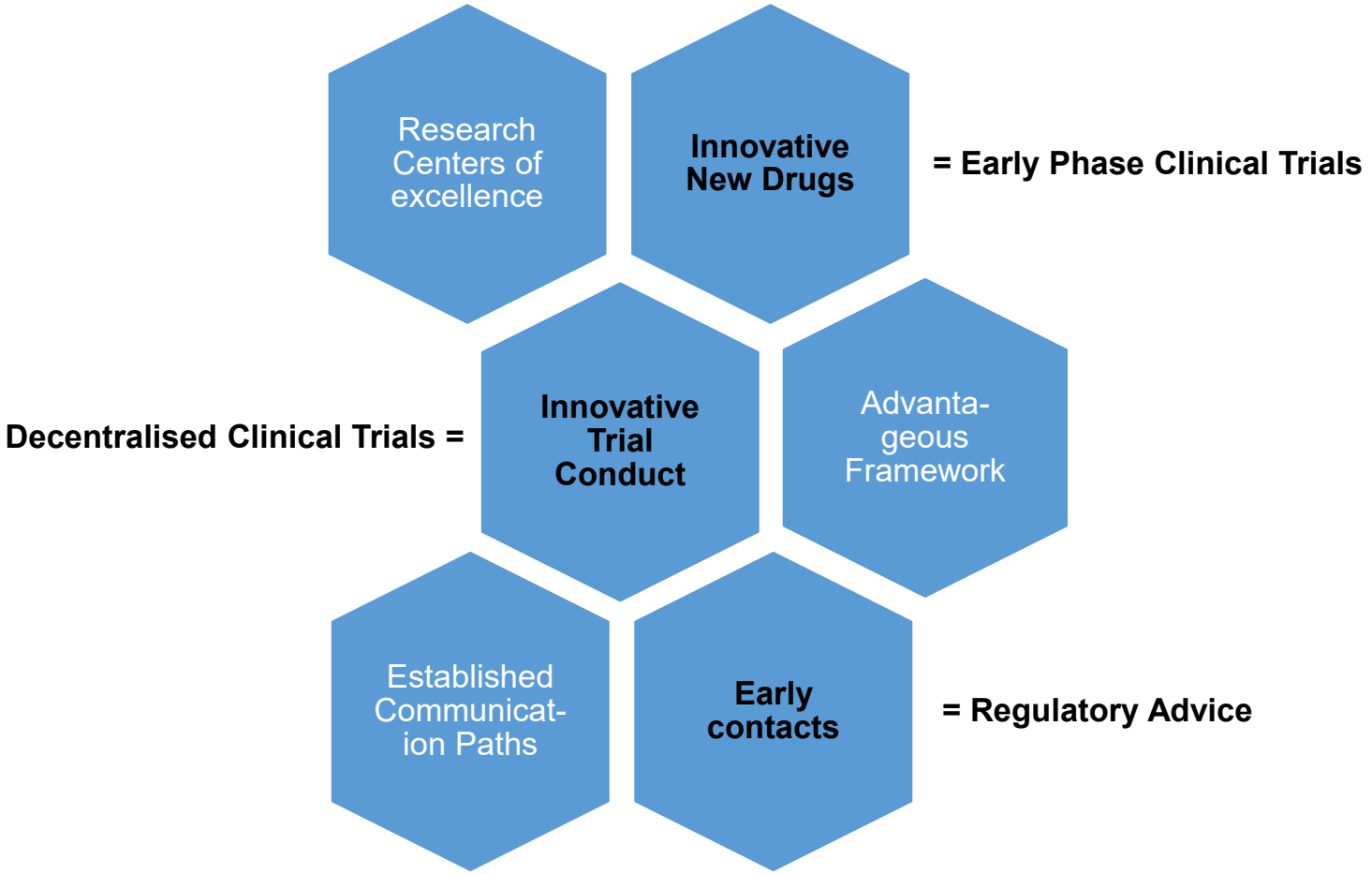
Focus on innovation:
Early phase clinical trials and DCTs

Alexander Mion, Leiter Abteilung Klinische Versuche

Focus on innovation



Pandemiesituation:
Beschleunigte Evaluation von «Covid-19»-Studien

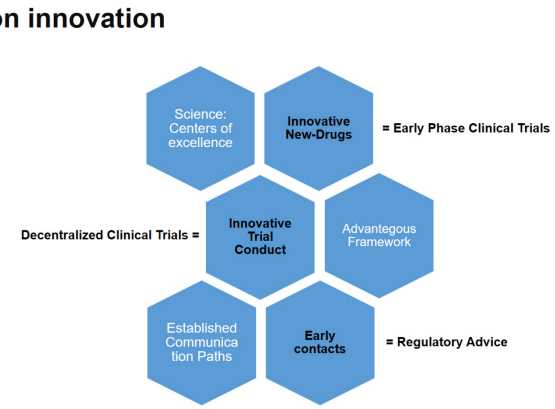
Priorisierung der Evaluation von Covid-19-Studien (Arzneimittel)

➢ **Alle im Jahr 2020 bei Swissmedic eingereichten**

Gesuche für <u>Covid-19-Studien</u> wurden <u>innerhalb von 7 Tagen bewilligt</u>

(gerechnet ab Zeitpunkt der Vollständigkeit der Gesuchs-Unterlagen).

Die gesetzliche Frist beträgt gemäss KlinV
7 Tage
zur Überprüfung der formalen Vollständigkeit der Unterlagen
plus **30 Tage (bzw. 60 Tage)**
bis zum Entscheid.



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Early phase clinical trials:
Beschleunigte Evaluation von frühe Phase Studien

- Die Beschleunigte Bearbeitung ist möglich (vgl. Covid-19-Studien).
- Der Fokus auf Sicherheit und Qualität bleibt zentral !

Ist es möglich frühe Phasen-Studien mit **innovativen Arzneimitteln**

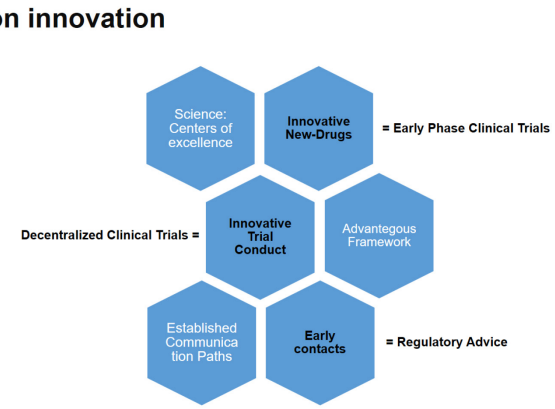
beschleunigt zu evaluieren?

Pilotversuch 2022:

14 frühe Phase Studien

(Ph 1, Ph 1-FIH, Ph 1A/B, Ph 1/2, Ph 1-Bioequivalence)

Interim Analyse: JAN-JUN 2022



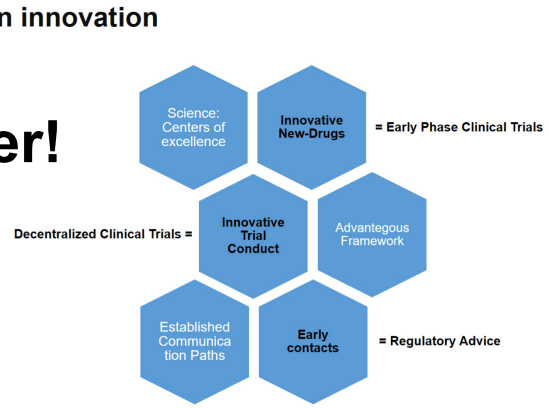
Early phase clinical trials:
Beschleunigte Evaluation von frühe Phase Gesuchen

Interim-Analyse → Pilotversuch POSITIV !

- Evaluation **bei allen 14 Studien schneller** als die gesetzliche Frist.
  - Bei 5 Studien: Bearbeitungsdauer **um 50% reduziert**.
  - Bei weiteren 5 Studien: Bearbeitungsdauer **um 25% reduziert**.

FAZIT

Evaluation bei 10 von 14 Studien deutlich schneller!



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Early phase clinical trials:
Beschleunigte Evaluation von frühe Phase Gesuchen

Evaluation bei 10 von 14 Studien deutlich (**50%** / **25%**) schneller:

SA-Number	Title (Shortened)	Time
102669735	Phase Ib/II open label dose confirmation study	28/37
102669736	Phase I/II, Multicenter, Open-label, Clinical and Pharmacokinetic Study	32/37
102671805	Phase 1b Study Evaluating the Safety and Efficacy	13/37
102671930	Phase Ib Dose Finding Study Assessing Safety and Activity	23/67
102674957	Phase 1b/2, Multicenter, Open-label Basket Study Evaluating the Safety and Efficacy	25/67
102675060	Phase IA/B open-label study to evaluate Safety, Pharmacokinetics and preliminary clinical activity	43/67
102675429	A dose-response metabolic balance study	14/37
102677645	Phase 1, Open-Label, Multicenter Study	37/67
102677727	A Phase 1/Phase 2 Study to Evaluate the Safety and Tolerability	39/67
102678715	Phase 1 First-In-Human Study to Explore the Safety, Tolerability, and Pharmacokinetics	40/67
102679846	Comparative bioavailability study	22/67
102680775	Phase 1 Study to Investigate the Safety, Pharmacokinetics, and Efficacy	30/37
102680776	A Phase 1 Study Evaluating the Safety, Tolerability, Pharmacokinetics, and Efficacy	60/67
102681250	Multicentric phase I study	24/37

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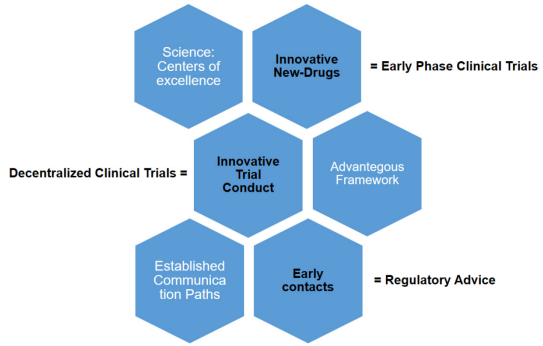

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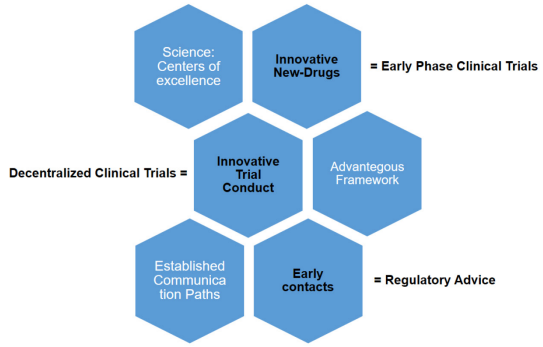
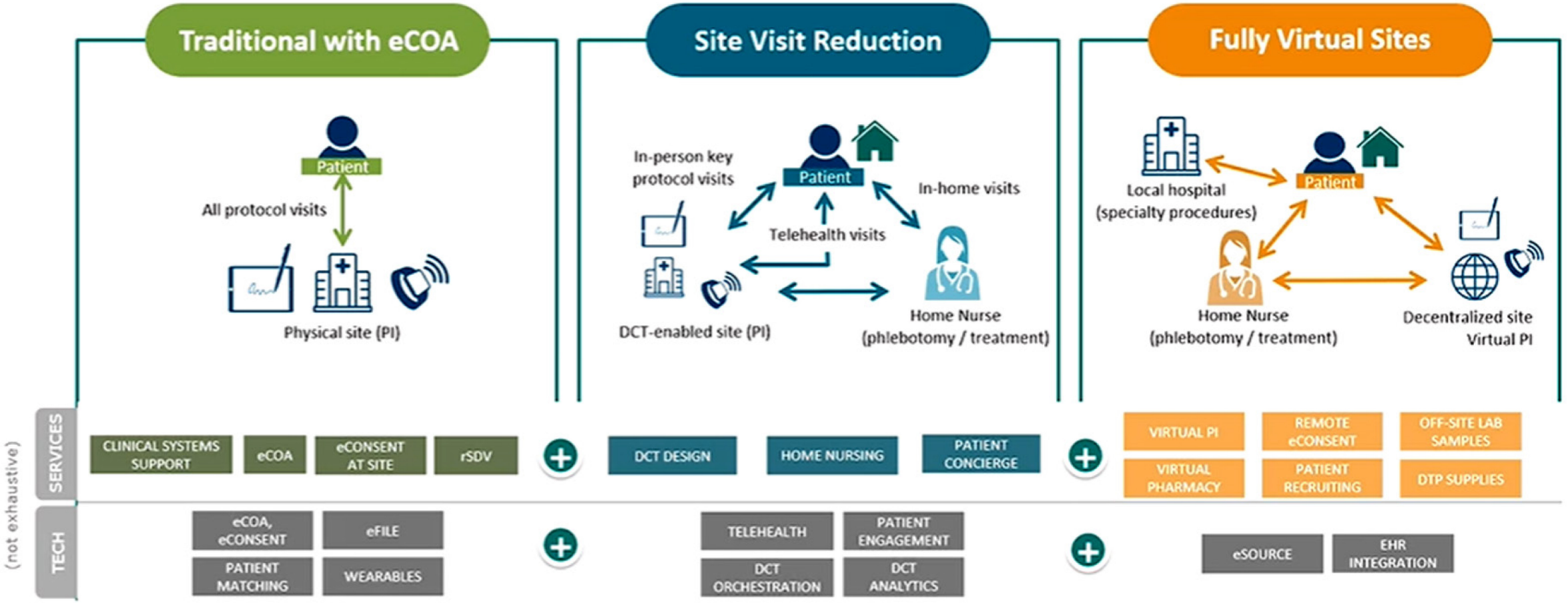
Decentralised Clinical Trials (DCTs)

- Key features of DCTs
- Learning from C19 experience in Switzerland
- DCT position paper Swissmedic-swissethics: Invite for early dialogue

Focus on innovation



Decentralised Clinical Trials (DCTs): Key features



Decentralised Clinical Trials (DCTs): Build on experience for trial conduct during C19 pandemic

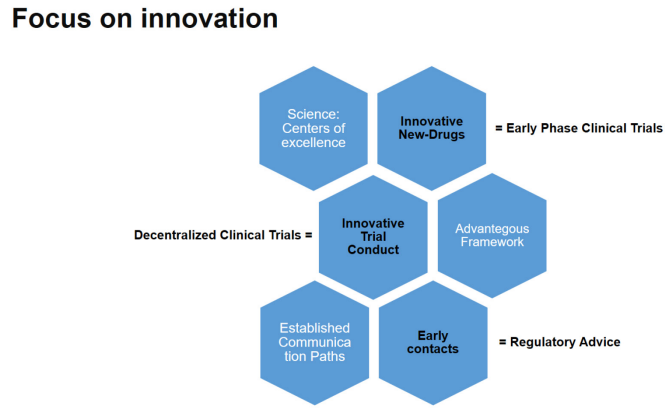
26.03.2020

The spread of the new coronavirus (SARS-CoV-2) also poses a major challenge for clinical trials of medicinal products in Switzerland.

Swissmedic and swissethics have therefore published a joint document, which describes the most important recommendations for the treatment of patients in clinical trials of medicinal products.

- Somehow «*enhanced*» by the pandemic situation, some of the DCT features (e.g. in-home visits) have already been applied in CH.

➢ **Increased understanding of challenges & opportunities for <u>innovative clinical trial conduct</u> in Switzerland.**



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Decentralised Clinical Trials (DCTs): Invite for early dialogue

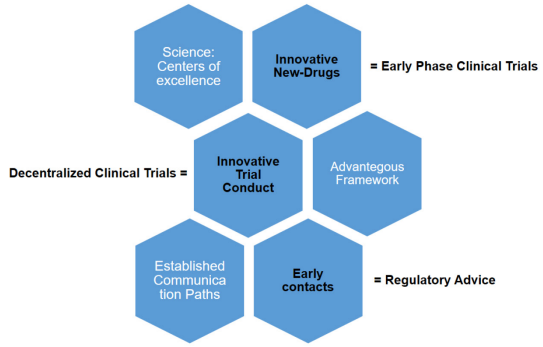
- **Focus on innovation: DCTs as innovative clinical trials in Switzerland.**

01.11.2021

Position paper by Swissmedic and swissethics on decentralized clinical trials (DCTs) with medicinal products

There is great interest, both internationally and in Switzerland, in performing decentralised clinical trials. Both Swissmedic and swissethics are committed to support researchers and sponsors in this innovative step. The present document focuses on clinical trials with medicinal products and is intended for sponsors and researchers who are planning DCTs and want to perform them in Switzerland.

- **Invite to Regulatory Advice: → Early dialogue for upcoming DCTs**



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Weitere Informationen

- https://www.swissmedic.ch/swissmedic/de/home/news/coronavirus-covid-19/klv-cov-2-pandemie.html
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