swissmedic
20 Jahre 2002 - 2022

Introduzione
Sessione: sperimentazioni cliniche e autorizzazioni

Alexander Mion, capo divisione Sperimentazioni cliniche

Sperimentazioni cliniche e autorizzazioni

Focus sull'innovazione: sperimentazioni cliniche di Early Phase e DCT	Alexander Mion
Digitalizzazione: opportunità, sfide e limiti	Federico Cimini Georges Meseguer Christian Schärer
Approcci remoti alla vigilanza normativa GCP e GVP	Simone Ferbitz
Revisione della legislazione sugli stupefacenti per l'uso medico della cannabis	Monika Joos
Infine (16:00-17:30): *Piazza informativa di Swissmedic incluso aperitivo*	*Tutti invitati*

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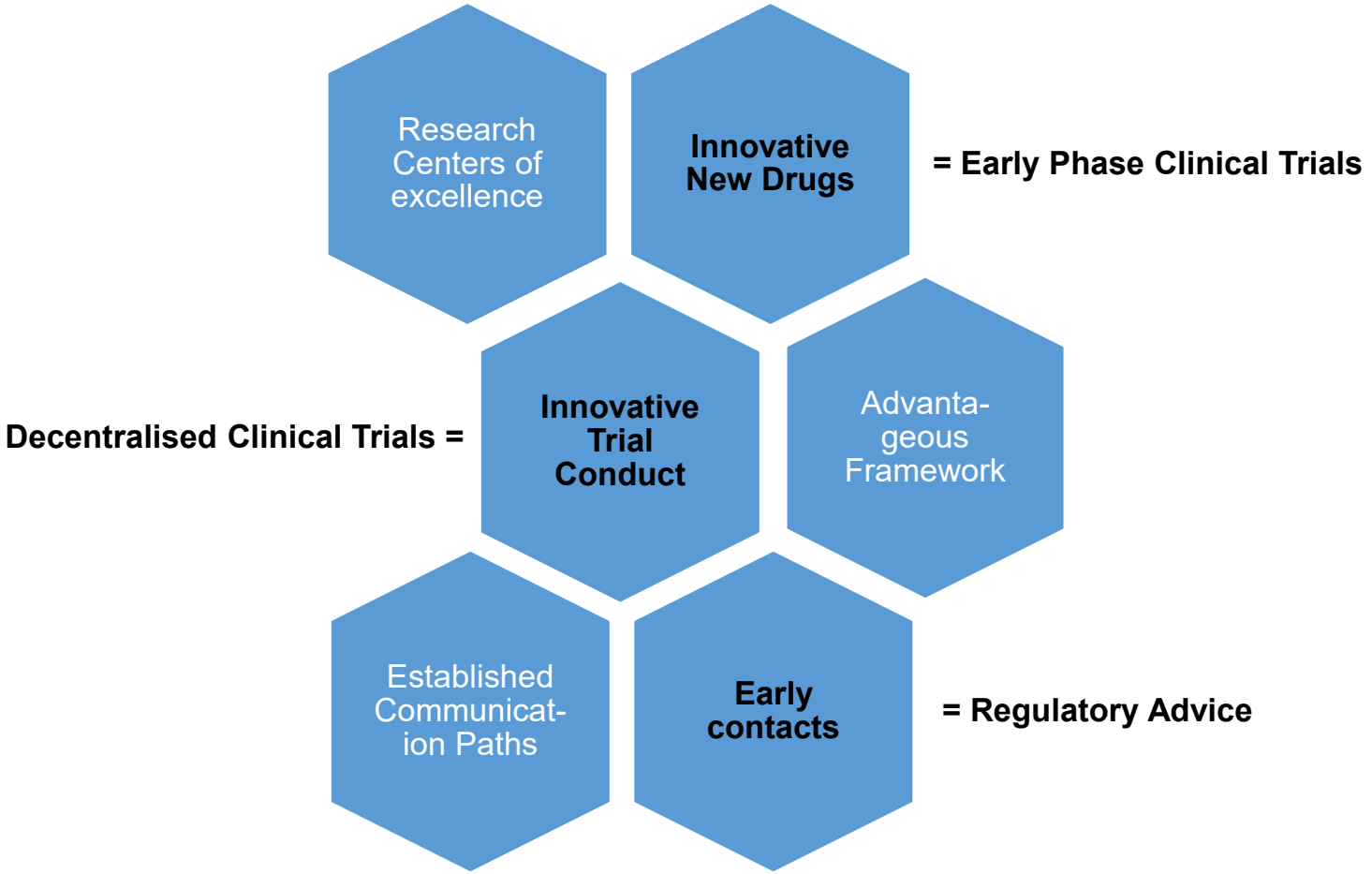
Focus sull’innovazione: sperimentazioni cliniche di Early Phase e DCT

Alexander Mion, capo divisione Sperimentazioni cliniche

Focus sull’innovazione



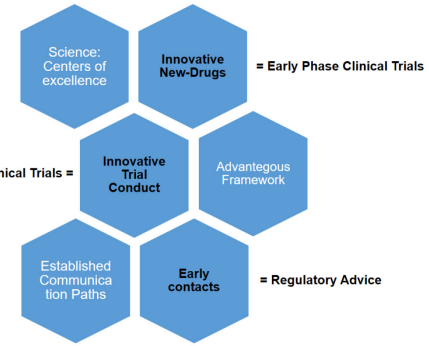
Situazione pandemica: valutazione accelerata di sperimentazioni sul COVID-19

Priorità alla valutazione delle sperimentazioni sul COVID-19 (medicamenti)

➢ **Tutte le domande inoltrate a Swissmedic nel 2020 per sperimentazioni sul COVID-19 sono state autorizzate entro 7 giorni (a partire dal momento in cui la documentazione della domanda era completa).**

Ai sensi dell'OSRUm, il termine legale è di
7 giorni
per la verifica della completezza formale della documentazione
più **30 giorni (o 60 giorni)**
fino alla decisione.

Focus on innovation



Sperimentazioni cliniche di Early Phase: valutazione accelerata di sperimentazioni di Early Phase

- È possibile l'elaborazione accelerata (cfr. sperimentazione COVID-19).
- L'attenzione a sicurezza e qualità resta prioritaria!

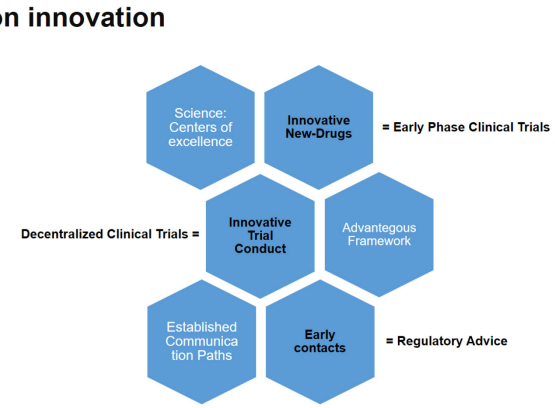
È possibile accelerare la valutazione delle sperimentazioni di Early Phase con **medicamenti innovativi**?

Esperimento pilota 2022:

<u>14 sperimentazioni di Early Phase</u>

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

Analisi intermedia: GEN-GIU 2022



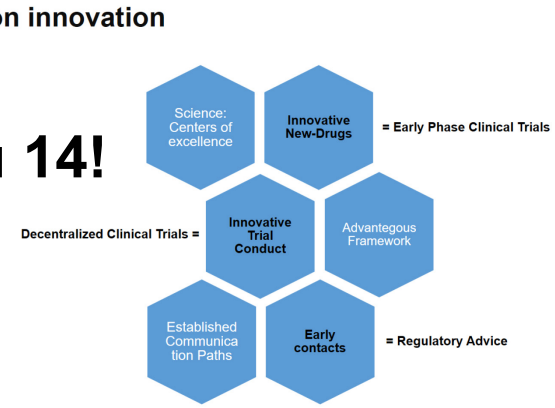
Sperimentazioni cliniche di Early Phase: valutazione accelerata di domande di Early Phase

Analisi intermedia → esperimento pilota POSITIVO!

- Valutazione **per tutte le 14 sperimentazioni più rapida** del termine legale.
  - Per 5 sperimentazioni: tempo di elaborazione **ridotto del 50%**.
  - Per altre 5 sperimentazioni: tempo di elaborazione **ridotto del 25%**.

CONCLUSIONE

Valutazione molto più veloce per 10 sperimentazioni su 14!

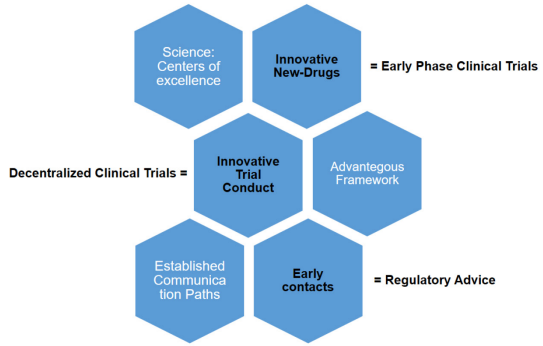


Sperimentazioni cliniche di Early Phase 1: valutazione accelerata di domande di Early Phase

Valutazione molto più veloce (**50% /25%**) per 10 sperimentazioni su 14:

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

Focus on innovation



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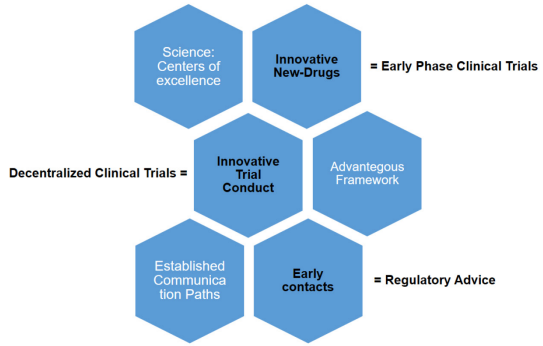
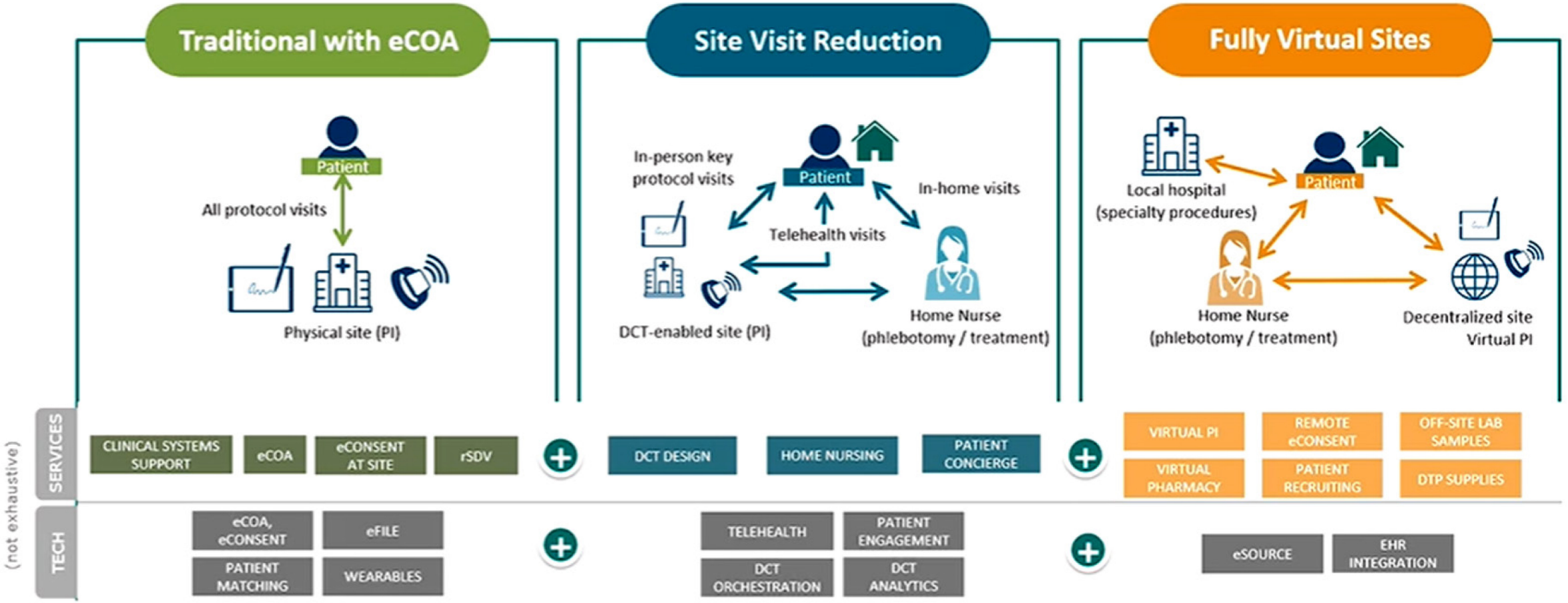
Decentralised Clinical Trials (DCTs)

- 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

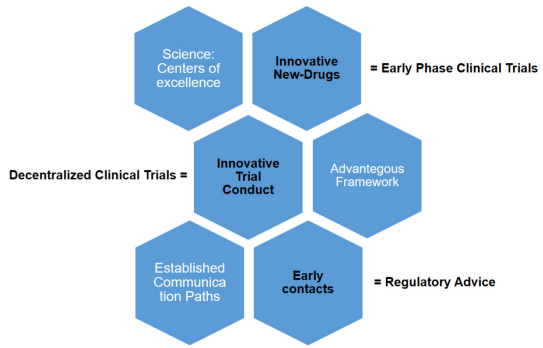
The spread of the new coronavirus (SARS-CoV-2) also poses a major challenge for clinical trials of medicinal products in Switzerland.

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.**

Focus on innovation



Decentralised Clinical Trials (DCTs): Invite for early dialogue

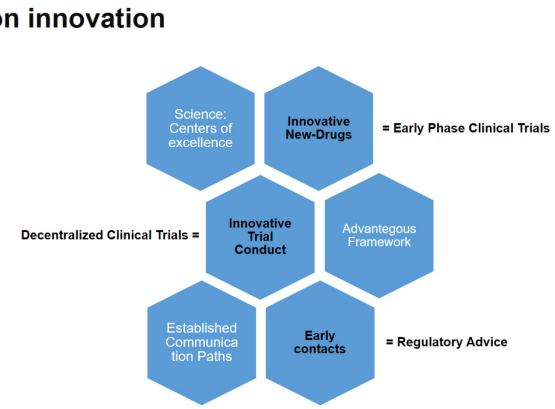
- **Focus on innovation: DCTs as innovative clinical trials in Switzerland.**

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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Maggiori informazioni

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