

Drug Safety and Efficacy - A Smart-Regulatory Solution

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About Us

- ❖ Founded in 1994 by Dr. Jürgen Regenold
- ❖ Initial focus → German pharmaceutical market, later → Increased international scope of projects
- ❖ Extended (pre-)clinical & regulatory advice to drug development projects
- ❖ Expanded geographically and established the international network, regulanet® in 2001, which today covers more than 90 countries with over 180 experts
- ❖ Started developing our presence in data science and analytics in 2015
- ❖ Currently establishing a validated AI platform (according to **GAMP**), for the development of solutions in the GxP and Medical Device area
- ❖ Today the Regenold Group has ~100 employees

Agenda

1. Regulatory Background
2. Smart Regulatory Solution
3. Demo: use-case



EPAR/PAR vs SmPC

- ❖ The European Public Assessment report **EPAR/PAR** (Public Assessment Report) → **Article 13(3) of Regulation (EC) No 726/2004** → Agency scientific conclusions & assessment process of EU drug approvals
- ❖ Summary of Product Characteristics (**SmPC**) → medico-legal evidence-medicine based scientific and medical information for health practitioners

Pre- and clinical drug development, regulatory and pharmacovigilance strategies

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lemsip Decongestant and Flu Blackcurrant tablets Paracetamol 500mg Phenylephrine hydrochloride 6.1mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 500 mg of paracetamol and 6.10 mg of phenylephrine hydrochloride.

Excipients:

Each tablet contains 40 mg of aspartame.

For a full list of excipients, see Section 6.1.

3 PHARMACEUTICAL FORM

Tablet

A convex pale purple oval shaped tablet with blackcurrant odour

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For relief of symptoms of colds and influenza, including the relief of aches and pains, sore throat, headache, nasal congestion and lowering of temperature.

4.2 Posology and method of administration

Adults (16 years and over): Two tablets every 4-6 hours to a maximum of four doses in any 24 hours.

Do not exceed eight tablets in any 24 hours.

Children 12-15 years: One tablet every 4-6 hours to a maximum of four doses in any 24 hours.

Do not exceed four tablets in any 24 hours.

Swallow whole with water. Do not chew.

OR

Oral administration after dissolution in water.

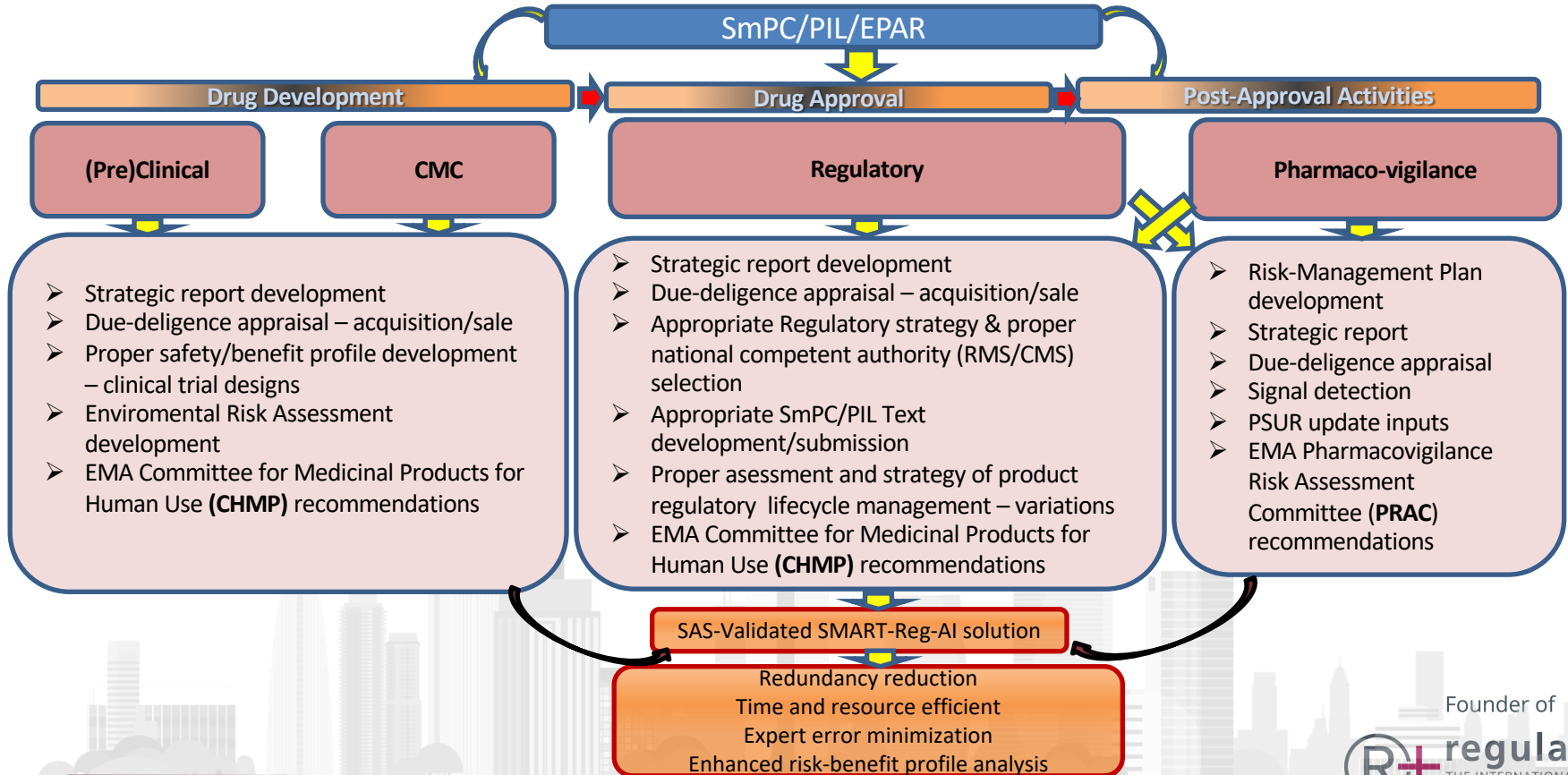
Adults 16 years and over: Two tablets dissolved by stirring in half a mug of hot, not boiling water and sweetened to taste.

Dose may be repeated in 4-6 hours. No more than four doses (eight tablets) should be taken in 24 hours.

Children 12 – 15 years: One tablet dissolved by stirring in half a mug of hot, not boiling water and sweetened to taste.

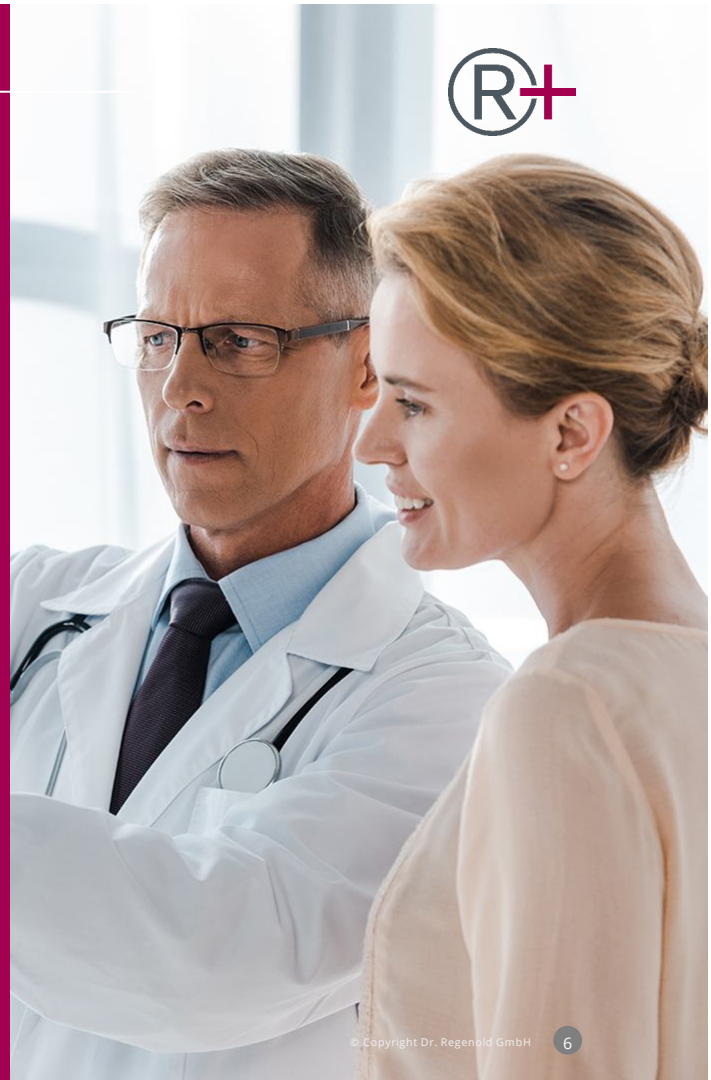
Dose may be repeated in 4-6 hours to a maximum of four doses in any 24 hours. Do not exceed four doses (four tablets)

Business Needs



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Smart Regulatory Solution: Overview

Source of Information & Data

Summary of product characteristics (**SmPC**)
Public Assessment Report (**EPAR/PAR**)

Needs

Overview of markets
Harmonization of Patient Information
Comparison of Patient Information
Regulatory Information



Type of Information & Data

MA-number, -holder, -date
Specific section information
Type of application
Reference Product

Difficulties

Tremendous amount of data to compare
Lack of time & resources
Numerous languages (**24 EU**)

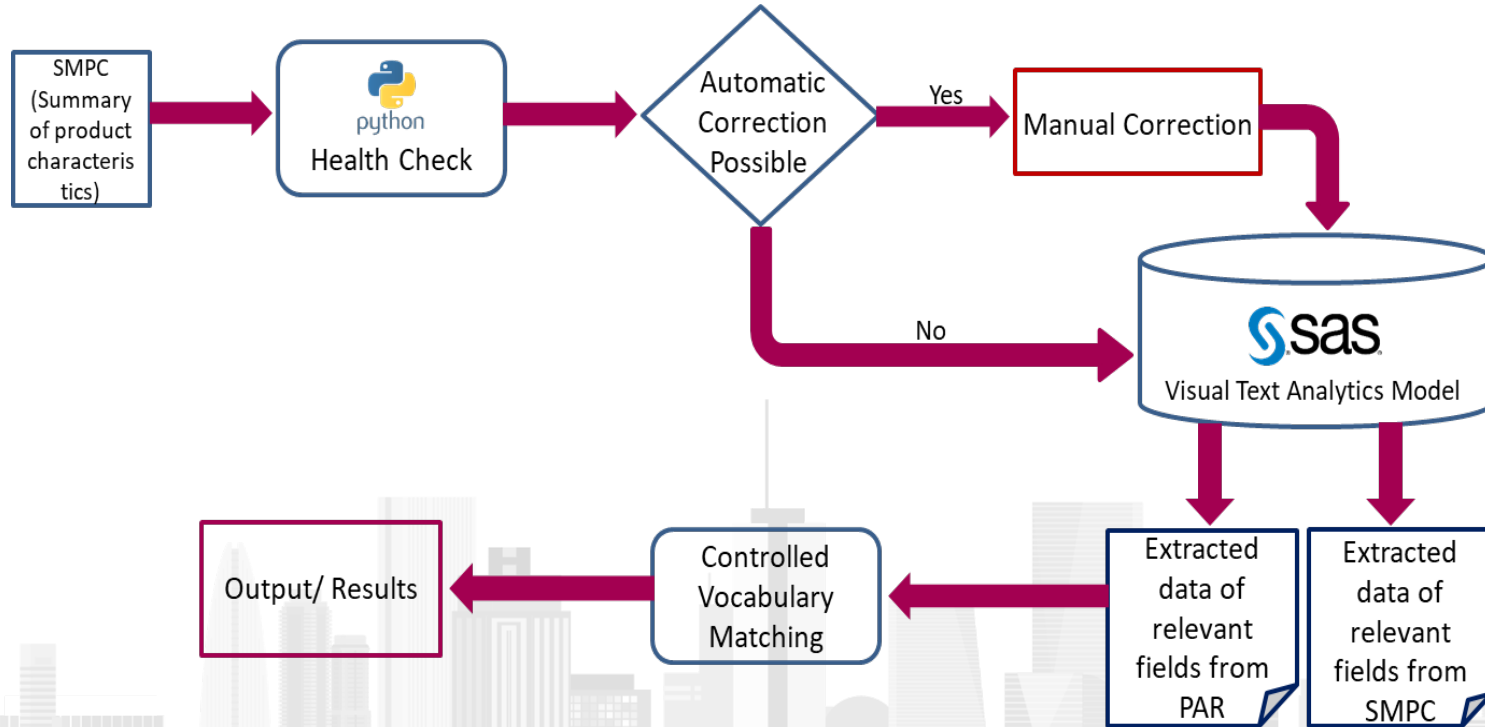
Founder of

Extracted Fields

Data and information from uploaded documents are automatically extracted and classified. Results can be reviewed, revised and approved by users/experts.

- ❖ Product name
- ❖ Marketing Authorisation Holder (MAH)
- ❖ MAH Number
- ❖ Composition (API info, Strength)
- ❖ Procedure
- ❖ Concerned Member State (CMS)
- ❖ Legal basis
- ❖ Prescription basis
- ❖ Indication (English translation)

Smart Regulatory Solution: Process Flow



Health Check

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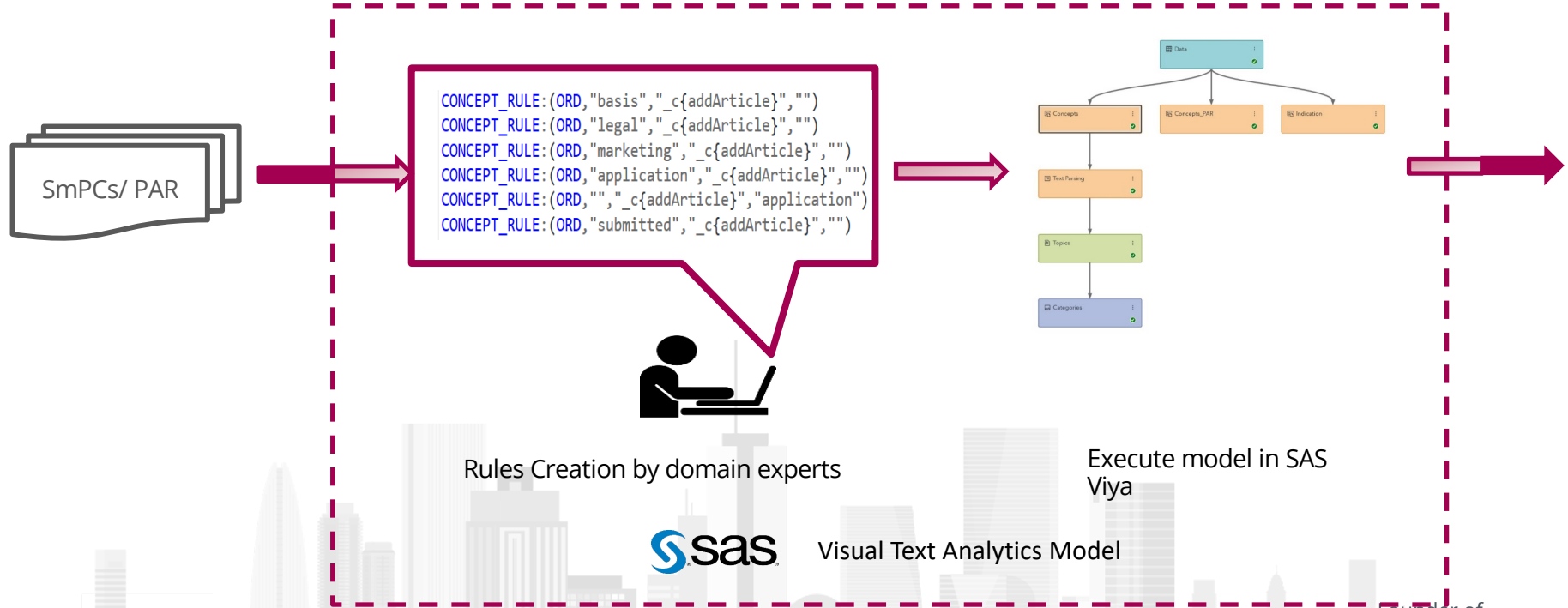
Children 12 – 15 years: One tablet dissolved by stirring in half a mug of hot, not boiling water and sweetened to taste.

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Validate/ Authenticate Section
Heading Names



SAS Visual Text Analytics



Extracted Text from SmPC and EPAR

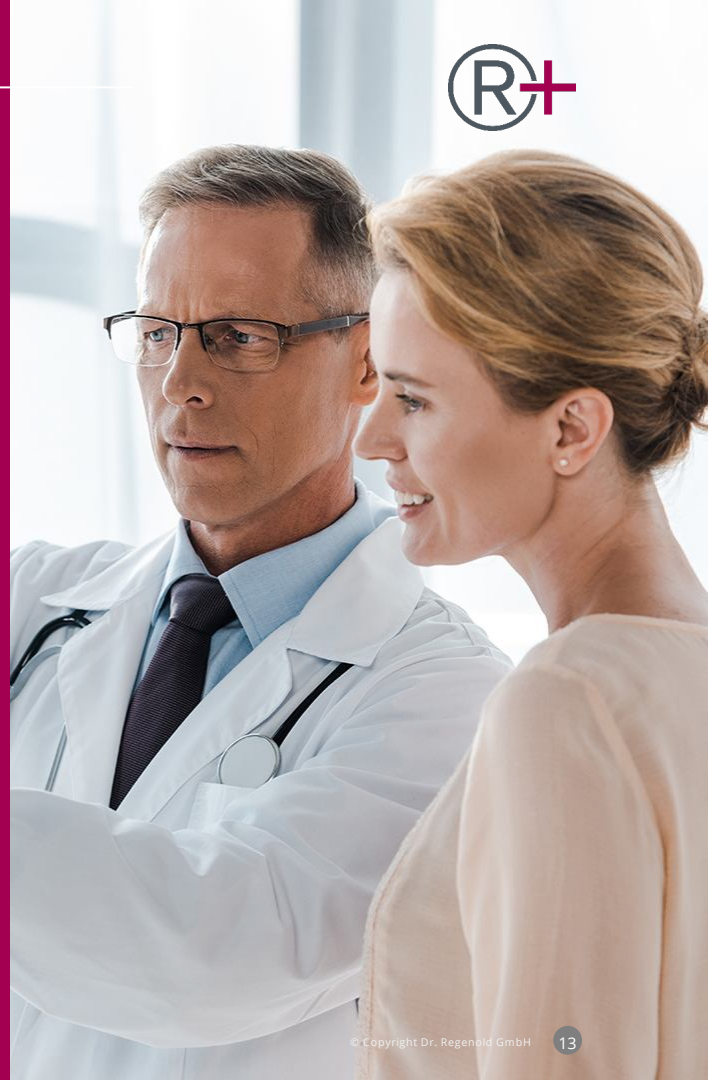
Product name	Marketing Authorisation Holder	MAH Number	Composition (API Info, Strength)	Procedure	CMS	Legal basis	Prescription Status	Indication (English translation)
Paracetamol /Fenilefrina Sandoz 1.000 mg/12,2 mg polvo para solución oral EFG	Sandoz	79272	1000mg paracetamol and 12,2 mg phenylephrine HCl	UK/H/5441/02/DC	BG, CZ, EE, EL, ES, HU, IE, LV, LT, RO	Art. 10.1 generic application	Rx, not marketed	For the relief of the symptoms of colds and flu-like infections, including the relief of pain, headache, fever and nasal congestion in adults and children over 16 years of age
Cinfacold 1000 mg/10 mg oral solution	Laboratorios Cinfa	69931	1000mg paracetamol and 12,2 mg phenylephrine HCl	National	N/A	Art. 10.1 generic application	Rx	Symptomatic relief of catarrh or flu-like processes with mild or moderate pain, fever and nasal congestion. in adults and children over 18 years of age
pharmagrip dúo 650 mg/8,2 mg oral solution	Sandoz	69932	650mg paracetamol and 10 mg phenylephrine HCl	National	N/A	N/A	OTC	For the relief of the symptoms of colds and flu-like infections, including the relief of pain, headache, fever and nasal congestion in adults and children over 14 years of age

Supported Document Formats



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Demo Use case – Smart xEVMPD Product Lifecycle Management

Extracted text

Product name	Marketing Authorisation Holder	MAH Number	Composition (API Info, Strength)
Paracetamol /Fenilefrina Sandoz 1.000 mg/12,2 mg polvo para solución oral EFG	Sandoz	79272	1000mg paracetamol and 12,2 mg phenylephrine HCl
Cinfacold 1000 mg/10 mg oral solution	Laboratorios Cinfa	69931	1000mg paracetamol and 12,2 mg phenylephrine HCl

CV Matching

CV Matching: Agency (EMA-SPOR)

AF_CODE	AF_TEXT
547	CONCENTRATE FOR ORAL SOLUTION
548	CONCENTRATE FOR ORAL/RECTAL SOLUTION
549	CONCENTRATE FOR RECTAL SOLUTION
550	CONCENTRATE FOR SOLUTION FOR INFUSION
551	CONCENTRATE FOR SOLUTION FOR INJECTION
552	CONCENTRATE FOR SOLUTION FOR INJECTION/INFUSION
553	CONCENTRATE FOR SOLUTION FOR PERITONEAL DIALYSIS

Data Transfer

xEVMPD Submission
(Agency- EMA)

Submission

XML Generation

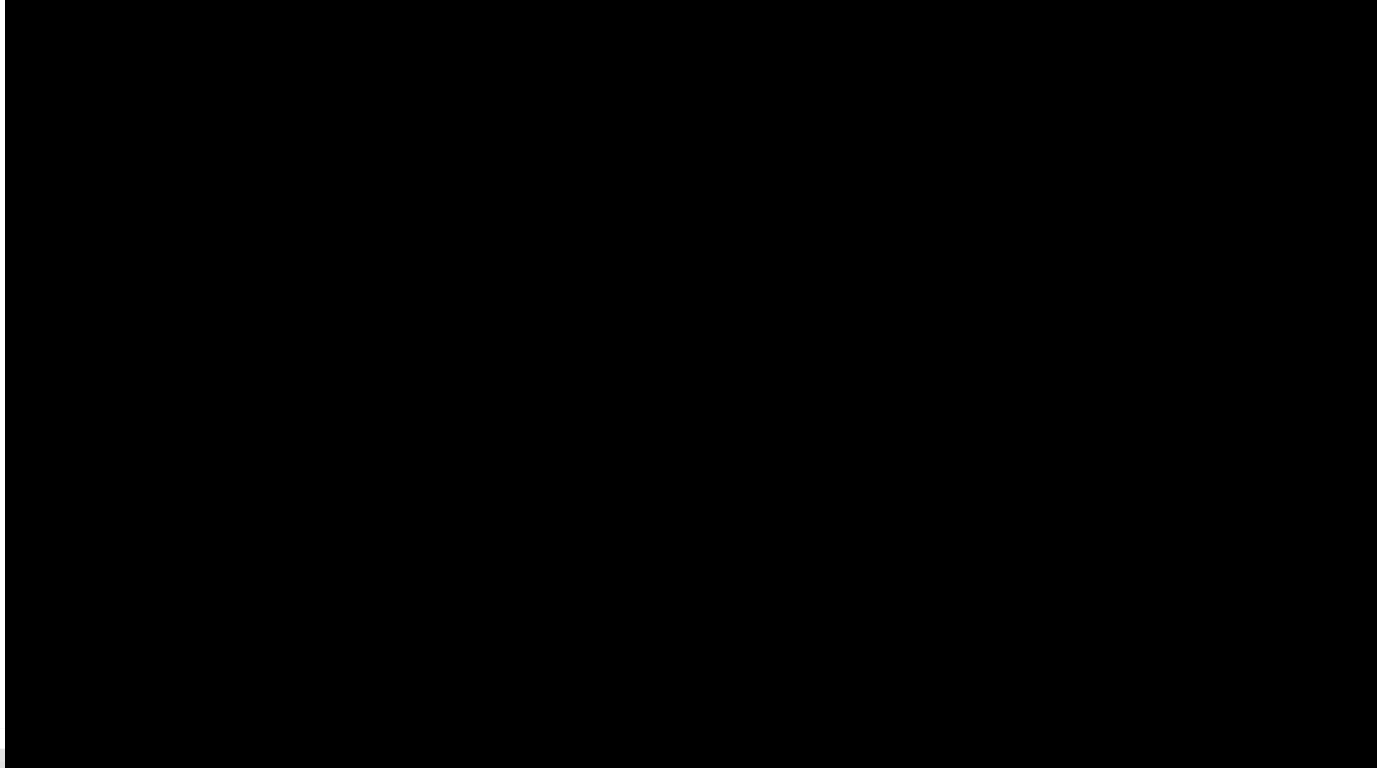
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Founder of

Demo



Questions & Answers



Thank you.

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