eIFU at Geistlich Pharma AG – the decision pathway

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21.01.2021

eIFU implementation at Geistlich Pharma AG

- Reasons for implementing eIFU
- Environmental factors to consider
- Decision points
- Conclusion on the implementation

Reasons for implementing an eIFU

- Financial and ecological aspects
  - Manufacturing costs and ecological fingerprint
  - No scrap costs
- Commercial aspects
  - Customers expectations
  - State of the art information channels
- Regulatory aspects
  - Motivation factor MDR
    - Further labelling changes to be expected
    - MDR requirement for making labelling available on webpage (GSPR 23.1)
  - Tendency in other countries to get challenged on labelling
  - General flexibility and speed for changes

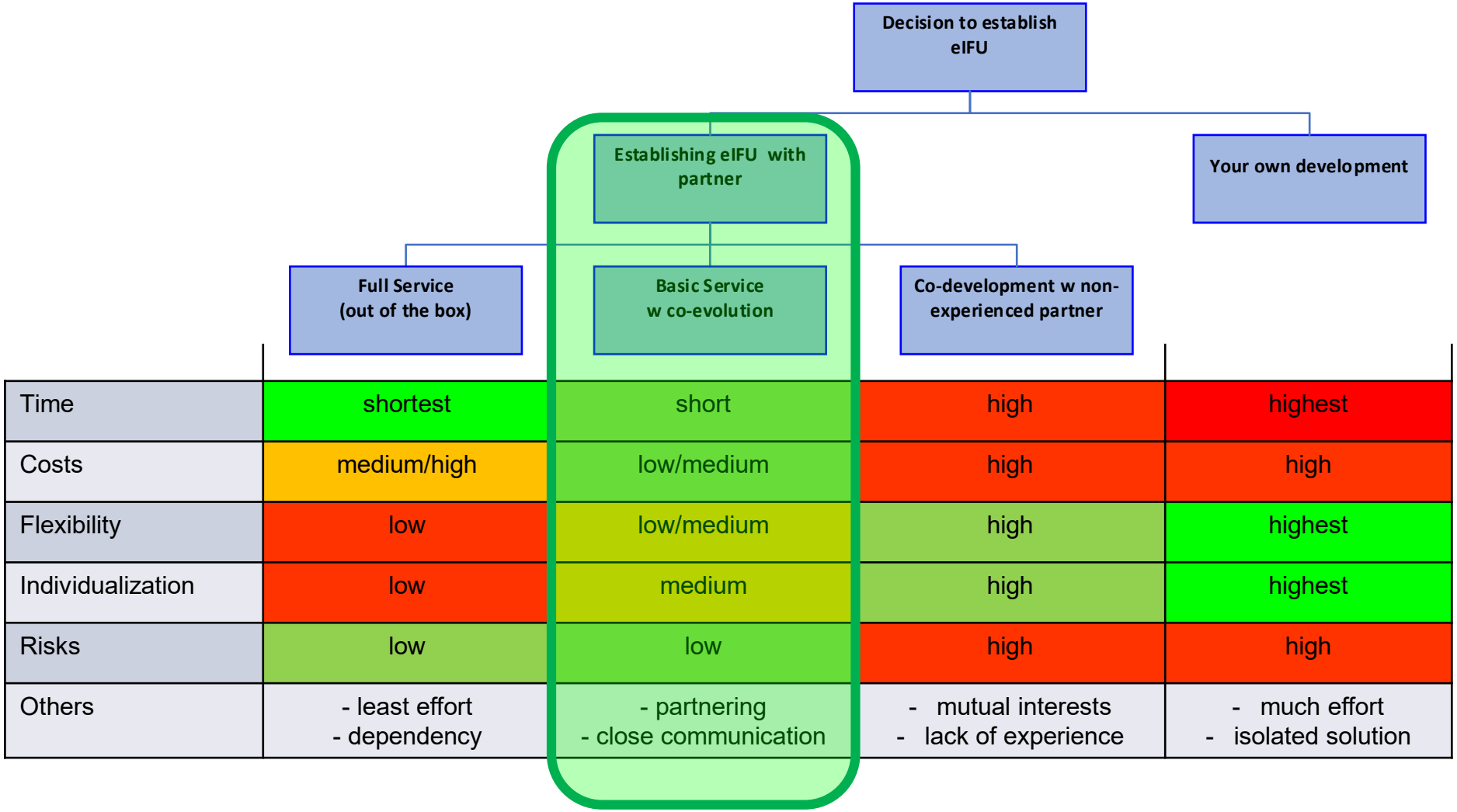
Environmental circumstances to consider

- Product portfolio
- Global landscape: acceptance of eIFU
  - Moving target
- Costs and time for establishing the eIFU system
  - 2-step approval by Notified Body (cl. III)
  - Initial budget: 300k
- System requirements
  - Regulation 207/2012 requirements
  - Communication to your processes and systems

Decision points for implementing an eIFU

- Broad set of functionalities or scalable solution? [→ Geistlich view]
  - Nice-to-have functionalities vs. minimal requirements [-> minimal requirements]
  - Are costs and time relevant? [-> costs & time relevant]
- Minimal requirements for YOUR products/customers
  - Exclusive or additive to paper-IFU? [-> eIFU only]
  - Which markets and regions to cover? [-> EU first]
  - How dealing with countries not accepting eIFU (yet)? [-> staged entry plan]
  - HCP platform only? [-> HCP only]
- Prospective potential for future use
  - Expanding scope of markets covered by eIFU [-> needed]
  - Using eIFU platform for other information content? [-> needed]

Development pathways



	Full Service (out of the box)	Basic Service w co-evolution	Co-development w non-experienced partner	Your own development
Time	shortest	short	high	highest
Costs	medium/high	low/medium	high	high
Flexibility	low	low/medium	high	highest
Individualization	low	medium	high	highest
Risks	low	low	high	high
Others	- least effort - dependency	- partnering - close communication	- mutual interests - lack of experience	- much effort - isolated solution

Conclusion on the implementation

- Duration/costs
  - 10-12 mt from decision to go live (incl. 2 mt Notified Body approvals)
  - Costs far below budget

- Basic solution continuously under co-evolution w partner
  - Patient Implant Card functions (instructions, re-ordering, printing)
  - List of Distributors as separate document
  - Regional filters
  - Flexible and closely communicating partner for adaptations

- Confirmed benefits
  - Existing processes well interfacing with the eIFU platform (faster workflow)
  - Reduced production and scrap costs
  - Positive impact on ERP System (less material numbers for IFUs necessary)
  - High flexibility and speed for IFU changes and for regional/country-specific IFU
  - Production and logistics benefit (easier and faster)

Geistlich Pharma

The Regeneration Company