

Table of contents

1	Introduction—the digital transformation of medicine	1
2	I don't have time for this! An overview	7
3	A turning point for the German healthcare system	15
4	Hello, I am new here, how does the German healthcare system work?	23
5	Pathways for digital solutions to enter the statutory (regulated) healthcare market	31
6	Development of digital health tools	37
6.1	Involvement of care expertise—ask a doctor or ...	39
6.2	Involvement of patient expertise	47
6.3	Hospitals—digital health tools	49
6.4	Interoperability and data formats—the interaction of people and systems	53
6.5	Data protection and information security “by design”	59
6.6	Regulation of medical devices	61
7	The DiGA Fast-Track	79
7.1	The definition of a DiGA	80
7.2	Basic requirements	84
7.3	Positive care effects	105
7.4	Application for inclusion in the DiGA Directory	121
8	The DiGA is listed—now what?	129
8.1	And that was just the beginning: Price negotiations	129
8.2	And who will prescribe me now? Change of perspective: Ambulatory care	138
8.3	From prescription to DiGA	140
9	Buy my DiGA; it's very good! Marketing of digital medical devices	147
9.1	Clash of cultures—modern marketing vs. the Therapeutics Advertisement Law	147
9.2	What could possibly go wrong?—legal consequences	148

9.3	The Therapeutics Advertisement Law	149
9.4	Advertising regulations for DiGA	155
10	The electronic patient record and the telematics infrastructure — a look beyond the DiGA horizon	159
10.1	Secure e-mail communication among healthcare providers through KIM	162
10.2	The electronic health card	163
10.3	The electronic patient record (ePA)	164
10.4	There was something else: The e-prescription	166
11	Summary and outlook	169
	Literature	173
	Websites	176