CGM Investor & Analyst Conference 2015

Status and outlook for the German Telematics Infrastructure

Uwe Eibich, Executive Vice President

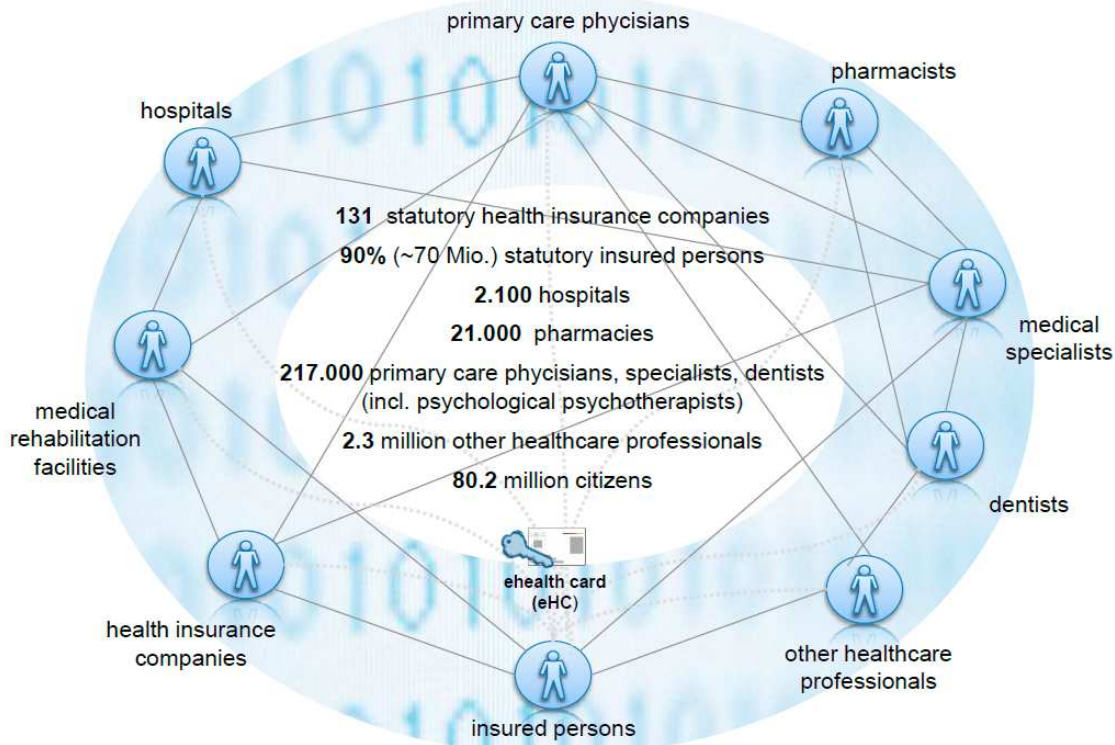**9th October, 2015**
Innovationsforum, Koblenz

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Status and outlook for the German Telematics Infrastructure

Background

The pilot project

The German eHealth law

Potential nationwide roll-out and operation

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The coming secure communication arena in German healthcare

primary care phycisians

hospitals

pharmacists

medical specialists

medical rehabilitation facilities

dentists

health insurance companies

other healthcare professionals

insured persons

ehealth card (eHC)

131 statutory health insurance companies

90% (~70 Mio.) statutory insured persons

2.100 hospitals

21.000 pharmacies

217.000 primary care phycisians, specialists, dentists (incl. psychological psychotherapists)

2.3 million other healthcare professionals

80.2 million citizens

Source: gematik

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The Telematics Infrastructure is based on the eGK

The purpose of the German "Electronic Health Card" (eGK) is to improve the medical care of patients
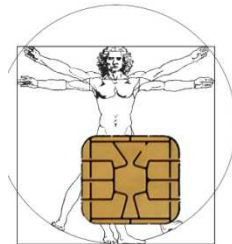
The eGK shall ensure that all healthcare providers have immediate access to all necessary medical information to deliver high quality and cost efficient care

Gematik GmbH is behind the eGK / TI roll-out

Facts

- Founded in January 2005
- Owned by the 15 top organizations of the German health system (e.g. Bundesärztekammer, DAV - Deutscher Apothekerverband, Deutsche Krankenhausgesellschaft, GKV-Spitzenverband, KBV - Kassenärztliche Bundesvereinigung)
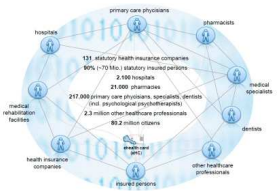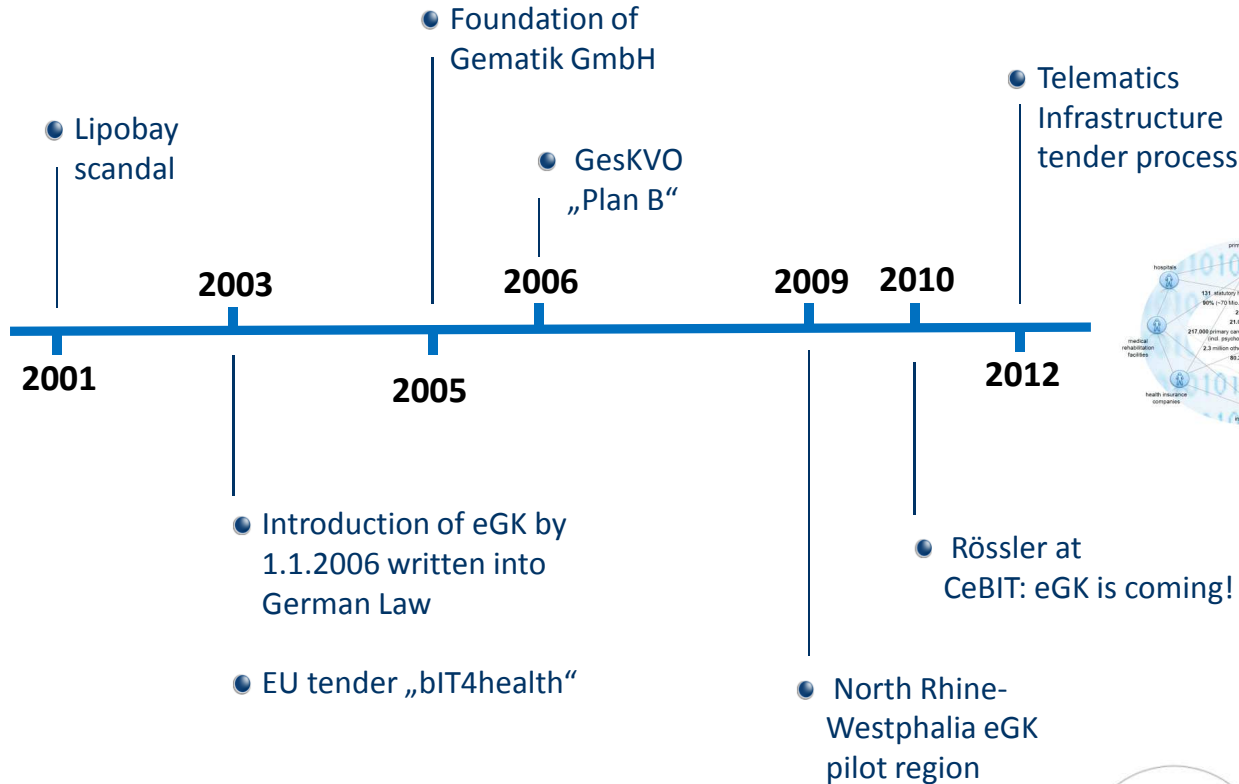- Working closely with the Federal Ministry of Health

Tasks

- Defining withing technical specifications for components, services and applications to be used in the Telematics Infrastructure
- Introduction, maintenance and enhancement of
  - eGK
  - electronic prescriptions
  - and additional applications

Realizing the Telematics Infrastructure has been a long process

- Foundation of Gematik GmbH

- Telematics Infrastructure tender process

- Lipobay scandal

- GesKVO „Plan B"

2003

2006

2009 **2010**

2001

2005

2012

- Introduction of eGK by 1.1.2006 written into German Law

- Rössler at CeBIT: eGK is coming!

- EU tender „bIT4health"

- North Rhine-Westphalia eGK pilot region

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Tender process for 2 pilot regions began 2012

Tender process

December 11
Gematik reaches a new decision to test the Telematics Infrastructure

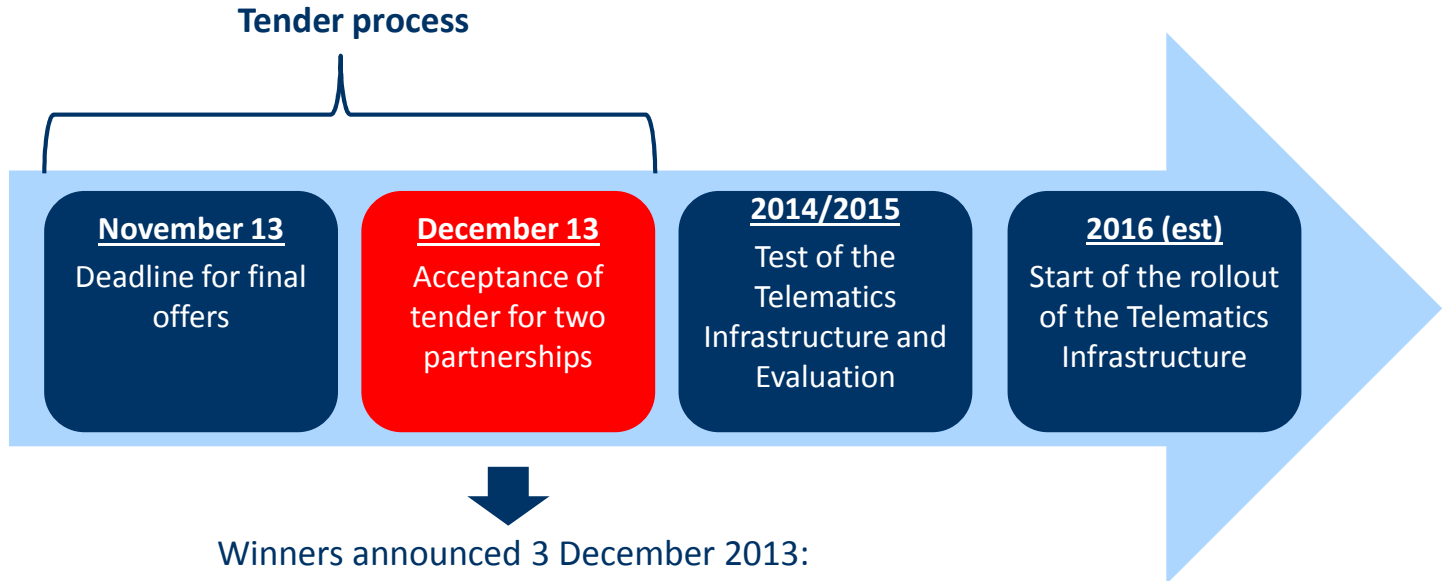**May 12**
Bidder Contest

October 12
Confirmation of five qualified vendors for the final offering

November 12
Publication of specifications and request for final offers

Two contracts were awarded in December 2013

Tender process

November 13	December 13	2014/2015	2016 (est)
Deadline for final offers	Acceptance of tender for two partnerships	Test of the Telematics Infrastructure and Evaluation	Start of the rollout of the Telematics Infrastructure

Winners announced 3 December 2013:

- Region North-West[1]: Booz / CGM / KoCo consortium
- Region South-East[2]: T-Systems

1: Schleswig-Holstein, Nordrhein-Westfalen, Rheinland-Pfalz
2: Sachsen, Bayern

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Already the largest IT project ever in German healthcare

A total of 9 EU-wide tender processes have been completed:

- **Online Rollout Level 1 (ORS-1):** Testing of the Telematics Infrastructure in 2 test regions, each with 500 providers (doctors, dentists and hospitals). 3 contracts awarded through EU-wide tenders:
  - **LOS 1:** Construction and operation of decentralized components and necessary infrastructure services; testing in Region South-East (Award: T-Systems)
  - **LOS 2:** Construction and operation of decentralized components and necessary infrastructure services; testing in Region North-West (Award: Booz/CGM/KoCo consortium)
  - **LOS 3:** Construction and operation of the central services and infrastructure surroundings for the Telematics Infrastructure (Award: Arvato Systems)

- **G2 Cards:** 5 contracts for a new generation of chip cards awarded through EU-wide tenders:
  - **LOS 1 & 2:** Card Operating System (COS) for all card systems: eGK, HBA, SMC-B, gSMC-K and gSMC-KT (Awards: Giesecke & Devrient, T-Systems)
  - **LOS 3 & 4:** Production of all relevant cards to be used in the ORS-1 test regions: eGK, HBA, SMC-B, gSMC-K and gSMC-KT (Awards: Bundesdruckerei, T-Systems)
  - **LOS 5:** PKI infrastructure and associated services for Card Verifiable Certificates (Award: Atos)

- **Scientific evaluation:** 1 contract awarded through EU-wide tender for scientific evaluation of the two ORS-1 test regions (Award: Friedrich-Alexander-Universität)

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Project scope of ORS 1 / LOS 2

Construction and operation of decentralized components and necessary infrastructure services:

- Phase 1: Insured Master Data Management(VSDM)
- Phase 2**:**
  - Qualified Electronic Signature (QES)
  - Secure communication between healthcare providers (KOM-LE)

Tasks

- Planning and conception
- Recruit providers to participate in the pilots: Doctors (375), Dentists (125), Hospitals (5)
- Build a central VPN-access service and ensure its operations
- Develop, test and certify the necessary decentralized components (Konnektor (1x), Card terminals (10x))
- Update and integrate existing doctor, dental and hospital software applications with the Telematics Infrastructure (13x)
- Rollout, service und support of the decentralized components for about 3 years

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The most important parties/products

Important milestones of the project have been achieved

- **Acquisition of doctors, dentists and clinics completed**

- **Testing VSDM with real components (e. g. by Bundesgesundheitsminister Gröhe)**

- **Own tests well advanced**
- **Tests by gematik started**

- **Products for approval submitted** (e. g. VPN-ZD, Intermediary VSDM, 3 x eHKT, 1 x mobKT, Konnektor)

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Overview of products

Type	#	Status development	Status product test
VPN-Access service	1	Completed	Completed
Intermediary VSDM	1	Completed	Completed
Konnektor	1	Completed	~98% completed (Completion with next release)
eHealth card terminal (stationary)	5	Completed	Completed for 3 card terminals (GT, CCV, ZF)
Mobile card terminal	5	Completed	Completed for 2 card terminals (GT, CCV)
Primary systems	13	Completed	Product test for all primary systems completed

More than 20 products to be tested and certified

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Testing and certification phase

Functionality

- **The first complete functional chain is ready**

Delivery of Konnektor to gematik / Arrival on 30th July 2015

- **Secure access to the TI is possible**
- Konnektor, Card terminal, VPN acces service, intermediary VSDM and dental software CGM Z1 are being tested by gematik
- Final adjustments have to be performed on the integrated solution

Performance

Sampling by gematik, 25th August 2015:
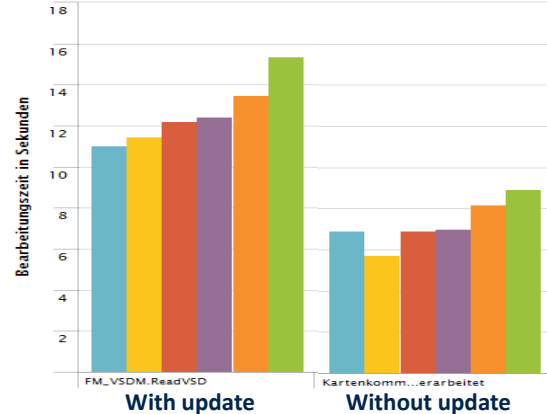
- **Performance standards are fulfilled stand-alone**
- Now every service of the TI has to be performance tested on the integrated solution

The project timeline has changed under way

- Extremely challenging original timeline

- Changing specifications under way (design freeze in August 2014 vs January 2014 as originally planned)

- Parallel finalization of security profiles (by the Federal Office for Information Security - BSI)

- Interdependencies between all 9 on-going projects (ORS-1, G2 Cards and scientific evaluation)

- Organizational changes

Current planning:

- Certification to be completed Q1 2016

- Sufficient field testing (>80%) to be completed by 30 June 2016

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The German eHealth Law – steps to date

- The federal Ministry of Health (BMG) has prepared a draft bill – "The eHealth Law" (Gesetz für sichere digitale Kommunikation und Anwendungen im Gesundheitswesen)

- On January 16th, the draft law went to all relevant ministries (e. g. finance, science) for public comments (Referententwurf). Other stakeholders were also invited to comment (including CGM)

- On May 27th, the Bundeskabinett (Government – all ministers, Merkel at top) decided that the law shall be pursued

- On July 3rd, the bill went to the Bundestag (Parliament) for 'Erste Lesung' – law brought in officially

- In the Bundestag, the bill has been transferred to the health committee (Gesundheitsausschuss) where the draft is now being discussed and amended

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The German eHealth Law – planned final steps

- November 4th : Public hearing in the health committee of the Bundestag
- December 2nd : „Zweite und Dritte Lesung" – the bill gets voted in the Bundestag
- The current coalition has enough majority to pass the bill
- In the current draft, it is written that the law will come into effect 1 January 2016

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Rollout timeline in the draft bill

The Law comes into force

Nation-wide roll-out of the Telematic Infrastructure has to be completed*

30.06.2016

1.1.2018

1.1.2016

1.7.2018

All pre-conditions for roll-out of VSDM must be in place*

Doctors' compensation will be reduced by flat rate of 1% if they are not using VSDM.
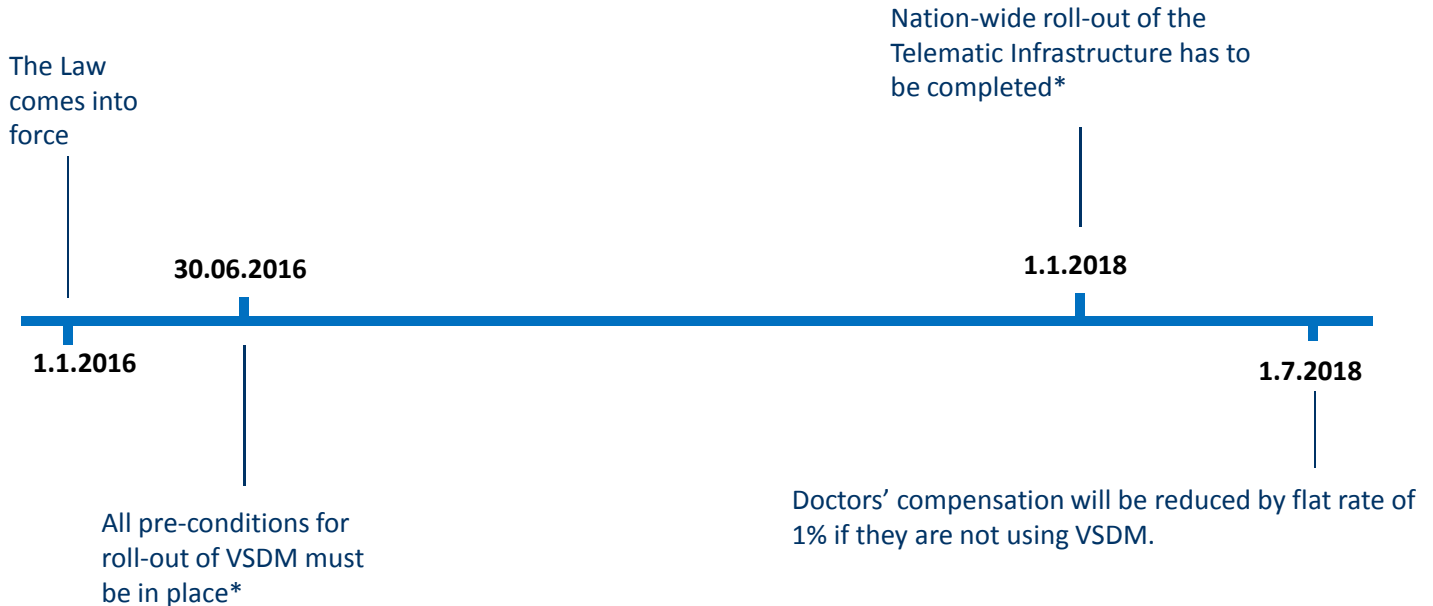
*   If the deadline is not met, from 2017 on the expenditure in the budgets of the GKV SpiBu and the KBV must not exceed the expenditure of 2014 minus 1% each year until the action is performed (1% = app. 100 mio €)

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Services prescribed in the draft bill

- **VSDM** (eligibility check and update of insurance data) is the core service of the Telematics Infrastructure.

- **Emergency Data Set** (blood type, chronic diseases, allergies etc.) stored on the electronic health card. Service must be available beginning 2018. Doctors who create and maintain such datasets on behalf of patients will be compensated (no amount given)

- **Medication plan** (for patients with more than 3 current prescriptions). Service must be available from October 2016 in paper form and then in the 'medium term' (Mittelfristig) be available over the electronic health card.

- **Electronic letters** (Medical reports, referrals and discharge letters between ambulatory doctors and hospitals). Doctors get an incentive of 55 cents per medical report sent electronically and 50 cents per discharge letter received electronically in 2016 and 2017. Hospitals get 1 Euro per discharge letter sent electronically from 1 July 2016. From 2018, the incentives for electronic letters will only be paid if the transmission is done over the Telematics Infrastructure (no amount given).

- **Telemedicine**. Electronically transmitted radiology reports will be compensated beginning 1 April 2017 (no amount given). The regions also has the mandate to consider additional paid telemedicine services.

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CGM rollout numbers

Opportunity for CGM to sell <u>new eGK-compliant online access products</u> to existing customers

- ~ 44.200 doctors offices / 69.400 doctors
- ~ 15.000 dentists offices / 19.800 dentists
- ~ 4 .000 pharmacies / 8.000 pharmacists
- ~ 100 hospitals
- ~ 300 rehabilitation centers
- ~ 550 social care institutions

OEM packages will be offered to other IT vendors

Estimated revenue per location

- Doctors: €2,000 – 4,000 (initial), €600 – 800 (annual)*
- Hospitals: €100k – 300k (initial), €15k – 45k (annual)

* DSL line, Konnektor service fee and software maintenance for integration module

Potential additional products and services

Nr.	Product / Service	Customer / User	Source
1	Elektronischer Entlassbrief	Krankenhaus	eHealth Law
2	Konsiliarische Befundbeurteilung	Ärzte	eHealth Law
3	Notfalldatensatz	Zahnärzte	eHealth Law
4	Arzneimitteltherapiesicherheit (AMTS)	Ärzte / Apotheke	eHealth Law
5	Medikationsplan	Ärzte / Apotheke	eHealth Law
6	Sicher Übermittlung elektronischer Briefe	Ärzte / Krankenhaus	eHealth Law
7	Organsspendeausweis	Krankenhaus	gematik
8	Elektronische Fallakte	Ärzte / Krankenhaus	gematik
9	Elektronisches Patientenfach	Ärzte / Krankenhaus	gematik
10	Elektronische Patienttenquittung	Ärzte / Krankenhaus / Zahnärzte	gematik
11	Fachdienst VSDM	Telematik Infrastruktur	gematik
12	VPN-Zugangsdienst	Telematik Infrastruktur	gematik
13	Patientenverfügung	Ärzte / Krankenhaus	CGM
14	Impfstatus und Impfplanung	Ärzte	CGM
15	Zahnstatus	Zahnärzte	CGM
16	Ernährungsplan	Ärzte	CGM
17	Elektronische Patienter...	... / Krankenhaus	CGM

Potential additional products and services (2)

Nr.	Product / Service	Customer / User	Source
18	Laborbefund	Ärzte / Krankenhaus	CGM
19	Röntgenbefund	Ärzte / Krankenhaus	CGM
20	AU - Bescheinigung	Ärzte	CGM
21	KH Einweisung	Ärzte / Krankenhaus	CGM
22	Heil- und Kostenplan	Zahnärzte	CGM
23	.. weitere Formulare	Ärzte / Krankenhaus	CGM
24	One-Klick Abrechnung (der KBV)	Ärzte	CGM
25	Zuzahlungsinformationen	Ärzte / Krankenhaus / Zahnärzte	CGM
36	Teilnahme an Selektivverträgen	Ärzte / Krankenhaus	CGM
27	Arzneimittelkonto	Ärzte / Krankenhaus	CGM
28	Software Assisted Medicine - Diabetes	Ärzte / Krankenhaus	CGM
29	Software Assisted Medicine - Herzinsuffizienz	Ärzte / Krankenhaus	CGM
30	Software Assisted Medicine - Rückenschmerz	Ärzte / Krankenhaus	CGM
31	Software Assisted Medicine - Depression	Ärzte / Krankenhaus	CGM
32	Software Assisted Medicine - Rauchentwöhnung	Ärzte	CGM
33	Software Assisted Medicine - Gesundes Gewicht	Ärzte / Krankenhaus	CGM
34	Software Assisted Medicine - Blutdruckstabilisierung	Ärzte / Krankenhaus	CGM

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Thank you for your attention!

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