Product Information 4.0
"Gebrauchsinformation 4.0 (GI 4.0)"

Digital Product Information System for Pharmaceuticals

Dr. Georg Lang

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„I downloaded the App and tested it with my medicines. I see an additional benefit by such an App for patients in having a knowledge basis in dialogues with their doctor. When new medications are being prescribed the doctor usually explains briefly the medicine and that is it.
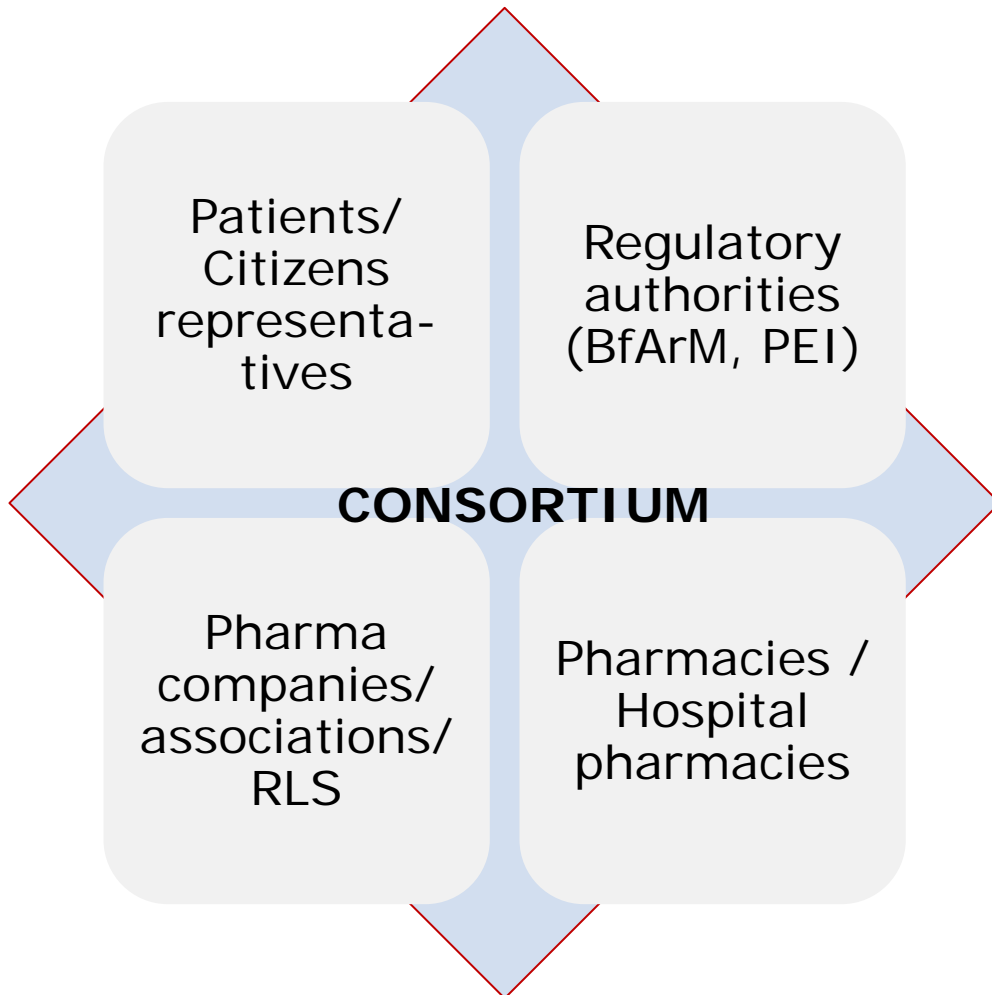
With this App patients have something at hand that significantly supports their discussion with the doctor and it is (in my view) easier and for the patient better to understand how the decision for a certain medicine has been made.“

Anonymous, online-survey

"I was pleased to participate in this project, because I am very much convinced that patients, who know, why they are taking a medicine, have better health outcomes. We must try – by all means - to overcome the weariness for small fonts, prints on thin paper and the paper leaflets left at home in a drawer."

Ludwig Hammel, Deutsche Vereinigung Morbus Bechterew e.V.

BPI Bundesverband der Pharmazeutischen Industrie e.V.

ROTE LISTE

vfa. Die forschenden Pharma-Unternehmen

GI 4.0 Project Outline

Patients/ Citizens representa- tives

Regulatory authorities (BfArM, PEI)

CONSORTIUM

Pharma companies/ associations/ RLS

Pharmacies / Hospital pharmacies

Identification of user-friendly features for electronic product information with

- **Patients / Senior citizens / Visually impaired citizens organisations**
- **Regulatory authorities**
- **Pharmacies**

Implementation via the trade associations **vfa** and **BPI** by

- **18 pharmaceutical companies**

(AbbVie, Amgen, Bayer, Boehringer Ingelheim, Daiichi Sankyo, DESITIN, Grünenthal, Hexal, Janssen-Cilag, Merck Serono, MSD, Mylan dura, Novartis, Pfizer, Roche, Sanofi, TAD, Takeda)
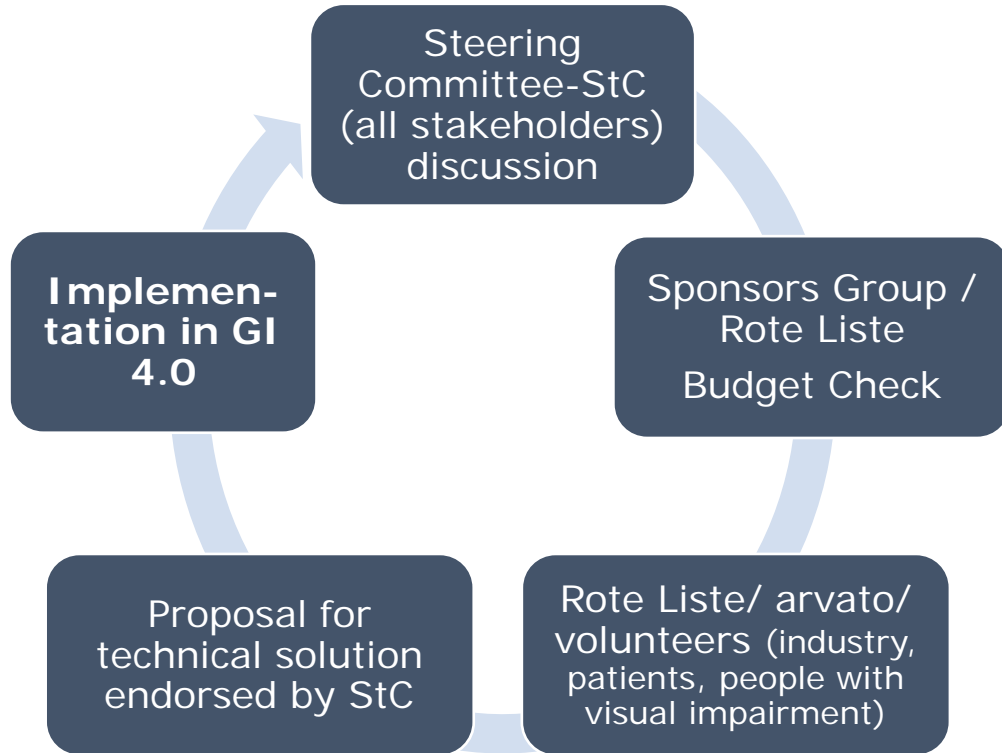
- **Rote Liste Service GmbH**

BPI | Bundesverband der Pharmazeutischen Industrie e.V.

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GI 4.0: scope and context

scope	**Digital product information system for pharmaceuticals**	Real time, widely-available
		Validated, authority approved information
		User friendly electronic format - accessible
		Print option
context	**Proof-of Concept** for the European initiative, IATF eProduct Information (EFPIA, Medicines for Europe, AESGP)	

Development of user-friendly product information

Steering Committee-StC (all stakeholders) discussion

Sponsors Group / Rote Liste

Budget Check

Rote Liste/ arvato/ volunteers (industry, patients, people with visual impairment)

Proposal for technical solution endorsed by StC

Implemen-tation in GI 4.0

✓ Successful cooperation with representatives of patients / citizens organisations and regulatory authorities

✓ Intensive testing and collection of feedback for continuous improvement

✓ Additional evaluation via online survey (360+ responses)

✓ Successfully established Rote Liste Service GmbH as reliable partner

GI 4.0: Sagen Sie uns Ihre Meinung zur Gebrauchsinformation der Zukunft!

Bewerten Sie den neuen Service Gebrauchsinformation 4.0/GI 4.0. Die „digitalen Beipackzettel" sollen zukünftig alle Patienten bei der Medikamentenanwendung unterstützen. Der Test dauert keine 5 Minuten und ist anonym.
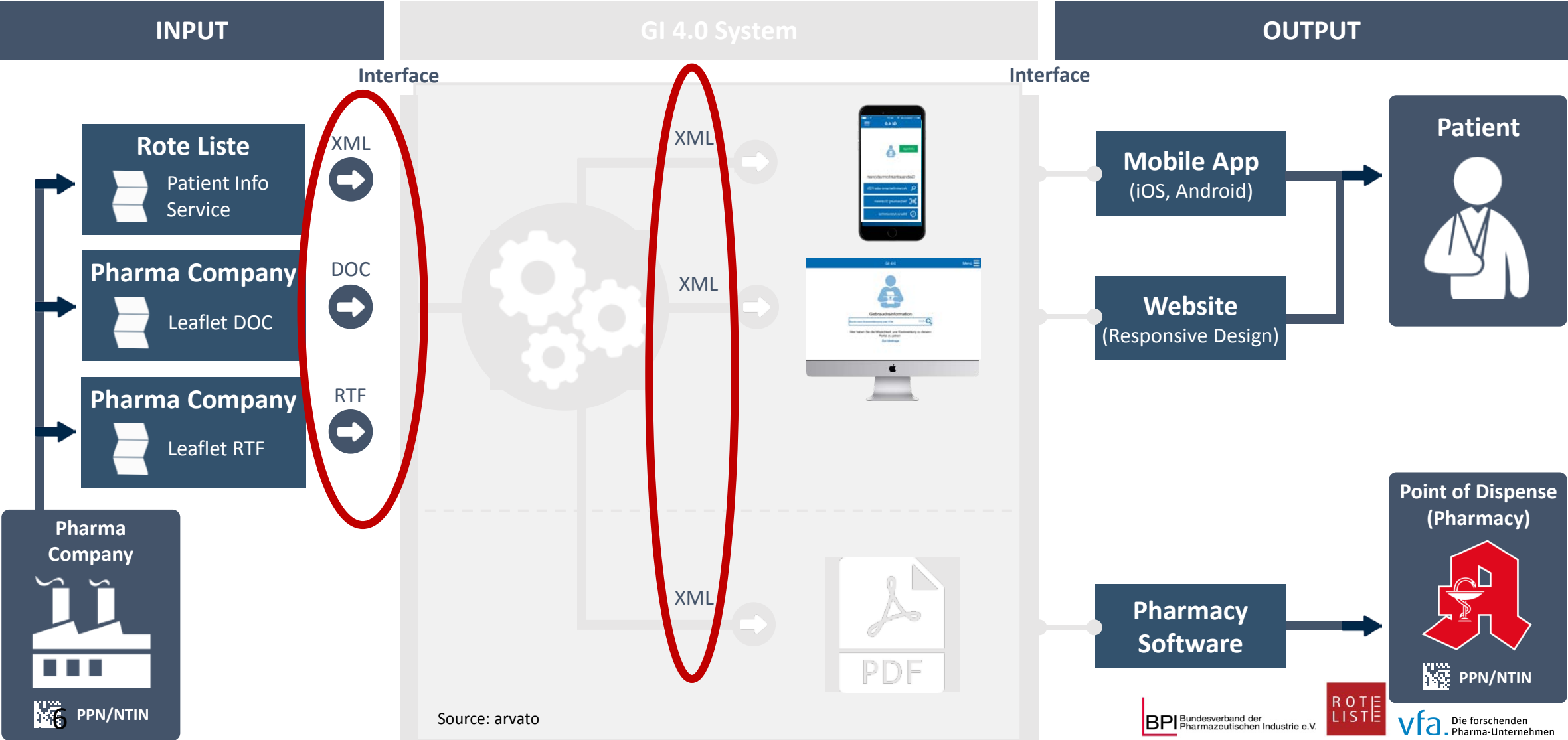
Hier finden Sie GI 4.0:
Webseite
www.gebrauchsinformation4-0.de/
Android Play Store Link
https://play.google.com/store/apps/details?id=de.roteliste.gi40&hl=de
Apple App Store
https://itunes.apple.com/de/app/gebrauchsinformation-4-0/id1274413138

Benutzer: GI40
Passwort: test

Danke für Ihren wertvollen Beitrag, das System GI 4.0 zu verbessern!

Google/Android

Apple/iOS

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GI 4.0 – STRUCTURED content; advanced validated technical solution for automated data input/output

INPUT | GI 4.0 System | OUTPUT

Interface | Interface

Rote Liste — Patient Info Service
Pharma Company — Leaflet DOC
Pharma Company — Leaflet RTF
Pharma Company — PPN/NTIN

XML
DOC
RTF
XML
XML
XML

Mobile App (iOS, Android)
Website (Responsive Design)
Pharmacy Software

Patient
Point of Dispense (Pharmacy) — PPN/NTIN

Source: arvato

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Achievements – Proof of the project outline

Mobile Apps
- Integrated function for Data Matrix and Barcode scan

⑩ installed

Online Website
- Responsive Design
- Print option PDF

⑩ installed

Software link to pharmacy
- Interface with software
- Print option

⑩ tested

✓ **Positive evaluation by all stakeholders**: Authorities, patient organisations, patients, senior citizens, visually impaired citizens, individual users, industry, pharmacists

Commitment of BPI and vfa for further engagement:

- Development of additional services

- Active support of European project towards an EU wide harmonized approach

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