



***targoDoc – PMCF-Tool
... for structured data collections
in Ophthalmic Surgery***

August 2023



Structured clinical data collections benefit the entire healthcare industry

- Medical Device Manufacturers
 - Regulatory requirements, e.g., proof of efficacy and performance for maintaining the CE-mark (MDR), PMS, Clinical Evaluation Reports
 - Data for product brochures
 - Data for strategic decisions in (further) product development
- Doctors and Clinics
 - Data for publications and presentations
 - Quality assurance
- Medical organisations, associations and networks
 - Quality assurance
 - Healthcare research
 - Availability of Big Data based on standardised data collections

targomed's solution to facilitate the collection of clinical data

- Standardised – configurable electronic case report forms (eCRFs) with standard parameters
- Flexible – eCRFs can be individualised per product type via a configurator
- Simple – easy and clear data entry for users
- Transparent – 24/7 access for registered users and sponsors (read-only)
- Secure – password/PIN-protected access with SSL encryption
- Automated - for fast availability of evaluation with tables and figures
- Validated - web-based GAMP5-validated system
- Cost-efficient – allows comprehensive data collection for several products of a product class even with tight budgets

The PMCF-Tool* in Screenshots

*Currently, the PMCF tool is only available for intraocular lenses, but can be extended to other medical devices at any time.

Generation of Forms

Example of selecting parameters and marking fields as mandatory

| Field identifier | Use for form? | | | |
|--|---------------------------------------|---|--|--|
| Visual Acuity & Refraction | <input checked="" type="radio"/> Show | <input type="radio"/> Don't show | | |
| Photopic UDVA | <input checked="" type="radio"/> Show | <input type="radio"/> Don't show | <input checked="" type="radio"/> Mandatory | <input type="radio"/> Not Mandatory |
| Photopic UIVA | <input checked="" type="radio"/> Show | <input type="radio"/> Don't show | <input checked="" type="radio"/> Mandatory | <input type="radio"/> Not Mandatory |
| Photopic UIVA: measured at distance [cm] | <input checked="" type="radio"/> Show | <input type="radio"/> Don't show | <input checked="" type="radio"/> Mandatory | <input type="radio"/> Not Mandatory |
| Preferred intermediate distance [cm] | <input type="radio"/> Show | <input checked="" type="radio"/> Don't show | <input type="radio"/> Mandatory | <input checked="" type="radio"/> Not Mandatory |
| Photopic UNVA | <input checked="" type="radio"/> Show | <input type="radio"/> Don't show | <input type="radio"/> Mandatory | <input checked="" type="radio"/> Not Mandatory |
| Photopic UNVA: measured at distance [cm] | <input type="radio"/> Show | <input checked="" type="radio"/> Don't show | <input checked="" type="radio"/> Mandatory | <input type="radio"/> Not Mandatory |
| Photopic Preferred reading distance [cm] | <input type="radio"/> Show | <input checked="" type="radio"/> Don't show | <input type="radio"/> Mandatory | <input checked="" type="radio"/> Not Mandatory |
| Photopic Binocular UDVA | <input checked="" type="radio"/> Show | <input type="radio"/> Don't show | <input type="radio"/> Mandatory | <input checked="" type="radio"/> Not Mandatory |
| Photopic Binocular UIVA | <input checked="" type="radio"/> Show | <input type="radio"/> Don't show | <input type="radio"/> Mandatory | <input checked="" type="radio"/> Not Mandatory |
| Photopic Binocular UIVA: measured at distance [cm] | <input type="radio"/> Show | <input checked="" type="radio"/> Don't show | <input type="radio"/> Mandatory | <input checked="" type="radio"/> Not Mandatory |
| Binocular Preferred intermediate distance [cm] | <input type="radio"/> Show | <input checked="" type="radio"/> Don't show | <input type="radio"/> Mandatory | <input checked="" type="radio"/> Not Mandatory |
| Photopic Binocular UNVA | <input checked="" type="radio"/> Show | <input type="radio"/> Don't show | <input type="radio"/> Mandatory | <input checked="" type="radio"/> Not Mandatory |

The fields are configured once per IOL model.

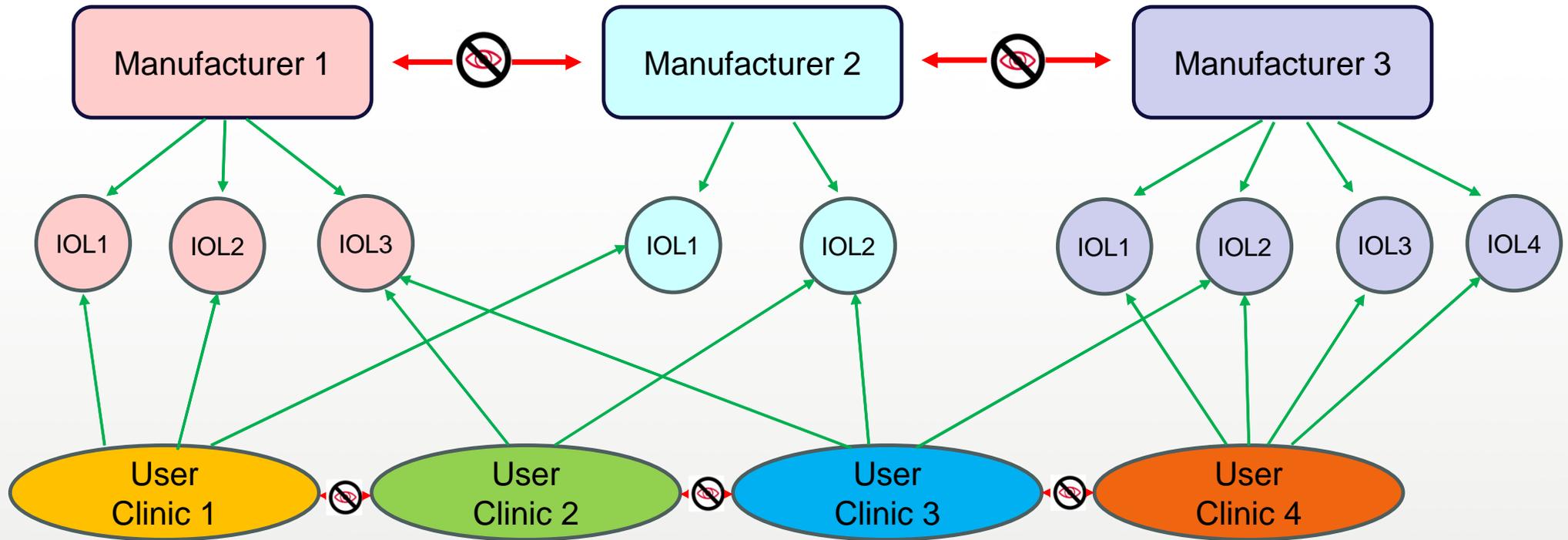
The following forms are available:

- *Screening¹*
- *Last Preoperative Visit*
- *Surgery*
- *Postoperative Visit²*
- *(Contrast sensitivity)²*
- *(Defocus curve)²*
- *Study Exit*
- *Adverse Event/Incident²*
- *Device Deficiencies²*
- *Protocol Deviation²*
- *Concomitant Medication²*

1 – Inclusion / Exclusion criteria

2 – Forms can be generated as often as required

User Access



- Manufacturers can have data documented for any number of IOL models; only the data of their own IOL models are accessible to each manufacturer.
- Doctors/clinics are given access to all IOLs (also from different manufacturers) to be documented; they can access only their own data.

Data capture: colour code & plausibility check

Colour code at patient overview:

Test IOL1

Center ID: 20
Company: Test Company
(2023/07/13)
No. enrolled patients: 3
No. finalised patients: 0

- Not enrolled
- In Progress
- In Progress, Discrepancies
- Complete and Finished

Colour code at visit overview of individual patients

Patient ID: 20-001
Company: Test Company
(2023/07/13)
Lens: Test IOL1
Year of birth: 1980
Gender: Male
Ethnicity: Caucasian
Date of Informed consent: 27/03/2020
Operative Eye: OD

- Created
- Incomplete
- Complete, but not confirmed
- Confirmed, but with discrepancies
- Confirmed, is being monitored
- Confirmed, with comments
- Complete, signed by monitor
- Complete, signed by Monitor and Investigator

"On the Fly" plausibility check

-1 D 5 D@ 270 °

Sphere Cylinder Requirement: Range (-15 to 0)

i

-1 D 5 D@ 270 °

Sphere Cylinder Axis Requirement: Range (0 to 180)

i

Data Analysis – Tables

Examples of tables

- Descriptive statistics
 - ✓ Absolute and relative frequencies
 - ✓ Central tendency → mean and median
 - ✓ Variability → standard deviation (SD) and value range (min and max)
 - ✓ Number of eyes/patients

| | | UDVA, Monocular (Photopic) | | | | | | |
|--|----------|----------------------------|------|-------|-------|-------|-------|-------|
| | | TariOL | | | | | | |
| | | Preop | 1-2D | 1-2W | 1-3M | 4-6M | 7-12M | >12M |
| UDVA, Monocular (Photopic) [logMAR] | Mean | 0.42 | 0.10 | 0.08 | 0.05 | 0.06 | | 0.09 |
| | SD | 0.15 | 0.11 | 0.11 | 0.06 | 0.06 | | 0.07 |
| | Median | 0.40 | 0.10 | 0.07 | 0.08 | 0.06 | | 0.10 |
| | Min | 0.20 | 0.00 | -0.10 | -0.10 | -0.10 | | -0.10 |
| | Max | 0.70 | 0.40 | 0.30 | 0.16 | 0.16 | | 0.20 |
| | Subtotal | 20 | 20 | 20 | 20 | 20 | 0 | 18 |

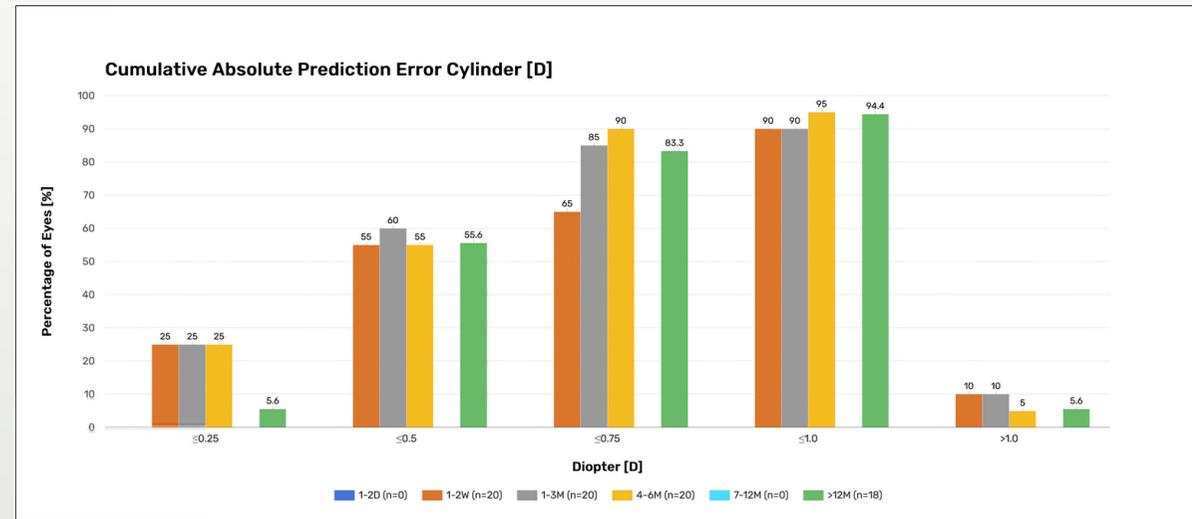
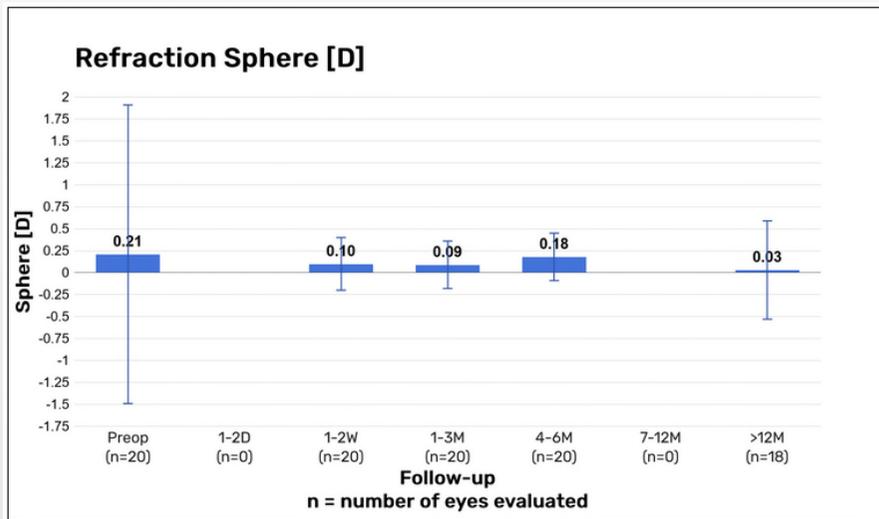
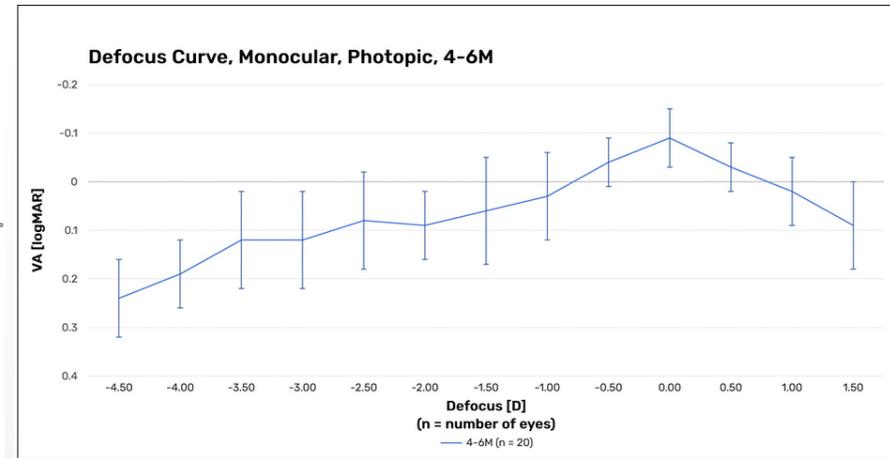
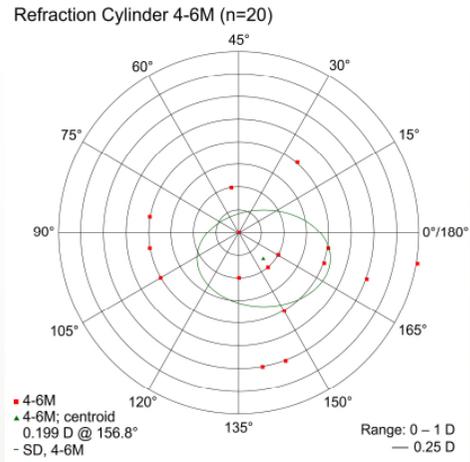
| | | TariOL | |
|--------|----------|----------|------------|
| | | Patients | Percentage |
| Gender | Female | 3 | 30.00 % |
| | Male | 5 | 50.00 % |
| | Diverse | 2 | 20.00 % |
| | Subtotal | 10 | 100.00 % |

| Range [logMAR] | Cumulative Monocular CDVA (Photopic) | | | | | | | | | | | | | |
|----------------|--------------------------------------|--------|-----------|------|------------|--------|------------|--------|------------|--------|------------|------|------------|--------|
| | TariOL | | | | | | | | | | | | | |
| | Preop, N=20 | | 1-2D, N=0 | | 1-2W, N=20 | | 1-3M, N=20 | | 4-6M, N=20 | | 7-12M, N=0 | | >12M, N=18 | |
| | N | % | N | % | N | % | N | % | N | % | N | % | N | % |
| ≤ -0.2 | 0 | 0.00 | 0 | 0.00 | 0 | 0.00 | 0 | 0.00 | 0 | 0.00 | 0 | 0.00 | 18 | 100.00 |
| ≤ -0.1 | 0 | 0.00 | 0 | 0.00 | 7 | 35.00 | 10 | 50.00 | 11 | 55.00 | 0 | 0.00 | 8 | 44.44 |
| ≤ 0.0 | 3 | 15.00 | 0 | 0.00 | 15 | 75.00 | 19 | 95.00 | 19 | 95.00 | 0 | 0.00 | 15 | 83.33 |
| ≤ 0.1 | 8 | 40.00 | 0 | 0.00 | 18 | 90.00 | 20 | 100.00 | 20 | 100.00 | 0 | 0.00 | 18 | 100.00 |
| ≤ 0.2 | 14 | 70.00 | 0 | 0.00 | 20 | 100.00 | 20 | 100.00 | 20 | 100.00 | 0 | 0.00 | 18 | 100.00 |
| ≤ 0.3 | 17 | 85.00 | 0 | 0.00 | 20 | 100.00 | 20 | 100.00 | 20 | 100.00 | 0 | 0.00 | 18 | 100.00 |
| ≤ 0.4 | 18 | 90.00 | 0 | 0.00 | 20 | 100.00 | 20 | 100.00 | 20 | 100.00 | 0 | 0.00 | 18 | 100.00 |
| ≤ 0.5 | 19 | 95.00 | 0 | 0.00 | 20 | 100.00 | 20 | 100.00 | 20 | 100.00 | 0 | 0.00 | 18 | 100.00 |
| ≤ 0.6 | 20 | 100.00 | 0 | 0.00 | 20 | 100.00 | 20 | 100.00 | 20 | 100.00 | 0 | 0.00 | 18 | 100.00 |
| ≤ 0.7 | 20 | 100.00 | 0 | 0.00 | 20 | 100.00 | 20 | 100.00 | 20 | 100.00 | 0 | 0.00 | 18 | 100.00 |
| > 0.7 | 0 | 0.00 | 0 | 0.00 | 0 | 0.00 | 0 | 0.00 | 0 | 0.00 | 0 | 0.00 | 0 | 0.00 |

Data Analysis – Figures

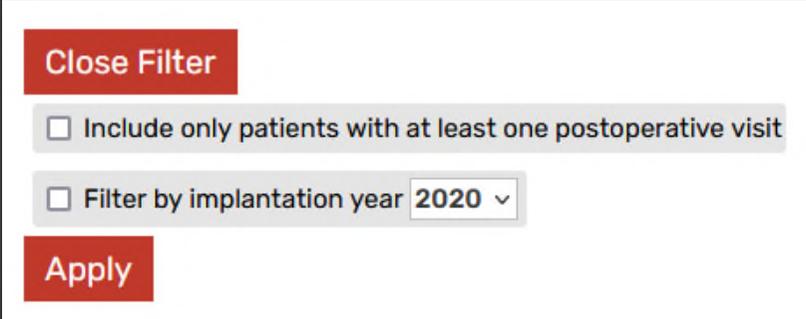
Examples of figures

- Display of figures:
 - ✓ Bar charts (mean and SD)
 - ✓ Cumulative bar charts
 - ✓ Line charts (mean and SD)
 - ✓ Double-angle Plots
 - ✓ Vector analysis for cylinder & axis



Data Analysis – Filter options / download

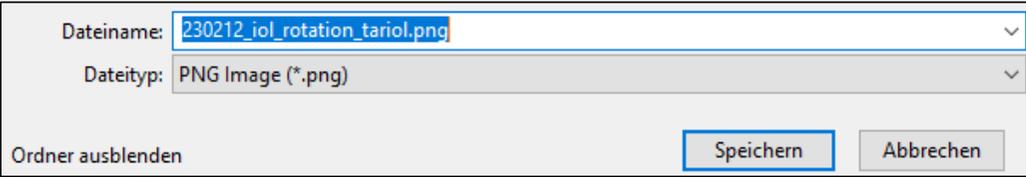
Example of a filter function:



A screenshot of a filter dialog box. It features a red 'Close Filter' button at the top left. Below it are two filter options, each with an unchecked checkbox: 'Include only patients with at least one postoperative visit' and 'Filter by implantation year 2020'. The year '2020' is shown in a dropdown menu. At the bottom left is a red 'Apply' button.

Download of results

- Figures per click: single image file (jpg or png) per figure
- Tables via download button: All tables of a category or subcategory in one Excel file
- Uniform file naming of figures and tables: YYYYMMDD_Parameter/Category_lensname



A screenshot of a file download dialog box. It has two input fields: 'Dateiname:' with the value '230212_iol_rotation_tariol.png' and 'Dateityp:' with the value 'PNG Image (*.png)'. Both fields have dropdown arrows on the right. At the bottom left is the text 'Ordner ausblenden'. At the bottom right are two buttons: 'Speichern' (highlighted in blue) and 'Abbrechen'.

Data Analysis - Categories

Categories:

- Demographic data
- Biometry
- Surgical data
- IOP
- Uncorrected visual acuity
- Corrected visual acuity
- Refraction
- Cylinder
- Contrast sensitivity
- Visual symptoms
- Defocus curves
- IOL-Rotation
- Adverse Events / Device Deficiencies
- Patient questionnaires
- Etc.

| | | | | | | | | | | | |
|------------------------------|----------|----------|-----|------------|----------|----------------|--------------|----------------------|---------|----------|---------------|
| Demographics | Biometry | Surgical | IOP | Refraction | Cylinder | Uncorrected VA | Corrected VA | Contrast Sensitivity | Defocus | Rotation | Adverse Event |
| Please select one tab | | | | | | | | | | | |

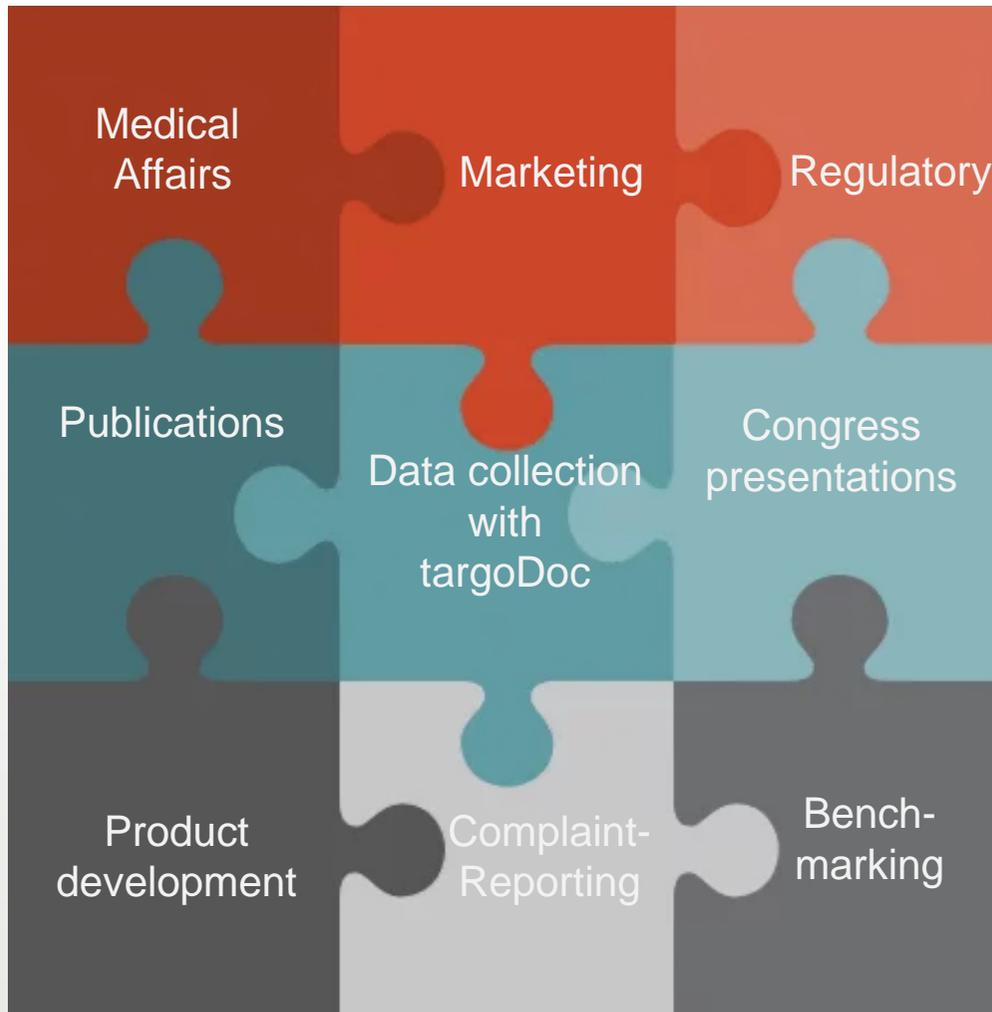


- Modular cost model – Costs arise only for required functionality
- Transparent cost matrix –
 - Basic programming
 - Monthly costs
- The more IOLs documented, the more cost-effective per IOL
 - Low surcharge for second IOL in the same category (e.g., EDOF1, EDOF)
 - Lower surcharge for second category (e.g., EDOF1/EDOF2; EDOF Toric)
 - *Simplified example: Tool for 1 IOL over 2 years = amount X; Tool for 2 IOL over 2 years = 1.2x amount X; Tool for 8 IOLs over 2 years = 2x amount X*
- Individual evaluations, medical writing of reports or manuscripts can be purchased separately



The targoDoc PMCF-Tool

- Allows user-friendly documentation of clinical data
- Promotes high data quality due to implemented plausibility checks and query management system
- Allows data exports at any time
- Provides overviews of Adverse Events, Device Deficiencies and Protocol Deviations
- Provides data overviews for individual patients
- Provides up-to-date statistical analysis with figures and tables at the touch of a button
- Is cost efficient



Do not hesitate to contact us if you have any questions, if you prefer a detailed presentation of the features or if you would like to see a live demo of the targoDoc PMCF tool:

 *targomed GmbH*
Amalienstr. 2
76646 Bruchsal, Germany
 Phone: +49 7251/32654-30
Fax: +49 7251/32654-31
 targodoc-pmcf@targomed.de