

Product presentation



electronic case report forms | www.ecrom.at

COOT - GmbH Heiligenstädter Lände 29 1190 Wien, Österreich

About us



| Management consultancy | IT Consulting | Projects | | |
|--------------------------------|-----------------------|----------|--|--|
| Strategy consulting | Software Engineering | ViPOC | | |
| Process management | Software Testing | ecrom | | |
| Project management | Document management | | | |
| Compliance and data projection | CRM | | | |
| GxP validation | IT Service Management | | | |
| Lean and SFM | | | | |

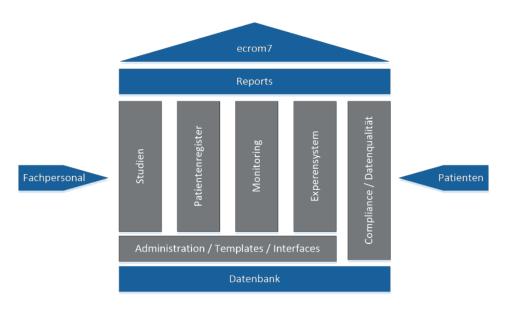
We offer you support in designing and realizing solutions, which are critical for the company, taking account of all regulatory requirements.

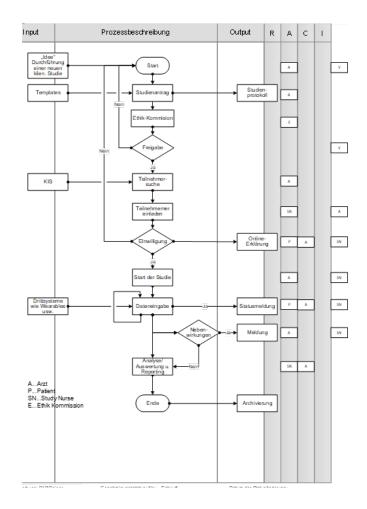
ecrom – electronic case report form



Ecrom enables you to conduct clinical studies faster and more reliable!

Due to the first-time analysis of a clinical study as a performance process (from the planning, participant selection, execution and retrospective analysis) and the derivation of the technical requirements and realization, we can manage it!





Different application scenarios



Ecrom can be applied in all companies which are conducting studies.

Different applications:

- Clinical studies
- Non-interventional studies
- Patient register
- Monitoring und documentary of chronical diseases (Diabetes, metabolic disorder, ...)
- Monitoring and documentation in the field of performance diagnostics
- Expert systems for patients
- For granting licenses of nutritional supplements

Your advantage



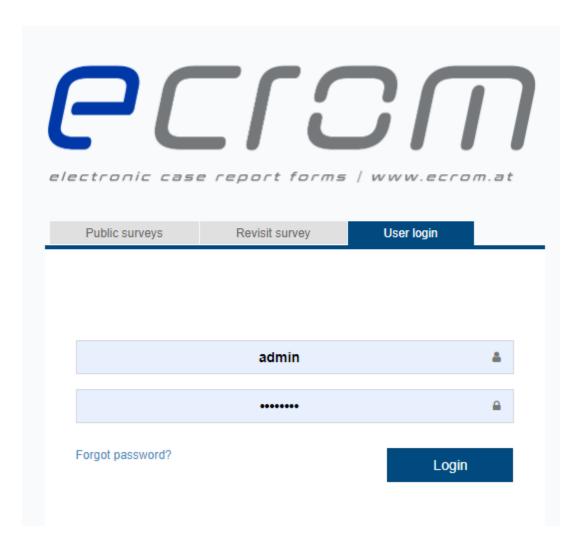
With ecrom customers receive the chance to plan and conduct patient-focused studies with a modern, generic tool.

<u>Advantages</u>

- Consistent support
 – from the idea to the long-term archiving of a study
- Modern and intuitive design simple extensibility
- Easy design of the forms
- Improvement of data quality by input assistance, automatic verirfication of values, formulas and dependencies
- Generic interfaces (import and export) HL7, DICOM, ecrom-API,...
- Wearables support
- Workflows and reminder functions
- Dashboards (progress monitoring etc.)
- Progressive Web App (works without installation on PCs, Tablets, Smartphones etc. online and offline)
- fast and simple installation on premise or as a cloud-solution
- GCP, GLP, 21 CFR Part 11, GDPR, anonymization and pseudonymization

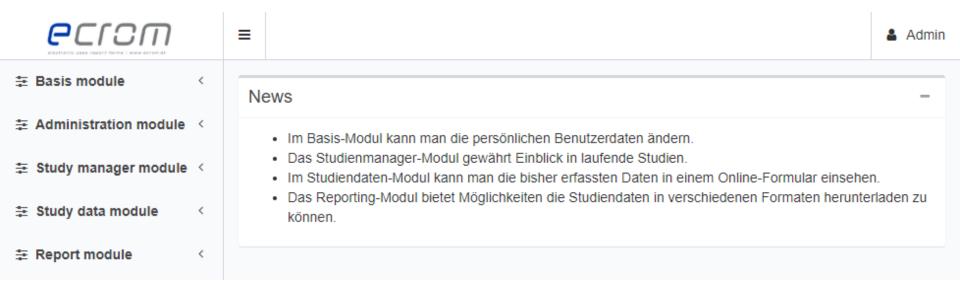
Login





Modules





Basis module

Personal profile settings and time recording

Administration module

• User administration and permissions

Study manager module

Form desgin and data types

Study data module

Collection of study data

Reporting

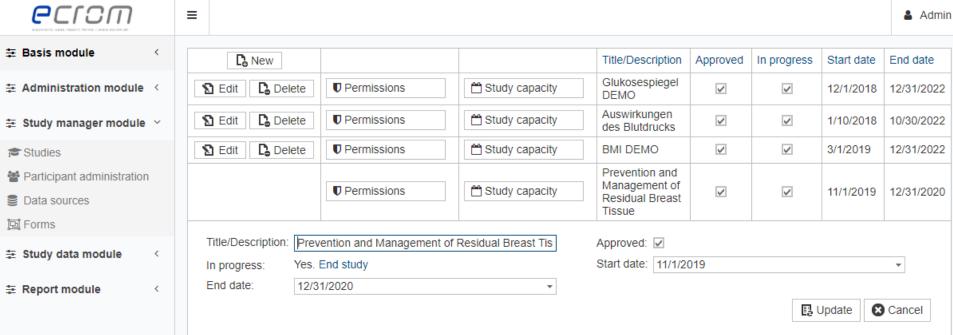
• Design and display of dashboards

Study administration



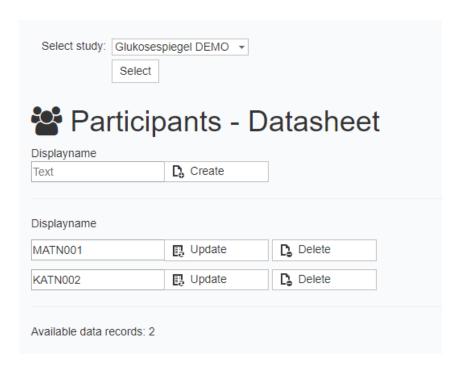


Details:



Participant administration

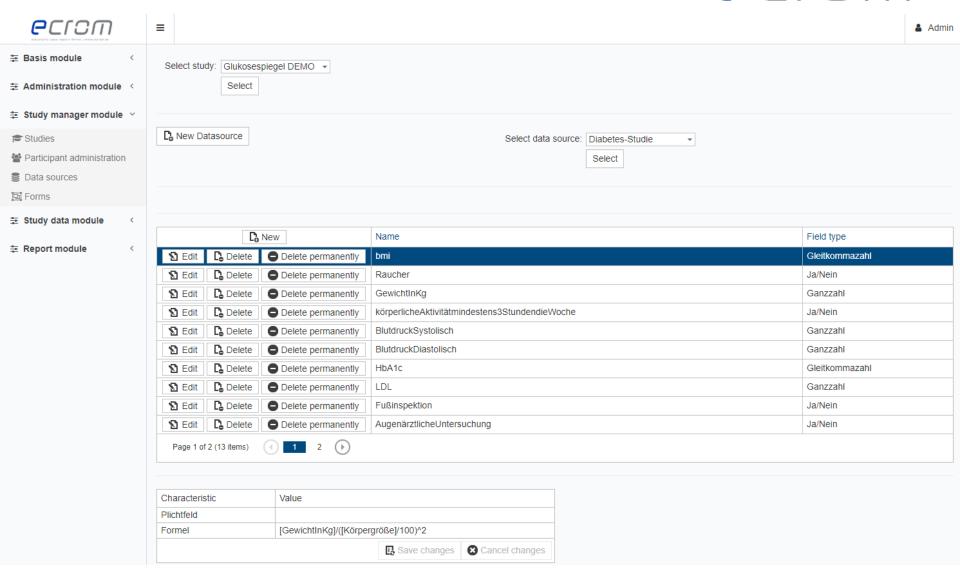




Participants of a study can be generated manually or an ID will be imported from a third-party system.

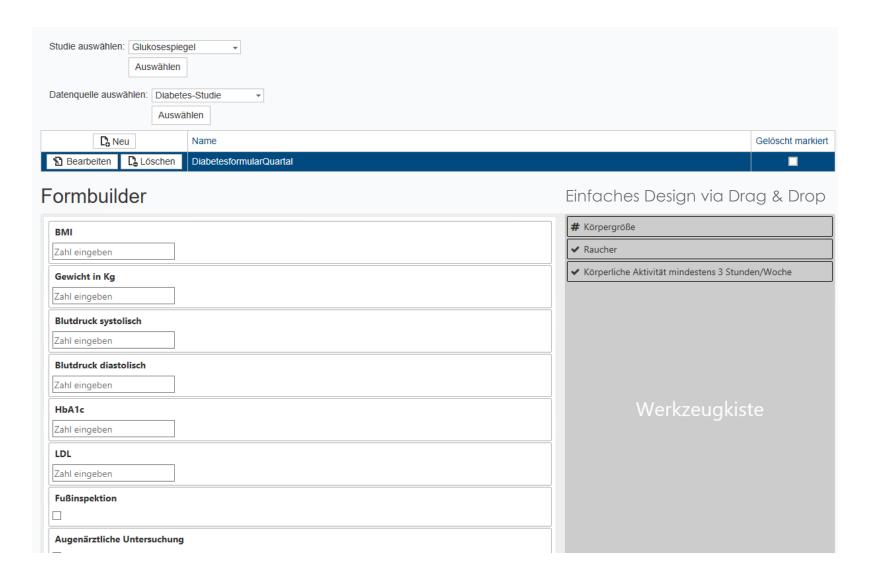
Datasources/Datatypes





Form design





Data collection



View of collected data of one participant

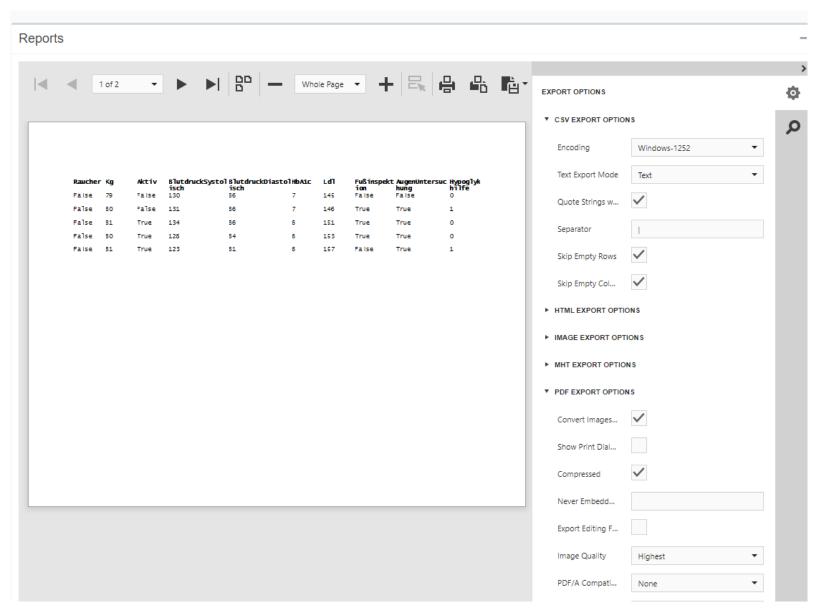
| Study: Glukosespiegel DEMO Participants: MATN001 Form: DiabetesformularQuarta Select | | | | | | | | | | | | |
|--|--------|---------|------------|------------|-------------|-----------|-------|-----|------------|-------------|-----------|--|
| New | ВМІ | Raucher | Gewicht in | Körperlich | Blutdruck s | Blutdruck | HbA1c | LDL | Fußinspekt | Augenärztli | Hypoglykä | |
| Edit New Delet | 24.251 | ~ | 83 | ✓ | 121 | 80 | 6.000 | 150 | ~ | ✓ | 1 | |
| Edit New Delet | 24.251 | ~ | 83 | ✓ | 123 | 82 | 6.000 | 147 | ✓ | ✓ | 0 | |
| Edit New Delet | 24.543 | ~ | 84 | ✓ | 121 | 81 | 5.000 | 151 | ✓ | V | 1 | |
| Edit New Delet | 24.251 | ~ | 83 | ✓ | 119 | 78 | 6.000 | 151 | ~ | | 0 | |
| Edit New Delet | 24.836 | ~ | 85 | ✓ | 124 | 84 | 6.000 | 150 | | ✓ | 2 | |

Collection or editing of a data record

| <u>New</u> | BMI | Raucher | Gewicht in | Körperlich | Blutdruck s | Blutdruck | HbA1c | LDL | Fußinspekt | Augenärztli | Hypoglykä | |
|---|------------|----------|------------|--|------------------------------|-----------------|----------------------------|-----|------------|--------------|-----------|--|
| BMI: 24.2512783053324 ‡ | | | | | Raucher:* | | | | | | | |
| Gewicht in Kg:* | | | | Körperliche Aktivität mindestens 3 Stunden/Woche:* 🔽 | | | | | | | | |
| Blutdruck sy | stolisch:* | | 121 | | * | Blutdruck diast | Blutdruck diastolisch:* 80 | | | | * | |
| HbA1c:* | | | 6.000 | | ‡ | LDL:* 150 | | | | | A ¥ | |
| Fußinspektion: | | | | | Augenärztliche Untersuchung: | | | | | | | |
| Hypoglykämien mit Fremdhilfe (letzte12 Monaten):* 1 | | | | Erfassungszeitpunkt:* 12/1/2018 12:00 AM ▼ | | | | | • | | | |
| | | | | | | | | | <u>U</u> | odate Cancel | | |
| Edit New Delet | 24.251 | V | 83 | ~ | 123 | 82 | 6.000 | 147 | ~ | V | 0 | |
| Edit New Delet | 24.543 | ✓ | 84 | ✓ | 121 | 81 | 5.000 | 151 | ✓ | ✓ | 1 | |
| Edit New Delet | 24.251 | ✓ | 83 | ✓ | 119 | 78 | 6.000 | 151 | ✓ | | 0 | |
| Edit New Delet | 24.836 | ~ | 85 | ~ | 124 | 84 | 6.000 | 150 | | ✓ | 2 | |
| | | | | | | | | | | | | |

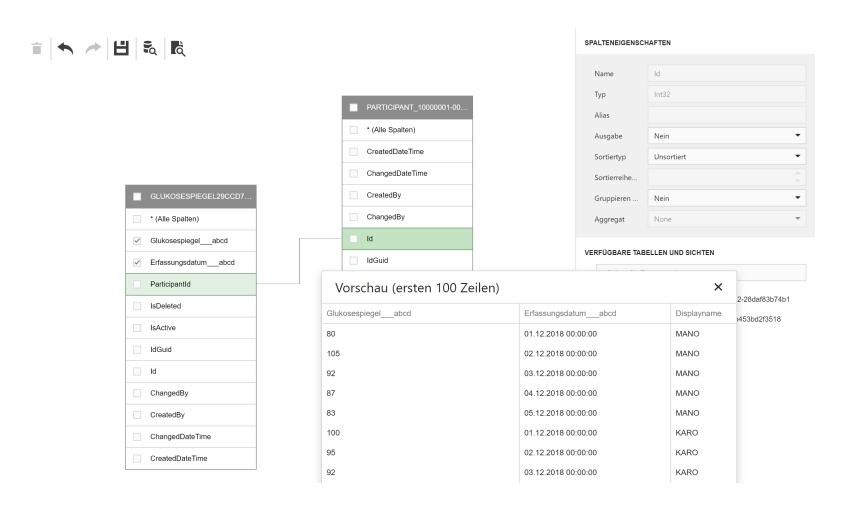
Reports





Query Builder





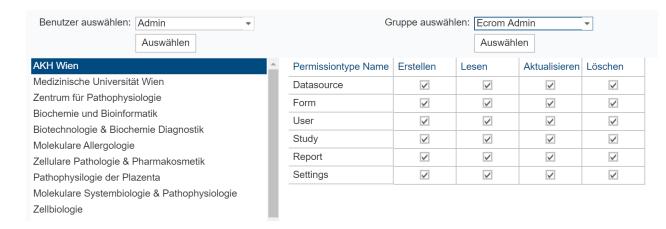
Administration



User administration

| New New | | User name | Last name | First name | E-mail | Telephone number | Mobile | Group Assignment |
|---------------|--------|--|-------------|------------|--|------------------|----------------|------------------|
| | | | | | | | | |
| S Edit | Delete | Alexander. Holzer | Holzer | Alexander | a.holzer@gmail.com | +433165346218 | +4306607489130 | |
| S Edit | Delete | AnnaRich | Richter | Anna-Maria | a.m.richter@aon.at | +435126532173 | +4306673109882 | |
| S Edit | Delete | Arjen.deBoer | | | | | | |
| ∑ Edit | Delete | christine.deutschmann@meduniwien.ac.at | Deutschmann | Christine | christine.deutschmann@meduniwien.ac.at | | | |
| S Edit | Delete | EVJJES56 | | | | | | |
| ∑ Edit | Delete | FrédRanc | Rancé | Frédérique | frederique.rance@gmail.com | +33376541098 | +33654928633 | |
| S Edit | Delete | GAL12PMQ | | | | | | |
| S Edit | Delete | Giovanni.Martinelli | | | | | | |
| S Edit | Delete | isabel.decosta@emails.es | de Costa | Isabel | isabel.decosta@emails.es | +349152369411 | +346072355489 | |
| S Edit | Delete | laszlo.horvath@vodafone.hu | | | | | | |

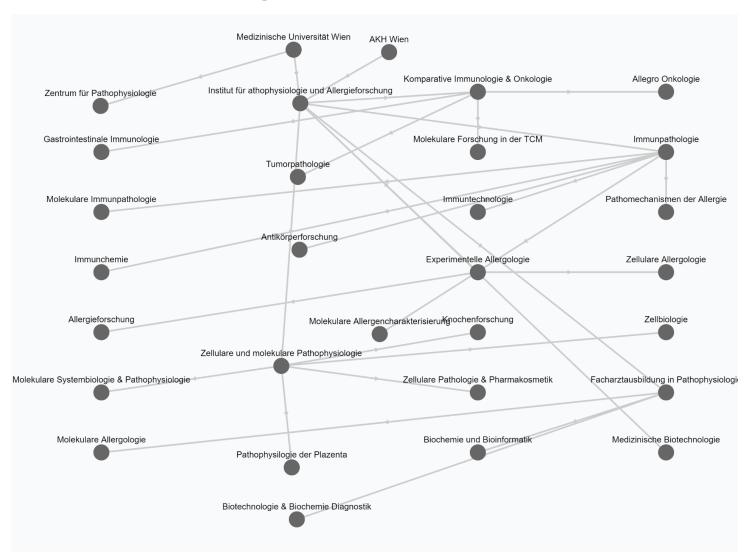
Permissions



Administration

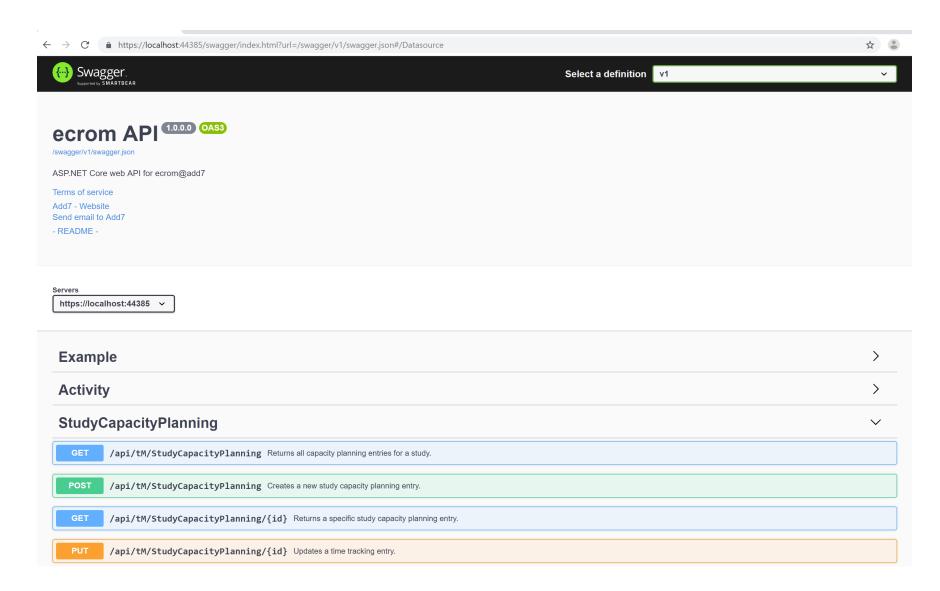


Graph-oriented regional administration



ecrom API





Study example: Prevention and Management of Residual Breast Tissue – Medical University of Vienna/ Univ. Klinik für Frauenheilkunde



| 1. General Data | | |
|---|--|--|
| 11 Section at Section | | |
| 4.4 Institution | | |
| 1.1. Institution | 4.4.2 Parastructus (4.1.24 and 1.1.11) | |
| 1.1.1. Hospital name: (typed answer) | 1.1.2. Department: (typed answ | |
| 1.1.2 City /typed engage) | 1 1 4 Country (typed anguer) | 5. Management of residual breast tissue |
| 1.1.3. City: (typed answer) | 1.1.4. Country: (typed answer) | |
| 1.1.5. University hospital: | | 5.1. Is residual breast tissue an indication for reoperation in a patient with breast cancer and negative resection margins? Yes |
| O Yes | | 5.1.1. What is your cut-off value of residual breast tissue for |
| O No | | 5.1.1. what is your during walled in estudial breast assue for reoperation (in mm); (typed answer) |
| 0.10 | | 0 |
| 1.2. What is your profession? | | 5.1.2. Does the ratio of residual breast tissue to primary breast tissue volume play a role for you in the course of deciding on reoperation? |
| ☐ General surgery | | ○ Yes |
| Gynecology | | ○ No |
| ☐ Plastic surgery | | ○ No |
| Other: (typed answer) | | 5.2. Is residual breast tissue an indication for reoperation in a high-risk patient? |
| | | O Yes |
| 1.3. Average number of operations your institution performs in 1 year: | | 5.2.1. What is your cut-off value of residual breast tissue for |
| Radical ME: (typed answer) | NSM: (typed answer) | reoperation (in mm): (typed answer) |
| 0 ‡ | 0 | |
| SSM: (typed answer) | | 5.2.2. Does the ratio of residual breast tissue to primary breast tissue volume plays a role for you in the course of deciding on reoperation? Yes |
| 0 | | O No |
| - · | | ○ No |
| 1.4. Average number of operations you - as a surgeon - perform in 1 year: | | |
| Radical ME: (typed answer) | NSM:(typed answer) | 5.3. Is residual breast tissue an indication for post-mastectomy radiotherapy in a patient with breast cancer and negative resection margins? |
| 0 | 0 | ○ Yes |
| SSM:(typed answer) | | 5.3.1. What is your cut-off value of residual breast tissue for radiotherapy(in mm): (typed answer) |
| 0 | | 0 |
| Ψ. | | 5.3.2. Does the ratio of residual breast tissue to primary breast tissue volume play a role for you in the course of deciding on radiotherapy? |
| 2. Preventive Measures | | O Yes |
| | | ○ No |
| 2.1. In case of NSM/SSM do you determine the thickness of the subcutaneou | ue tienue propogrativoly (multiple e | ○ No |
| , | us ussue preoperatively (multiple al | |
| Yes, in case of therapeutic NSM/SSM | | 5.4. In case of residual breast tissue do you intensify your follow-up care (multiple answers possible)? Yes, in case of |
| Yes, in case of prophylactic NSM/SSM | | therapeutic radical ME, to what extent: (typed answer) |
| □ No | | therapeutic NSM, to what extent: (typed answer) |
| 2.2. In case of NSM/SSM do you mark sites where fibroglandular breast tissu | ue annovimates close to the ekinne | therapeutic SSM, to what extent: (typed answer) |
| possible)? | ac approximates close to the skillpi | □ propriyactic radical ini⊏, to wriat extent. (typed answer) |
| Yes, in case of therapeutic NSM/SSM | | □ rophylactic NSM, to what extent: (typed answer) □ prophylactic SSM, to what extent: (typed answer) |
| Yes, in case of prophylactic NSM/SSM | | No, in none of the cases |
| □No | l | |

References































und viele mehr ...

Further steps



Interested?

If so, we would be very happy if you would use our services. For further steps, please contact Mr. Mag. Martin Reiser.

E-mail: martin.reiser@add7.at

Tel.: +43 699/ 18 19 20 65

Web: www.add7.at