





PRECISION THERAPY CLUSTER FOR SAXONY SaxoCell - How to transfer Anril 201









How to transfer Agenda & Speaker



- What is meant by "technology transfer"

- Transfer options and best practice examples
 Typical contracts in technology
- How to find transfer partners
- Speaker
 - Dorit Teichmann, SaxoCell® HUB, Startup Managerin Life Science dresden exists
 - Dr. Thomas Tradler, SaxoCell® HUB, Head of Business Development, Fraunhofer IZI



- Excellence in Research and Innovation no conflict but prerequisite
- Recent examples
- mRNA-based SARS CoV-2 vaccine (BioNTech SE)
 HPV vaccine for cervical cancer (DKFZ invention)
 CRISPR/Cas 9 (= hest and ward)
 - CRISPR/Cas 9 (= best <u>and</u> worst practice example)
- All these inventions are from academia and created a considerable economic impact
- But how does everything start?



- What can be the results of research activities?
 - Knowledge, skills
 - Highly qualified staff
 - Intellectual property rights
 - Infrastructure
 - Physical products
- Visition purpose within SaxoCell® Technology transfer is the exploitation of ideas and results coming out of the scientific community -> FOCUS on economic exploitation
- Active step to make research activities accessible for economic activities of third parties (outside of your own institution)

How to transfer Transfer at academic institutions



- Universities traditionally focus on basic research but growing importance of transfer and economic impact – TUD transfer examples:
 Spin-outs like Novaled, DyNAbind, ...
 Strategic cooperation with i.e. Carl Zeiss AG
 Fraunhofer-Gesellschaft has a strong focus on applied research and
- develops future technologies together with partners from academia and industry - Transfer examples from Fraunhofer IZI:
 - Spin-off companies like PerioTrap GmbH, epitopic GmbH and many others
 - Collaboration with Novartis and manufacturing of Kymriah® in Leipzig
 - Strategic partnership and license agreement with Bausch + Ströbel (LEEI technology*)

^{*} Fraunhofer-Preis »Technik für den Menschen und seine Umwelt« 2021



- Results of research activities can be broad
- There is intellectual properties (intangible assets) and other tangible assets like data, material, infrastructure,
- Over the years growing importance of intagible assets
- But companies build valuable portfolios by having both – tangible and intangible assets

COMPONENTS of S&P 500 MARKET VALUE



SOURCE: OCEAN TOMO, LLC

How to transfer Different types of intellectual property



Protection of a technological invention Patents:

Protection of a technological invention • Utility model:

Protection of an aesthetic appearance Registered designs:

Protection of a context-specific mark Trade marks:

Protection of authorship (i. e. software) Copyright:

• Trade secrets: **Unpublished Know-how**

How to transfer Role of freedom to operate and own IPR*



- Freedom to operate (FTO)
 - = No other party has blocking IPR granted = No one has the right to prohibit commercial use of your technology
 How to solve in case FTO is not given?
 - - Blocking IPR exist option to negotiate a license or to seek not addressed geographic justisdictions and/or technology/application areas
- Own protection us
 - Own IPR granted (patents, utility model, others) You have the right to exclude others from using your technology
 - Be aware the need to comply with all patentability requirements

^{*} Intellectual property rights (Schutzrechte)



- Inventions are intellectual assets
- They become Intellectual Property if positive steps are taken to convert the assets into property
 - Keep it secret if you don't want to give your invention away fo
 - Be careful when you publish, give symposia or hold classes
 PATENT FIRST PUBLISH LATER!
- Inventions are owned by the inventors unless they sign this right away
- Typically signed away by signing an employment contract (Arbeitnehmererfindungsgesetz)
- Transfer begins with the disclosure of your invention to technology transfer staff (patent office, start-up manager,...) or to anyone else outside



Disclosure of patentable invention

Official step: invention disclosure to the patent office of your institution (see official documents provided by your institution).
 Legal aspects
 Distinguish between ownership and inventorship of IP

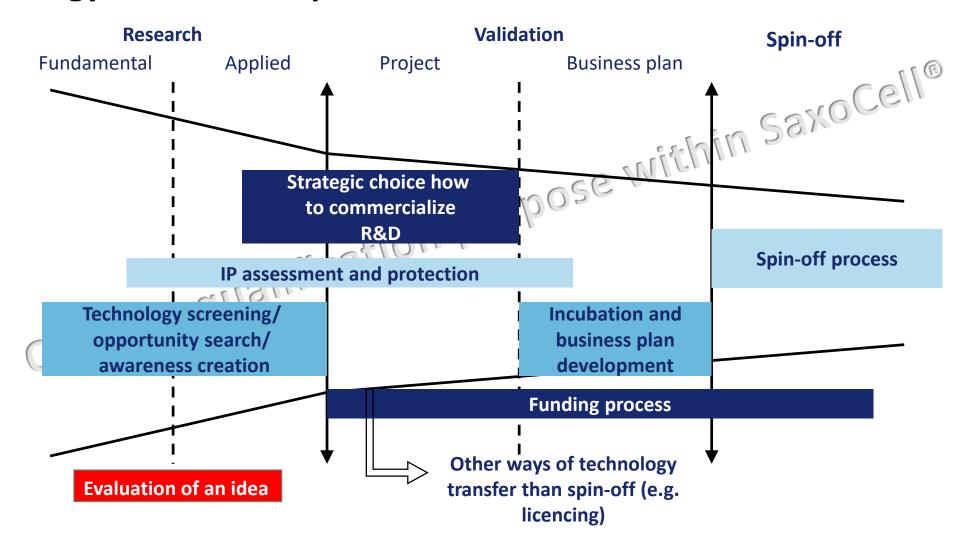
- Basis: Arbeitnehmererfindungsgesetz in Germany (in other countries similar regulations)
- Negotiations on IP transfer to companies and start-ups are done by owner of IP in close collaboration with inventors



- Growing importance of transfer and impact of research in public
- BMBF specific programs exploitation strategies ithin
 Typically ideas are evaluated at the step between basic and applied research

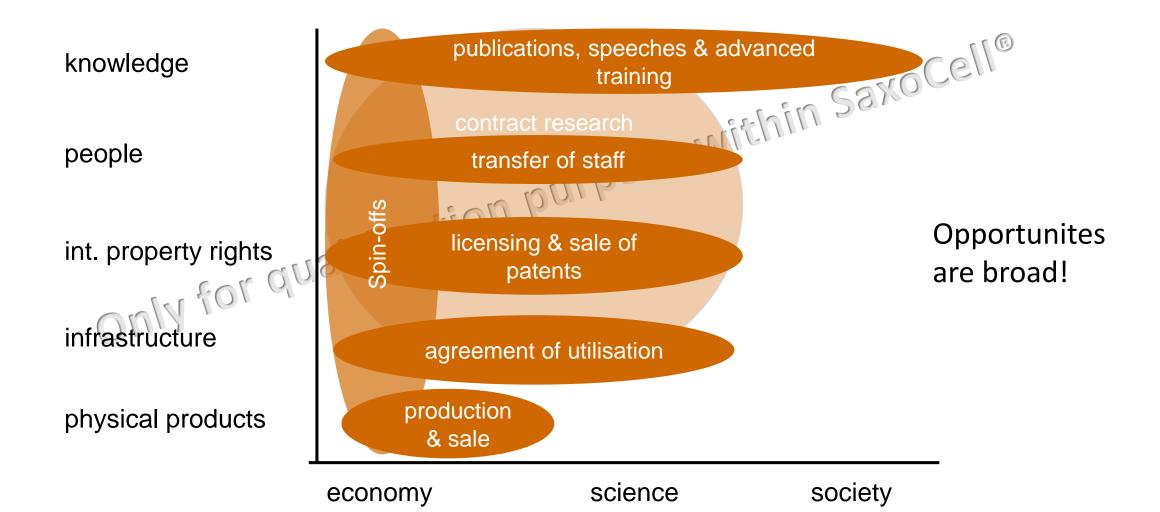


Technology transfer as a process





In which way do we transfer the results of our activities?



How to transfer Transfer via licensing to third parties



- Licensing enables access to use an IP (not only patents, also material, data, software,...) for commercial purposes
- A third party will use this IP as protection for its own products and services
- Realised by specific license agreements, but can be also in combination with cooperation agreements/ research agreements (!! Always check the IP part in cooperation agreements)
- Before closing a license consider you own plans and try to understand the business case of your partner and evaluate the value your IP provides to the partner

How to transfer Transfer via Spin-off (Start-up)



- A team out of a scientific institution creates a start-up based on idea/IP from the institution
- Specific case of a license agreement (between parent institution and start-up), option that institutions take shares in the start-up
- In most cases cooperation agreements between parent institutions and start-ups for further developments
- Career option for scientists and valuable for local value creation
- Institutions support scientists in their journey for a start-up with i.e. consulting, qualification programs and access to accelerators
 - Dresden: joint start-up service dresden exists
 - Leipzig: Fraunhofer IZI BD/PM, Fraunhofer Venture Group, University SMILE

How to transfer Transfer via R&D cooperation



- Min. 2 partners cooperate to reach a joint aim (scope of the cooperation), open research character
- Defined work packages of the partners normally specific IP brought in by each partner to reach the aim (background IP)
- Could be between academic partners and/or industry
- Could be with or without public funding (in case of funding check the strings attached)
- Always go along with rules on how to handle / get access to the IP (background, and the newly created (foreground) as well as jointly created IP) – always check!

How to transferTransfer via contract research



- Important (and often underestimated) technology transfer option
 - Industry partner has a specific R&D challenge to address orders academic partner to provide relevant service (testing, manufacturing etc.)
- Particularly important for FhG but of increasing importance for universities as well \rightarrow valuable source of revenues
 - In case of FhG: based on Fraunhofer General Terms and Conditions
- Compared to "R&D collaboration models" usually connected with better IP terms for the industry partner but details are important:
 - FhG position: Don't give away rights for model-/service related IP
 - Specific financial rules to be followed by academic institutions (calculation at full costs – avoid cross-subsidy issues/state-aid)

How to transfer Other ways of transfer – Knowledge transfer



- Qualification / Advanced trainings in specific fields (GMP, Regulatory etc.)
 - Pretty attractive but sometimes difficult cost/benefit ratio
- Transfer via staff (Transfer über Köpfe) people change from academia nto industry
 Not always appreciated by the academic institution (as the loss of valuable staff) into industry
 - resources is sometimes difficult to compensate)
 - But do not forget resulting benefits for the academic institution staff gets lost but valuable industry connections result
 - Fraunhofer: Seeks to compensate institutes/groups for associated expertise losses - "Ausgründungsprämie" with specific incentives in case of staff loss
- Transfer via sc. publications/other forms of dissemination in the public



- There are different ways to do transfer it is always a case by case decision which way we will go
- Just a few criteria:
- Field of application (platform / product) within Saxocell®
 Market size / market characterists • Market size / market characteristics (emerging, how disruptive is your solution, competition, ...)
 - Team (your own vision start-up?; what experts are on board?)

Typical contracts in technology transfer Agenda



- CDAs/NDAs
- MTAs
- Collaboration contracts
- License/option agreements Only for qualification pul
- GTCs

All of these contractual things usually will get supported comprehensively by your local legal department – and might be handled by those people - but for successful technology transfer, you need to understand a few important contract terms!

Note/Disclaimer: These slides do not represent any official opinion of FhG, TUD and UL - and do not represent any legal advice. Regarding all legal questions, please always contact your legal department or an attorney.

Typical contracts in technology transfer CDAs/NDAs - 1



• CDA/NDA – $\underline{\mathbf{C}}$ onfidential $\underline{\mathbf{D}}$ isclosure/ $\underline{\mathbf{N}}$ on- $\underline{\mathbf{D}}$ isclosure $\underline{\mathbf{A}}$ greement

• Typically, CDAs/NDAs represent the very first contract that is negotiated with the industry partner - chance to generate a positive (or negative...) first impression for the partner of how collaboration with your entity feels like

Many transfer projects at academic institutions fail in early phase due to mistakes in negotiating CDAs (e.g. long delays in answering to contract proposals, improper negotiation behavior, unrealistic terms etc.)

Typical contracts in technology transfer CDAs/NDAs - 2



- Why a CDA: Prerequisite for any exchange of confidential information
 - Intention is to regulate conditions for the exchange of confidential information during the early phase <u>until another contract comes into force*</u> (e.g. collaboration contract with confidentiality terms)
- Make sure that all people having access to the confidential information at your entity/institution know about the confidentiality of stored relevant information and keep specific handling rules
 - Fraunhofer guideline "Informationsklassifizierung" containing labelling obligations for information handling
- Mutual/one-way
 - Does your entity also want to disclose confidential information?

^{*} Do not mix CDA content with that of collaboration contracts (e.g. IP foreground ownership terms)

Typical contracts in technology transfer CDAs/NDAs - 3



Contract partners

- Contracting party must be identical with the information exchange party (carefully check the addresses, names and legal form!)
 • Frequently discussed: What affiliates do we want to accept as allowed
- recipients? Consider impact of foreign legal systems and impact on Talification puri information flow control

• Scope:

- Define the scope/technology field of relevant confidential information as clearly and detailed as possible – this is where your TTO/legal manager needs your comprehensive support
- Consider defining confidential information you don't want to receive (e.g. to avoid unwanted blending with own research results you later want to publish)

Typical contracts in technology transfer CDAs/NDAs - 4



- Technical definition of "confidential information"
 - Confidential information should always be labelled as "confidential" Option in case of verbal information exchange: Written summary exchanged AFTER verbal information exchange
- Information exchange
 Validity period of the CDA plus continuation of obligation to keep information exchanged under the agreement as "confidential"
 - Be aware the difference! Validity period: information exchange period; Follow-up time: No exchange anymore already exchanged info to kept confidential
 - Up to 10 yrs total CDA lifetime are usual make sure to keep obligation during that time and consider staff changes etc.
 - If not already present establish a contract management at your institution which has an eye on such things

Typical contracts in technology transfer CDAs/NDAs - 5



- Applicable law
 - Most frequently occurring for long reason discussions/negotiations
 - Do not accept foreign law that you don't know in detail opies



- If the CDA draft foresees that all copies made must be destroyed on demand → Consider what you really can realize (e.g. not applicable for IT backups!!)
- Violation of CDA terms
 - Do not overestimate your options in case your contract partner discloses your confidential information to third parties without permission
 - In such cases, you are certainly obliged to claim compensation → But it often turns out to be difficult to demonstrate a concrete loss

Typical contracts in technology transfer License agreements - Basics



- Some IP (e.g. secret know-how) = Owner keeps it confidential, thus avoiding use by others
- IPR (e.g. patent) = Owner can prohibit technology use by others for a limited period of time* in exchange for making the invention known to the public
 License = IP/IPR owner grants use rights to another party (= licensee)
 Note: Basically, you can grant a license ("Nutzungserlaubnis") for everything what
 - - is in your possession, including secret know-how!
- License agreement = Defines conditions under which licensor grants license to licensee in exchange for license fees

^{*} E.g. patent: 20 years starting from priority date

Typical contracts in technology transfer License agreements – License types



Kind of licensed IP/IPR:

• Patent, Know-How etc. → Often: Combinations

Type of allowed use:

• What does "use" exactly mean? E.g. manufacturing, distribution license

Allowed field of use:

Illowed field of use:

• What products, technology areas are allowed

Geographic validation:

In what countries is licensee allowed to use the IP

Allowed user number:

- Single use (unlimited number of licenses can be granted) "non-exclusive"
- Sole (ONE license holder/licensee AND licensor can use the IP)
- Exclusive (ONE license holder and licensor CANNOT continue using his own IP)

Advice: Always try to limit license content in any possible regard, keep revenue potential for further licenses!

Typical contracts in technology transfer License agreements – Further important terms



- Sublicenses
- Grant licensee the right to grant further licenses to third parties Helps to realize full commercial potential for your IP but be aware that licensee will negotiate with sublicensees directly so retain control and ensure revenues
 Maintenance of the IPR/Patent costs
- - ullet Without contractual agreement, licensor is obliged to maintain the IPR ullet In case of exclusive licenses patent costs are frequently carried by the licensee

Typical contracts in technology transfer License agreements – Further important terms



- Further development of the licensed technology/product
 - Can happen on both sides (licensor and/or license holder)
 agreed about how to deal with new IP
 iability

 Never ever give guarantees regarding
- Liability
 - - the absence of older IPR of third parties \rightarrow Find a suitable formulation that keeps you free from liability if an older IPR suddenly arises (e.g. "will inform licensee as soon as we become aware...")
 - usability (successful economic exploitation) of the licensed technology/product

Typical contracts in technology transfer License agreements – License fee basics



become License revenues can an for important source revenue academic institutions



- Typical components
 - Upfront fees (Einstiegszahlung)
 - Annual maintenance fees (auch als "Mindestlizenzgebühren")
 - Milestone payments
 - Royalties
- Also to consider
 - Patent costs coverage

Beachte: Royaltys (DE), Royalties (EN)

Typical contracts in technology transfer License agreements – License fees



- Upfront payment
- "Einstiegszahlung" → Hard to negotiate for early stage academic inventions, but you should really try (all further payments bear higher drop-out risk) \rightarrow E.g. should at least cover already realized patent costs
 Annual maintenance fees (AMF)
 Usually charged against relevant annual royalties (you won't get both),
- - Important strategic aspect: increasing AMF motivate licensee!!
- Milestone payments/Annual license fees
 - Increasing fee acc. to the achieved development stage
- Royalties
 - 0.5 15% of the net sales of licensed products
 - Do not forget "taxable" non-sales revenues of licensee!

Advice: Never accept profit as royalties base (1) and carefully watch costs the licensee want to deduct from net sales in the license agreement definition section (2)

How to find transfer partners (licensees, sponsors, investors, ...) Agenda



- Marketing mix* relevant key parameters
- Ways to find transfer partners → Marketing channels
 Scientific publications/talks given at scientific conferences
 Press & social media
 Trade fairs
 Partnering

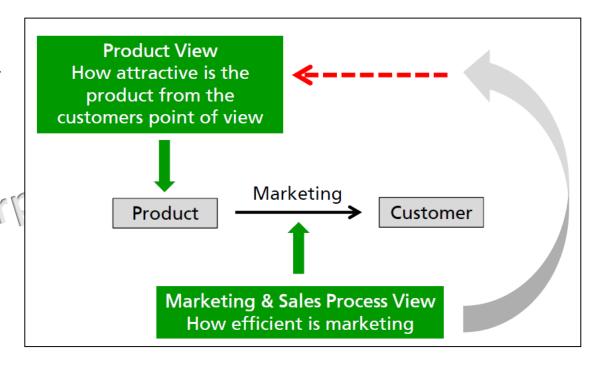
 - Partnering conferences
 - Cold calling
 - Network

^{*} Product development/design + pricing strategy/conditions + distribution/communication

How to find transfer partners Marketing process vs. product perspective



- Basic TTO marketing/sales process:
- There are two key parameters/ perspectives to watch/to control
 - Marketing process view
 - Product perspective
- In a typical TTO environment, the product perspective sometimes is underestimated and often uncoupled from TTO activities
 - Thus, consider both perspectives when setting-up optimal technology transfer activities



How to find transfer partners Marketing process perspective



- How to improve marketing processes?
 - Key questions: How to find customers? How efficient is marketing?
 General advice*:
 Do not forget the customer after the 1st asset/service has been sold...
- General advice*:

 - Important role of an intensified intra-organizational communication (e.g.: get your TTO knowing about your work as early as possible)
 - Optimize marketing channels usage
 - Marketing must be a continuous process
 - Exploit the true customer data value (CRM systems, systematic approaches to select target customers etc.)

^{*} Discussion of marketing channels follows

How to find transfer partners Product perspective



- Product attractivity = most important transfer success factor!!!
- Customer value: What additional (risk-adjusted) value does it realize for the customer compared to existing solutions?
 How to optimize product attractivity? And when to start?
- - Know your target customers and their needs/demands/wishes/problems
 - Primary (research market) market (e.g. licensee for a drug candidate)
 - Secondary (enduser) market (e.g. patient/health insurance)
 - Know the value of your product by knowing about USPs of your solutions compared to offers from competitors/alternative products
 - Consider market demands and potential USPs before R&D project start and during project conduct, implement customer feedback as early as possible

How to find transfer partners Market analysis – Useful information sources



- How to "know"?
 - Review articles, general newsletters* and newsletters published by inter-trade organizations**, attending talks at area-specific conferences (e.g. ARM and ISCT meetings, BIOs)
 - Market reports offered by many companies (very expensive, ~ 5k€ but often publish free of charge abstracts)
 - Commercial databases (e.g. Global Data, very expensive, 10-15K€ p.a. for basic modules but very useful if one can afford)
 - Statista (basic account free of charge)
 - Unternehmensregister*** and company filings search at SEC****

How to find transfer partners Mrkt. Channels - Scientific publications/conferences SA CELL®

- Scientific publications effectively support marketing efforts
 - Reseach-oriented companies usually follow the state of research in their respective technology area closely – thus they should become aware your technology based on publications in high-ranking journals
- Even more promising are talks given at relevant scientific meetings
 - Most of the larger conferences enjoy substantial industry participation, at least at technology scout level
 - Good channel for assets and high-tech based service offers



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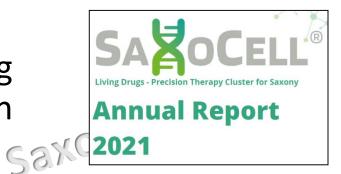




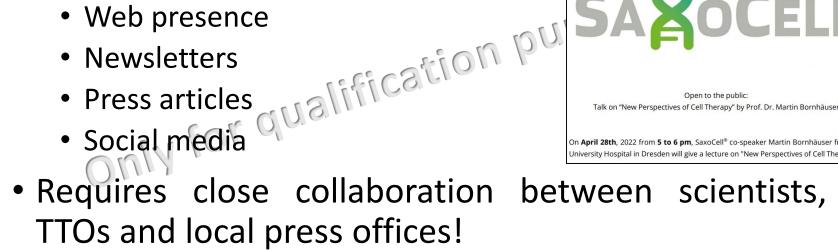
How to find transfer partners Marketing channels - Press/social media



 Generally helpful to facilitate transfer by creating public awareness - but pretty much depending on the type of activity and kind of asset/service offer:



- Printed media
- Web presence











How to find transfer partnersMarketing channels - Trade fairs



- Examples: MEDICA, BIOTECHNICA, ACHEMA, LABVOLUTION etc.
 - Having a booth at a trade fair can be very expensive (>10k€)
 cost/benefit ratio (costs/number of generated high value contacts) sometimes rather bad
- Some of these trade fairs are very big (e.g. MEDICA 6k exhibitors) thus think of how you would like to differentiate from all the other booths, to attract enough attention for your booth
 - Important role of items/exhibits sometimes difficult for pharma assets





How to find transfer partners Marketing channels - Partnering conferences 1



- Examples: BIO conference series (several events, global event + events focusing on specific regions), BioFIT (France, Europe), JPM/Biotech Showcase (global and US)
- Specific conference format in life sciences/pharma which is dedicated towards bringing offerers and potential customers/partners together efficiently
 - Many conference models, often combined with exhibition/lecture program
 - New: "partnering track" at scientific conferences (e.g. ARM, ISCT AM)
- Not really cheap but in optimal case best cost/benefit ratio at all – no other conference type can deliver so many qualified contacts and sales pitches
- Requires in-depth preparation as well as labor-intense conduct and follow-up









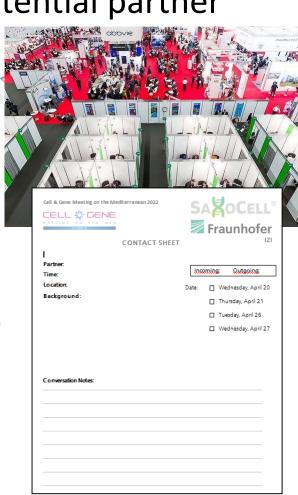




How to find transfer partners Marketing channels - Partnering conferences 2



- "Partnering" pre-scheduled 30min meeting with a potential partner
- Process:
 - 1. [~2m PTE] Enter company/offer profile in partnering DB ?
 - 2. [starting 2m PTE] Send meeting requests
 - 2.1. Other participants will contact you in case of interest
 - 2.2. Go through the other profiles contact potential partners too
 - 3. [starting 1m PTE] Meetings scheduled automatically
 - 4. [at the conference] Attend meeting, introduce your asset
 - Exchange contact data (business cards), agree on meeting follow-up
 - 5. [starting after the conference] Meeting follow-up (e.g. answer questions, provide further info, send CDA draft)



How to find transfer partners Marketing channels - Partnering conferences 3



- Things to be aware of:
 - Maintain high communication standards (avoid spam-type messages)
 Learn to deal with difficult meeting partners

 - Plan enough staff and time resources to allow professional preparation
 - A substantial share of meetings won't directly result in project closure stay on the ball*, and take advantage of negative meetings as well (every feedback is valuable)
 - Give comprehensive feedback to your scientists positive and negative
 - Quality, speed & partner orientation of the follow-up are key success factors
- Partnering conferences might be more suitable for BD/TTO people (combining several assets of their respective organization in one portfolio) but can be a valuable experience and time invest for scientists too

^{*} There are project examples at IZI where the deal finally got closed > 4 years after the initial contact

How to find transfer partners SaxoCell® offer



• The SaxoCell® HUB team is going to attend several partnering conferences, trade fairs and other events 2022 - 2024













• We'll be happy to introduce your CGT-related assets, platform technologies and services there towards potential customers, partners and investors → Please contact us in case you're interested

How to find transfer partners Marketing channels - Direct contact



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- Definition: Sales pitch with a potential partner who has never interacted with the sales person before \rightarrow But differentiate from standard "cold • Market analysis to identify potential customers/partners
 • Selection of target population, contact data for Send inquiry togget calling" = "unerwünschte Telefonanrufe"
- Typical process:

 - Send inquiry to selected partners (e.g. Email, contact form, LinkedIn), Follow-up
- Always keep ethical questions, employer branding and legal limits in mind → use business-related contact addresses only (e.g. company BD contacts, relevant social networks) → Can be a very efficient marketing channel, then

How to find transfer partners Network



- Can be a valuable source of potential customer contacts
- Use every chance to expand your network
- Implement work-related routine processes, e.g. get used to invite people you met at a conference the same day

 • But care the network quality too (carefully select whom to invite)







Well-suited for tech transfer matters but focused on German contacts

International professional network







Thank you for your attention?

For any questions and further information on technology transfer or just for discussing new ideas for transfer please contact your local HUB transfer person:

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