To Develop and Regulate Modern PCa-Care: a Secured, Integrated, Transversal Vision from Europe.

Pr Roland van Velthoven, MD, PhD
Dr Antoine Leroy, PhD – Koelis Founder&CEO
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Introduction on SPARED CRN objectives and situation in Europe
Coordinated Registry Network (CRN) Objectives and European Situation

• To improve and develop:
  – Patient information on Focal Treatment
  – Technical Innovation from Research and Industry
  – QoL and Economical data for Payers

• Through a comprehensive collaborative database, to collect and monitor standardized data from existing and emerging non surgical treatments of prostate cancer.
Press Statement: ESMO Welcomes Final Version of European Data Protection Regulation

Date: 14 Apr 2016

Topic: Bioethics, legal and economic issues

- Inclusion of one-time consent “crucial” for future of cancer research
- Regulation will aim to harmonise public health research across all 28 EU member states

Lugano, Switzerland -- ESMO -- the leading European professional organisation for medical oncology -- has today welcomed the European Parliament’s adoption of the EU General Data Protection Regulation, which it describes as being “crucial” for the future of cancer research.
In Europe:

EAU guidelines 2018 not in favor of mpMRI before first Bx nor Focal Therapy

In spite of multiple proofs of value for:
- MRI and MRI-guided prostate biopsy (eg PROMIS, Precision)
- Focal Energy Ablation (eg HIFU hemiablation)
Focal Therapy in Primary Localised Prostate Cancer: The European Association of Urology Position in 2018

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Focal Therapy in Primary Localised Prostate Cancer:

- **Patient summary**: Focal therapy of prostate cancer is the targeted destruction of cancer within a specific part of the prostate gland, sparing the rest of the prostate and nearby tissue.
- This procedure could potentially reduce side effects when compared with established standard treatments, such as surgery or radiotherapy, which treat the entire prostate.
- Studies show that for most men with low-risk cancer, active surveillance is the preferred treatment option.
- However, the available data regarding all forms of focal therapy are still poor and inconclusive. Consequently, due to both the lack of clear results associated with focal therapy and the difficulties in detecting all cancerous areas of the prostate, focal therapy should be considered an investigational modality only.
OUR VISION of a Secured, Integrated, Transversal REGISTRY

Data Protection Context for CRN: GDPR and HIPAA
## Coordinated Registry Network (CRN) data protection context

<table>
<thead>
<tr>
<th><strong>EU - GDPR</strong></th>
<th><strong>US - HIPAA</strong></th>
</tr>
</thead>
</table>
| • any information that can be used to directly or indirectly identify **EU citizens** such as  
  – race, religion,  
  – political affiliations,  
  – sexual preferences,  
  – biometric  
  – genetic data,  
  – any other information relating to their **health** (=PHI) | • Scope limited to dealing with protected **health information (PHI)**.  
• PHI includes any information that can be used to **identify a patient**,  
  – name, address, DOB,  
  – bank/credit card details,  
  – social security number, photos  
  – and insurance information. |
Coordinated Registry Network (CRN)

GDPR in Healthcare

• Creating a uniform set of rules governing how personal data can be used in today’s digital age, the Regulation will aim to harmonise the different frameworks governing health research across the EU’s 28 Member States.

• In particular, the Regulation includes provision for a ‘one-time consent’ from patients allowing their data and tissues to be used for future research, which will also ensure the viability of bio-banking.
Coordinated Registry Network (CRN)

GDPR in Healthcare

• The new Regulation also ensures that researchers have access to high-quality, population-wide data, which by definition must include the entire population, and therefore cannot be subject to patient consent.

• This exemption from consent is important because it allows disease-based registries to continue to exist and benefits not only cancer research but medical research in general.

• In the case of cancer, this data is collected and stored in cancer registries, which are used by governments to formulate new cancer control policies and update national cancer plans and ultimately improve patient outcomes.
Coordinated Registry Network (CRN)

GDPR in Healthcare

• Scientific steering committee
• Data Protection Officer (DPO)
• Explicit Consent
  – The definition of consent is stricter – requiring that consent be “freely given, specific, informed and unambiguous,”
• Right to access, correct, erasure
• Secure sensitive data
Coordinated Registry Network (CRN) GDPR: Sensitive Data (How to protect?)

• Each greater level of de-identification provides more protection and further reduces risk to individuals

• GDPR-Through-the-De-Identification-Lens-describes four levels of identifiability,
  – (1) Identified,
  – (2) Identifiable,
  – (3) Article 11 De-Identified, and
  – (4) Anonymous / Aggregated
Coordinated Registry Network (CRN)

GDPR: Sensitive Data (How to protect?)

• **Protected Health Information (PHI data)**
  – Phi data are separated from medical data in other server and de-identified.
  – Phi data are encrypted
  – Patient key dependent encryption (Each patient has its own encryption)

• **GDPR Sensitive Non PHI data**
  – Non PHI data are stored in medical data.
  – Every medical data are **pseudonymized**
  – Every medical data are encrypted and key encryption is item dependent
Sample implementation of an International Secured Registry
GDPR: Sensitive Data (How to protect?)
eNewborn Functionalities

- Statistics
  - Patients AHA/AGA/All
    - Annual report
    - Cumulative report
  - Customized networks
    - Drilldown list

- Collect data
  - Data entry
  - Data cleaning
  - Error value
  - Periodical validation

- Security
  - Individual data restricted to owner
    - Encrypted data and encryption keys not on same server
    - Hidden host server encryption keys
  - 2-phase login
    - Non PHI data
    - Multi-tier encryption
  - Login
    - PHI data

- New studies
  - Neo-Kiss
  - Followup
  - Hi-Lo

Users demands:
- Clean data

Clinicians:
- Quality control
- Benchmarking

Researchers:
- Statistical research tools
- Customized data entry

Servers focus on:
- Availability
- Response time
- Security

RVV/AL SPARED CRN 5/3/18 17
GDPR: Sensitive Data (How to protect?)
eNewborn GDPR Compliance

**eNewborn Real Word Data**

- eNewborn encryption system
- De-identification key

**PHI data**
- Any data that can be used to identify a patient

**Medical data**
- Medical data
  - Anonymous data
  - Aggregate data
  - Pseudominization

**Real World Evidence**
Coordinated Registry Network (CRN)

GDPR: Sensitive Data (How to process?)

• **Protected Health Information (PHI data):**
  – Phi data are not processed for statistical analysis.
  – Phi data can be decrypted by the owner / hospital / physician who has the privilege to access.
  – Each access is traced.

• **GDPR Sensitive Non PHI data**
  – Medical data can be de-crypted by the owner / hospital /physician with adequate privilege.
  – Medical data can be processed by statistical analysis.
  – When in aggregate form, medical data can be decrypted by users having statistical privilege or by statistical process.
  – Each access is traced.
Registry Items and need for standardization: 2 sample studies
Quality indicators for global benchmarking of localised prostate cancer management

Fanny Sampurno, Jia Zheng, Lydia Di Stefano, Jeremy L. Millar, Claire Foster, Ferran Fuedeas, Celestia Higano, Hartwig Hulan, Stephen Mark, Caroline Moore, Alison Richardson, Frank Sullivan, Neil S. Wenger, Daniela Wittmann, Sue Evans

Pll: S0022-5347(18)39377-7
DOI: 10.1016/j.juro.2018.02.071
Reference: JURO 15289

To appear in: The Journal of Urology
Accepted Date: 15 February 2018

**Figure 1:** The number of indicators involved in each stage of refinement and elimination

<table>
<thead>
<tr>
<th>Stage</th>
<th>Diagnosis</th>
<th>Primary Treatment</th>
<th>Salvage Treatment</th>
<th>Outcomes</th>
<th>TOTAL</th>
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</thead>
<tbody>
<tr>
<td>Literature Review</td>
<td>76</td>
<td>43</td>
<td>82</td>
<td>57</td>
<td>352</td>
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<tr>
<td>Feasibility Review</td>
<td>15</td>
<td>13</td>
<td>17</td>
<td>18</td>
<td>123</td>
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<tr>
<td>Online Survey</td>
<td>11</td>
<td>2</td>
<td>10</td>
<td>1</td>
<td>43</td>
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<tr>
<td>Panel Meeting</td>
<td>11</td>
<td>6</td>
<td>1</td>
<td>34</td>
<td>70</td>
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<tr>
<td>Final Review</td>
<td>9</td>
<td>5</td>
<td>7</td>
<td>18</td>
<td>55</td>
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<tr>
<td>Final Set</td>
<td>9</td>
<td>4</td>
<td>6</td>
<td>18</td>
<td>52</td>
</tr>
<tr>
<td>Implementation Set</td>
<td>7</td>
<td>7</td>
<td>1</td>
<td>18</td>
<td>33</td>
</tr>
</tbody>
</table>

MI: Median importance  
MF: Median feasibility  
DI: Disagreement index  
AS/WW: Active surveillance/watchful waiting  
RP: Radical prostatectomy  
RT: Radiotherapy

*6 indicators added (QI 22-27, Table 4) during the panel meeting.

◊ 34 indicators were removed during the panel meeting.
CONCLUSIONS

- This study defined a set of 33 indicators conceived on the basis of existing international evidence-based clinical guidelines and endorsed by an international multidisciplinary expert panel.
- The indicators encompass the diagnosis, treatment and outcome aspects of Pca management.
- This set will be used to benchmark performance internationally in order to improve consistency and quality of care for men with PCa on a global basis.
Outcomes of Focal Therapies for Prostate Cancer

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Know the risks and potential benefits of clinical studies and talk to your health care provider before participating. Read our disclaimer for details.

Sponsor:
Weill Medical College of Cornell University
<table>
<thead>
<tr>
<th><strong>Brief Title</strong></th>
<th>Outcomes of Focal Therapies for Prostate Cancer</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Official Title</strong></td>
<td>Outcomes of Focal Therapies for Prostate Cancer</td>
</tr>
<tr>
<td><strong>Brief Summary</strong></td>
<td>The purpose of this study is collect observational data regarding patterns of care and outcomes of focal therapies for prostate cancer, including but not limited to: high-intensity focused ultrasound (HIFU), cryotherapy, focal laser ablation, irreversible electroporation, photodynamic therapy, and brachytherapy.</td>
</tr>
<tr>
<td><strong>Detailed Description</strong></td>
<td>Through the use of a prospective registry, the investigators will collect information on patient characteristics including age, co-morbidities, imaging and biopsy information, and prior treatments. Information on treatment details will also be captured, including treatment time, anesthesia delivered, and length of stay, when applicable. Oncologic outcomes including PSA, post-treatment biopsy and imaging data, need for retreatment, and survival outcomes will also be captured. Safety outcomes will be captured using the Clavien-Dindo classification scale, and additional specific GU complications will be recorded, which include urinary retention, urethral stricture, recto-urethral fistula, osteomyelitis, and urinary tract infection. Finally, the investigators will capture functional outcomes using health related quality of life questionnaires including the EPIC questionnaire, IIEF-5, MSHQ-EjD, and IPSS.</td>
</tr>
<tr>
<td><strong>Study Type</strong></td>
<td>Observational [Patient Registry]</td>
</tr>
<tr>
<td><strong>Study Design</strong></td>
<td>Observational Model: Other</td>
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<tr>
<td><strong>Time Perspective</strong></td>
<td>Prospective</td>
</tr>
<tr>
<td><strong>Target Follow-Up Duration</strong></td>
<td>12 Months</td>
</tr>
<tr>
<td><strong>Biospecimen</strong></td>
<td>Not Provided</td>
</tr>
<tr>
<td><strong>Sampling Method</strong></td>
<td>Non-Probability Sample</td>
</tr>
<tr>
<td><strong>Study Population</strong></td>
<td>Participants are generally healthy men diagnosed with prostate cancer, undergoing focal therapy for treatment of prostate cancer.</td>
</tr>
<tr>
<td>Recruitment Information</td>
<td></td>
</tr>
<tr>
<td>-------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td><strong>Recruitment Status</strong></td>
<td>Recruiting</td>
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<tr>
<td><strong>Estimated Enrollment</strong></td>
<td>200</td>
</tr>
<tr>
<td>(submitted: April 6, 2018)</td>
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<tr>
<td><strong>Original Estimated Enrollment</strong></td>
<td>Same as current</td>
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<tr>
<td><strong>Estimated Study Completion Date</strong></td>
<td>March 1, 2020</td>
</tr>
<tr>
<td><strong>Estimated Primary Completion Date</strong></td>
<td>March 1, 2020 (Final data collection date for primary outcome measure)</td>
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<tr>
<td><strong>Eligibility Criteria</strong></td>
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<tr>
<td>Inclusion Criteria:</td>
<td></td>
</tr>
<tr>
<td>• &gt;18 years of age</td>
<td></td>
</tr>
<tr>
<td>• Undergoing focal therapy for primary or salvage treatment of prostate cancer, or</td>
<td></td>
</tr>
<tr>
<td>• Have received prior focal therapy</td>
<td></td>
</tr>
<tr>
<td>Exclusion Criteria:</td>
<td></td>
</tr>
<tr>
<td>• Clinically-evident metastatic disease</td>
<td></td>
</tr>
<tr>
<td>• Unable to fill out an English-language questionnaire</td>
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<tr>
<td><strong>Sex/Gender</strong></td>
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<tr>
<td>Sexes Eligible for Study:</td>
<td>Male</td>
</tr>
<tr>
<td><strong>Ages</strong></td>
<td>18 Years and older (Adult, Senior)</td>
</tr>
<tr>
<td><strong>Accepts Healthy Volunteers</strong></td>
<td>No</td>
</tr>
</tbody>
</table>
transrectal Koelis fusion biopsy from 2010 to 2017.
list of study items

<table>
<thead>
<tr>
<th>Clinical</th>
<th>mp-MRI</th>
<th>Biopsy strategy</th>
<th>Pathology of targeted biopsies</th>
<th>Pathology of randomized biopsies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Center</td>
<td>MRI date</td>
<td>Biopsy device</td>
<td>Pca on target 1</td>
<td>Pca on random biopsies</td>
</tr>
<tr>
<td>Surname</td>
<td>Number of targets</td>
<td>#Target cores taken</td>
<td>Primary Gleason score of target 1</td>
<td>Primary Gleason score of random biopsies</td>
</tr>
<tr>
<td>Name</td>
<td>Target 1</td>
<td>Number Random cores taken</td>
<td>Secondary Gleason score of target 1</td>
<td>Secondary Gleason score of random biopsies</td>
</tr>
<tr>
<td>Dossier number</td>
<td>Localisation of target 1</td>
<td>Number Total cores taken</td>
<td>#positive cores of target 1</td>
<td>#positive cores of random biopsies</td>
</tr>
<tr>
<td>Birthdate</td>
<td>mm</td>
<td>Max core length of Pca on target 1</td>
<td>Max core length of Pca on random biopsies</td>
<td></td>
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<tr>
<td>Biopsy date</td>
<td>ADC1</td>
<td>Pathology finding on biopsy</td>
<td>Pca on target 2</td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>Target 2</td>
<td>Localisation of Pca</td>
<td>Primary Gleason score of target 2</td>
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<tr>
<td>DRE</td>
<td>mm</td>
<td>Secondary Gleason score of target 2</td>
<td>#positive cores of target 2</td>
<td></td>
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<tr>
<td>Vol (cc)</td>
<td>PIRADS1</td>
<td>#positive cores of random biopsies</td>
<td>Max core length of Pca on target 2</td>
<td></td>
</tr>
</tbody>
</table>

Accrual: 2.115 patients retrospectively enrolled from 15 institutions in 4 European countries,

RVV/AL SPARED CRN 5/3/18
Global HIFU in Pca: patient’s data set

<table>
<thead>
<tr>
<th>Item</th>
<th>Value</th>
<th>Cell format</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient data</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Confidential identifier</td>
<td>Text</td>
<td>Auto</td>
</tr>
<tr>
<td>Patient initials</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inclusion date</td>
<td>DD/MM/YYYY</td>
<td>Date</td>
</tr>
<tr>
<td>Date of birth</td>
<td>DD/MM/YYYY</td>
<td>Date</td>
</tr>
<tr>
<td>Age at the biopsy exam date</td>
<td>Number</td>
<td>integer</td>
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<tr>
<td>Prostate cancer diagnostic date</td>
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<td>Date</td>
</tr>
<tr>
<td>PSA date</td>
<td>DD/MM/YYYY</td>
<td>Date</td>
</tr>
<tr>
<td>PSA value</td>
<td>Number</td>
<td>Integer</td>
</tr>
<tr>
<td>Free PSA rate before biopsy exam</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DRE result</td>
<td>Soft/suspect-left/suspect-right/suspect</td>
<td></td>
</tr>
<tr>
<td>Cancer grade from DRE</td>
<td>T1/T2a/T2b/T2c/T3a/T3b/T4</td>
<td></td>
</tr>
<tr>
<td>Indication</td>
<td>Early detection/active monitoring/suspicion</td>
<td></td>
</tr>
</tbody>
</table>

1995 up to now:

**Accrual:** about 30000 patients enrolled

Lack of comprehensive prospective registry

April 2015 gov.fr / AFU
Driven study:
Global hifu vs RP
Materials

- The National Library of Medicine Database was searched for articles published between January 2007 and April 2017.
- A wide search was performed including the combination of following words: “HIFU”, “prostate”, “cancer”, “focal”.
- Overall, 167 articles were reviewed. Of these, **7 articles** were identified and eligible for the pooled analysis.
- Data on HIFU hemiablation or focal prostate ablation oncologic and functional results were pooled from these 7 studies that included **366 men with unilateral PCa**.
# HIFU focal treatment for unilateral prostate cancer: a comprehensive study of pooled data

<table>
<thead>
<tr>
<th>Author</th>
<th>Year</th>
<th>Design</th>
<th>N patients</th>
<th>Age</th>
<th>PSA</th>
<th>Biopsy</th>
<th>Max Gleason for inclusion</th>
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<tbody>
<tr>
<td>Muto</td>
<td>2008</td>
<td>retrospective</td>
<td>29</td>
<td>72</td>
<td>5.4</td>
<td>Not specified</td>
<td>10 (5+5)</td>
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<tr>
<td>El Fegoun</td>
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<td>retrospective</td>
<td>12</td>
<td>70</td>
<td>7.3</td>
<td>random</td>
<td>7 (3+4)</td>
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<tr>
<td>Ahmed</td>
<td>2012</td>
<td>prospective</td>
<td>41</td>
<td>63</td>
<td>6.6</td>
<td>template biopsy</td>
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<td>prospective</td>
<td>56</td>
<td>64</td>
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<td>van Velthoven</td>
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<td>prospective</td>
<td>50</td>
<td>73</td>
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<td>Target and systematic</td>
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<td>prospective</td>
<td>67</td>
<td>70</td>
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<td>prospective</td>
<td>111</td>
<td>65</td>
<td>6.2</td>
<td>random and target</td>
<td>7 (3+4)</td>
</tr>
</tbody>
</table>

*Simone Albisinni, Christian Melot, Ksenija Limani, Alexandre Peltier, Pascal Rischmann and Roland van Velthoven*
HIFU focal treatment for unilateral prostate cancer: a comprehensive study of pooled data

Oncological outcomes

Simone Albisinni, Christian Melot, Ksenija Limani, Alexandre Peltier, Pascal Rischmann and Roland van Velthoven
HIFU focal treatment for unilateral prostate cancer: a comprehensive study of pooled data

Functional results

<table>
<thead>
<tr>
<th>Study</th>
<th>Urinary Continence at 12 months (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rischmann P et al (2017)</td>
<td>95% (91 – 100)</td>
</tr>
<tr>
<td>van Velthoven R et al (2016)</td>
<td></td>
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<tr>
<td>Cordeiro Feijoo ER et al (2016)</td>
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<tr>
<td>El Fegoun AB et al (2011)</td>
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<tr>
<td><strong>Total</strong></td>
<td>96% (91 – 100)</td>
</tr>
</tbody>
</table>

Mean (95% CI)
Technology update and personal view of modern PCA-Care & registry
COMPREHENSIVE PATIENT PATHWAY

**SCREENING**
- Pathology (Gleason, Epstein)
- Biomarkers (Epigenetics)

**DIAGNOSIS**
- Multiparametric (MRI - PET) image fusion
- Smart biopsy planning
- Live 3D viewing
- Targeted biopsies
- 3D Cartography

**PATIENT SELECTION**
- Confident patient selection
- Multi-disciplinary decision

**TREATMENT**
- Accurate guidance
- Confident and precise intervention
- Cost-efficient & time-efficient
- Targeted treatment

**FOLLOW-UP**
- Recall capability
- Streamlined Workflow
- Surveillance Active
- Quality control
- Data Management
- Registre
Fusion Targeted Biopsy: Precision Diagnosis proven by world RCT*
Organ Based Tracking

Optimal quality control

MRI image showing lesion-to-biopsy

Ultrasound image

Fusion image

Non elastic fusion image

Image treatment

Elastic fusion image

Motion compensation

- The Organ Based Tracking® is a patented real-time imaging algorithm that permits the automatic recalibration of the prostate position and shape during biopsy intervention.
- OBT® enables to grow an exclusively accurate cartography of biopsy cores and MRI lesions over time. OBT® also enables an exclusively accurate “Second Look® fusion” to enable targeted re-biopsy and treatment protocols.
- Consequence to OBT®, elastic fusion MRI/US image is updated everytime the patient moves. It repositions the MRI images instantly on the ultrasound image that has moved with the patient therefore achieving the highest level of targeting precision amongst all available devices on the market.

RVV/AL SPARED CRN 5/3/18
Optimal quality control
MRI/PET fusion + TRUS guided biopsy

PATIENT DATA TRACEABILITY AND QUALITY MANAGEMENT

HISTOLOGICAL DATA
Positive biopsy cores: 11/19
Cancerous tissue length: 126/183

<table>
<thead>
<tr>
<th>Biopsy No.</th>
<th>Biopsy length</th>
<th>Tumor length</th>
<th>Gleason score</th>
<th>PCI</th>
<th>PNI</th>
<th>ASAP</th>
<th>PIN</th>
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<tbody>
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<td>1</td>
<td>10</td>
<td>7</td>
<td>3+4</td>
<td></td>
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"Re-visiting-TBx"
from the positive trajectories on AS
("Documented trajectory is the target")

1st look biopsy, 3 cores (shown as a red arrow) positive for Gleason 3+3, in the right lobe only

2nd look biopsy: 5 cores positive for Gleason 3+3, in right-mid (n=3) and right-apex (n=2).

At 12-24 months follow-up

Ukimura et al. Prostate 2015. 75:863
A method to SEE, TARGET, REGISTER and RECALL biopsy cores’ position.
WRAP-UP and PROPOSAL
To Develop and Regulate Modern PCa-Care: a Secured, Integrated, Transversal PROPOSAL from Europe.

The READBRED Network:

Registry for Energy Ablative Devices, Big Real-world E-Data

Pr Roland van Velthoven, MD, PhD
Dr Antoine Leroy, PhD – Koelis Founder & CEO
The SPARED CRN meeting
FDA, Washington 5/3/2018

FIELD:  - localized prostate cancer (IPCa)

ACTORS: - health providers, organisations,
- industry: medical devices
- « 3rd party » stakeholders

METHOD:  PROSPECTIVE REGISTRY
- complying with IPHAA, GDPR regulations
- web based encrypted database
- real time access to data entry,
  local data management, individual benchmarking
- data quality control (CRA)
The SPARED CRN meeting
FDA, Washington 5/3/2018

METHOD: PROSPECTIVE REGISTRY ITEMS

- Preclinical data
- Clinical data
- Diagnosis data
- First intention treatment
- Second intention treatment
- Salvage treatment
- Outcomes
- Quality of life
- Quality Control

Standard Exchange Format: DICOM