

ABRAX study

- Inclusion criteria
 - Histologically confirmed invasive cervical cancer (Squamous cell carcinoma, Adenocarcinoma, Adenosquamous carcinoma) [No, Yes]
 - Stage pT1a – pT2b [No, Yes]
 - Patient referred for primary surgical treatment (including radical / simple hysterectomy / fertility sparing procedure) in combination with LN staging. [No, Yes]
 - Intraoperative detection of LN involvement (micrometastases or macrometastases). Grossly involved lymph nodes OR SLN/LN intraoperative pathologic evaluation (frozen section). [No, Yes]
 - Follow-up data available for ≥ 2 years [No, Yes]
 - Surgery performed between January 2005 and December 2015 [No, Yes]
- Patient's identification and history
 - Date of birth (month/year)
 - Second primary cancer (previous or simultaneous)
 - Breast cancer [No, Yes]
 - Date of diagnosis (year)
 - Treatment
 - Chemotherapy [No, Yes]
 - Radiotherapy [No, Yes]
 - Location
 - Abdominal [No, Yes]
 - Pelvic [No, Yes]
 - Other fields [No, Yes]
 - Surgery [No, Yes]
 - Haematological malignancy [No, Yes]
 - Date of diagnosis (year)
 - Treatment
 - Chemotherapy [No, Yes]
 - Radiotherapy [No, Yes]
 - Location
 - Abdominal [No, Yes]
 - Pelvic [No, Yes]
 - Other fields [No, Yes]
 - Surgery [No, Yes]
 - Other [No, Yes]
 - Cancer type description
 - Date of diagnosis (year)
 - Treatment
 - Chemotherapy [No, Yes]
 - Radiotherapy [No, Yes]
 - Location
 - Abdominal [No, Yes]
 - Pelvic [No, Yes]
 - Other fields [No, Yes]

- Surgery [No,Yes]
- Height (at the time of diagnosis)
- Weight (at the time of diagnosis)
- Performance status (ECOG at the time of diagnosis) [0,1,2,3,4,Not available]
- Diagnostics
 - Date of first diagnosis (month/year)
 - Diagnostic procedure [Biopsy,Conization (any technique including LEEP, LLETZ etc.),Other,Pap smear]
 - Imaging method used for clinical staging before primary surgery
 - CT [No,Yes]
 - Expert sonography [No,Yes]
 - MRI [No,Yes]
 - PET [No,Yes]
 - None [No,Yes]
 - Not available [No,Yes]
 - Pre-treatment clinical and radiological staging (TNM classification) [T1A1,T1A2,T1B1,T1B2,T2A1,T2A2,T2B]
 - Largest tumor size on radiological staging
 - Lymph nodes radiological staging [Normal,Not assessed,Not available]
 - Histological type [Adeno,Adenosquamous,Other,Squamous]
 - Horizontal dimension
 - Depth of invasion
- Treatment
 - Neoadjuvant chemotherapy was given [No,Yes]
 - Neoadjuvant chemotherapy
 - Regimen
 - Carboplatin [No,Yes]
 - Dose per cycle
 - No of cycles [1,2,3,4,5]
 - Paclitaxel [No,Yes]
 - Dose per cycle
 - No of cycles [1,2,3,4,5]
 - Cisplatin [No,Yes]
 - Dose per cycle
 - No of cycles [1,2,3,4,5]
 - Ifosfamide [No,Yes]
 - Dose per cycle
 - No of cycles [1,2,3,4,5]
 - Etoposide [No,Yes]
 - Dose per cycle
 - No of cycles [1,2,3,4,5]
 - Other [No,Yes]
 - Regimen description
 - Primary surgery
 - Surgery date (month/year)

- Intraoperative detection of LN involvement (micrometastases or macrometastases)
 - Macroscopic involvement = grossly involved lymph nodes (if confirmed by final pathology) [No, Yes]
 - Microscopic involvement = SLN / LN intraoperative pathologic evaluation (frozen section) [No, Yes]
- Intraoperative histological evaluation of LN (frozen section)
 - Type of LN submitted [Pelvic nonSLN lymph node(s), SLN]
 - Selection of LN for frozen section [All harvested LN submitted, Anatomical localisation, Not available, SLN, Suspicious LN]
 - No of SLN/LN evaluated intraoperatively
 - Type of metastasis reported from intraoperative evaluation (enter the largest type) [Macrometastases, Micrometastases]
- Cervical/uterine procedure abandoned [No, Yes]
- Reasons for abandoning cervical/uterine procedure
 - Distant metastatic spread of tumor [No, Yes]
 - LN involvement [No, Yes]
 - Local tumor spread [No, Yes]
 - Other [No, Yes]
 - Description
- Primary treatment
 - Cervical/uterine procedure [Conization (any technique including LEEP, LLETZ etc.), Radical hysterectomy (including parametrectomy), Radical trachelectomy (including parametrectomy), Simple hysterectomy, Simple trachelectomy (cervix amputation without parametrectomy)]
 - Parametrectomy (applied for radical hysterectomy and radical trachelectomy)
 - Type [Nerve sparing, Not classified, Other, Simple hysterectomy, TMMR, Type A, Type B, Type C1, Type C2, Type D, Type II, Type III]
 - Description
 - Adnexal procedure
 - Type [Adnexal preservation, BSO, Previous BSO, Salpingectomy and ovarian preservation]
 - Extrapelvic transposition [No, Yes]
 - Surgical approach [Laparo-vaginal, Laparoscopic, Open (laparotomy), Robotic, Vaginal]
 - Lymph node staging
 - SLN biopsy
 - SLN biopsy was done [No, Yes]
 - Laterality [Bilat, Unilat]
 - Pelvic lymphadenectomy
 - Pelvic lymphadenectomy was performed [No, Yes]
 - Paraaortic lymphadenectomy
 - Paraaortic lymphadenectomy was performed [No, Yes]
 - Location
 - Inframesenterial (below arteria mesenterica inferior) [No, Yes]

- Supramesenterial (up to the renal vessels) [No, Yes]
- Final histological report
 - Cervix/Uterus
 - Size of the tumor
 - Largest tumor dimension (Sum of largest dimension of the specimen from therapeutic and diagnostic procedures)
 - LVSI [No, Yes]
 - Parametrial invasion
 - Parametrial invasion detected [No, Yes]
 - Laterality [Bilat, Unilat]
 - Free vaginal margins [No, Yes]
 - Final lymph node status
 - SLN [No, Yes]
 - No of SLN removed
 - No of SLN with metastases
 - SLN ultrastaging was performed [No, Yes]
 - Type of metastases (enter the largest type) [Isolated tumor cells, Macrometastases, Micrometastases]
 - Non-SLN pelvic LNs [No, Yes]
 - No of LN removed
 - No of LN with metastases
 - Type of metastases (enter the largest type) [Isolated tumor cells, Macrometastases, Micrometastases]
 - Size of the largest macrometastases
 - Paraaortic LNs (if PALD performed) [No, Yes]
 - No of LN removed
 - No of LN with metastases
 - Type of metastases (enter the largest type) [Isolated tumor cells, Macrometastases, Micrometastases]
- Surgical data
 - Operation time
 - Blood loss
 - Surgical complication
 - Bowel injury [No, Yes]
 - Ureteral injury [No, Yes]
 - Urinary bladder injury [No, Yes]
 - Other [No, Yes]
 - Description
 - Serious early postoperative adverse-events ≥ 2 according to CTCAE grading (until 30th postoperative day)
 - 1. adverse event [No, Yes]
 - Type [Blood, Gastrointestinal, Infections, Other, Renal, Respiratory, Skin, Surgical, Vascular]
 - Grade [2, 3, 4, 5]

- 2. adverse event [No, Yes]
 - Type [Blood, Gastrointestinal, Infections, Other, Renal, Respiratory, Skin, Surgical, Vascular]
 - Grade [2, 3, 4, 5]
- 3. adverse event [No, Yes]
 - Type [Blood, Gastrointestinal, Infections, Other, Renal, Respiratory, Skin, Surgical, Vascular]
 - Grade [2, 3, 4, 5]
- 4. adverse event [No, Yes]
 - Type [Blood, Gastrointestinal, Infections, Other, Renal, Respiratory, Skin, Surgical, Vascular]
 - Grade [2, 3, 4, 5]
- 5. adverse event [No, Yes]
 - Type [Blood, Gastrointestinal, Infections, Other, Renal, Respiratory, Skin, Surgical, Vascular]
 - Grade [2, 3, 4, 5]
- Type of primary treatment [Chemotherapy only, Other, Radiochemotherapy, Radiotherapy only]
- Description of treatment
- External beam radiotherapy [No, Yes]
 - Type [2D, 3D, IMRT]
 - Machine [Cobalt source, Linear accelerator]
 - Area treated [Extended to paraaortic LN, Pelvis only]
 - Duration
 - Total dose
 - Number of fractions
- Brachytherapy [No, Yes]
 - Type [High dose rate, Low dose rate, PDR]
 - Total dose
 - Number of fractions
- Concomitant chemotherapy
 - Regimen
 - Carboplatin [No, Yes]
 - Dose per cycle
 - No of cycles [1, 2, 3, 4, 5]
 - Cisplatin [No, Yes]
 - Dose per cycle
 - No of cycles [1, 2, 3, 4, 5]
 - Other [No, Yes]
 - Description
- Overall treatment (radiotherapy) time
- Reason why concomitant chemotherapy was not applied

- Impaired renal function [No, Yes]
- Local standard [No, Yes]
- Poor performance status [No, Yes]
- Other [No, Yes]
 - Description
- Regimen
 - Carboplatin [No, Yes]
 - Dose per cycle
 - No of cycles [1,2,3,4,5]
 - Cisplatin [No, Yes]
 - Dose per cycle
 - No of cycles [1,2,3,4,5]
 - Docetaxel [No, Yes]
 - Dose per cycle
 - No of cycles [1,2,3,4,5]
 - Paclitaxel [No, Yes]
 - Dose per cycle
 - No of cycles [1,2,3,4,5]
 - Topotecan [No, Yes]
 - Dose per cycle
 - No of cycles [1,2,3,4,5]
 - Other [No, Yes]
 - Description
- Reason why radiotherapy was not given
 - Impaired renal function [No, Yes]
 - Local standard [No, Yes]
 - Poor performance status [No, Yes]
 - Other [No, Yes]
 - Description
- Adjuvant treatment was given [No, Yes]
- Adjuvant treatment
 - Indication
 - LN involvement [No, Yes]
 - Parametrial involvement [No, Yes]
 - Sedlis criteria (high risk tumor based on the size, stromal invasion, LVSI) [No, Yes]
 - Other [No, Yes]
 - Type of adjuvant treatment [Chemotherapy only, Other, Radiochemotherapy, Radiotherapy only]
 - Description of adjuvant treatment
 - Brachytherapy [No, Yes]
 - Type [High dose rate, Low dose rate, PDR]
 - Total dose
 - Number of fractions
 - Date when adjuvant treatment was finished (month/year)
 - External beam radiotherapy [No, Yes]

- Type [2D,3D,IMRT]
- Machine [Cobalt source,Linear accelerator]
- Area treated [Extended to paraaortic LN,Pelvis only]
- Duration
- Total dose
- Number of fractions
- Concomitant chemotherapy
 - Regimen
 - Carboplatin [No,Yes]
 - Dose per cycle
 - No of cycles [1,2,3,4,5]
 - Cisplatin [No,Yes]
 - Dose per cycle
 - No of cycles [1,2,3,4,5]
 - Other [No,Yes]
 - Description
- Overall treatment (radiotherapy) time
- Reason why concomitant chemotherapy was not applied
 - Impaired renal function [No, Yes]
 - Local standard [No, Yes]
 - Poor performance status [No, Yes]
 - Other [No, Yes]
 - Description
- Regimen
 - Carboplatin [No, Yes]
 - Dose per cycle
 - No of cycles [1,2,3,4,5]
 - Docetaxel [No, Yes]
 - Dose per cycle
 - No of cycles [1,2,3,4,5]
 - Paclitaxel [No, Yes]
 - Dose per cycle
 - No of cycles [1,2,3,4,5]
 - Cisplatin [No, Yes]
 - Dose per cycle
 - No of cycles [1,2,3,4,5]
 - Topotecan [No, Yes]
 - Dose per cycle
 - No of cycles [1,2,3,4,5]
 - Other [No, Yes]
 - Description
- Reason why radiotherapy was not given
 - Impaired renal function [No, Yes]
 - Local standard [No, Yes]
 - Poor performance status [No, Yes]
 - Other [No, Yes]

- Description
- Date when treatment was finished (month/year)
- Method used for the response to definitive treatment assessment
 - CT [No, Yes]
 - MRI [No, Yes]
 - PET [No, Yes]
 - Physical examination [No, Yes]
 - US [No, Yes]
- Definitive treatment outcome [Complete response, Partial response, Progressive disease, Stable disease]
- Follow-up
 - Follow-up procedure
 - CT [No, Yes]
 - 1. year [No, Yes]
 - If clinically indicated [No, Yes]
 - Routinely [No, Yes]
 - Frequency every [12 month, 3 month, 6 month]
 - 2. year [No, Yes]
 - If clinically indicated [No, Yes]
 - Routinely [No, Yes]
 - Frequency every [12 month, 3 month, 6 month]
 - 3. year [No, Yes]
 - If clinically indicated [No, Yes]
 - Routinely [No, Yes]
 - Frequency every [12 month, 3 month, 6 month]
 - 4. year [No, Yes]
 - If clinically indicated [No, Yes]
 - Routinely [No, Yes]
 - Frequency every [12 month, 3 month, 6 month]
 - 5. year [No, Yes]
 - If clinically indicated [No, Yes]
 - Routinely [No, Yes]
 - Frequency every [12 month, 3 month, 6 month]
 - Expert ultrasound [No, Yes]
 - 1. year [No, Yes]
 - If clinically indicated [No, Yes]
 - Routinely [No, Yes]
 - Frequency every [12 month, 3 month, 6 month]
 - 2. year [No, Yes]
 - If clinically indicated [No, Yes]
 - Routinely [No, Yes]
 - Frequency every [12 month, 3 month, 6 month]
 - 3. year [No, Yes]
 - If clinically indicated [No, Yes]
 - Routinely [No, Yes]
 - Frequency every [12 month, 3 month, 6 month]

- 4. year [No, Yes]
 - If clinically indicated [No, Yes]
 - Routinely [No, Yes]
 - Frequency every [12 month, 3 month, 6 month]
- 5. year [No, Yes]
 - If clinically indicated [No, Yes]
 - Routinely [No, Yes]
 - Frequency every [12 month, 3 month, 6 month]
- Gynecological examination [No, Yes]
 - 1. year [No, Yes]
 - If clinically indicated [No, Yes]
 - Routinely [No, Yes]
 - Frequency every [12 month, 3 month, 6 month]
 - 2. year [No, Yes]
 - If clinically indicated [No, Yes]
 - Routinely [No, Yes]
 - Frequency every [12 month, 3 month, 6 month]
 - 3. year [No, Yes]
 - If clinically indicated [No, Yes]
 - Routinely [No, Yes]
 - Frequency every [12 month, 3 month, 6 month]
 - 4. year [No, Yes]
 - If clinically indicated [No, Yes]
 - Routinely [No, Yes]
 - Frequency every [12 month, 3 month, 6 month]
 - 5. year [No, Yes]
 - If clinically indicated [No, Yes]
 - Routinely [No, Yes]
 - Frequency every [12 month, 3 month, 6 month]
- HPV test [No, Yes]
 - 1. year [No, Yes]
 - If clinically indicated [No, Yes]
 - Routinely [No, Yes]
 - Frequency every [12 month, 3 month, 6 month]
 - 2. year [No, Yes]
 - If clinically indicated [No, Yes]
 - Routinely [No, Yes]
 - Frequency every [12 month, 3 month, 6 month]
 - 3. year [No, Yes]
 - If clinically indicated [No, Yes]
 - Routinely [No, Yes]
 - Frequency every [12 month, 3 month, 6 month]
 - 4. year [No, Yes]
 - If clinically indicated [No, Yes]
 - Routinely [No, Yes]
 - Frequency every [12 month, 3 month, 6 month]

- 5. year [No, Yes]
 - If clinically indicated [No, Yes]
 - Routinely [No, Yes]
 - Frequency every [12 month, 3 month, 6 month]
- MRI [No, Yes]
 - 1. year [No, Yes]
 - If clinically indicated [No, Yes]
 - Routinely [No, Yes]
 - Frequency every [12 month, 3 month, 6 month]
 - 2. year [No, Yes]
 - If clinically indicated [No, Yes]
 - Routinely [No, Yes]
 - Frequency every [12 month, 3 month, 6 month]
 - 3. year [No, Yes]
 - If clinically indicated [No, Yes]
 - Routinely [No, Yes]
 - Frequency every [12 month, 3 month, 6 month]
 - 4. year [No, Yes]
 - If clinically indicated [No, Yes]
 - Routinely [No, Yes]
 - Frequency every [12 month, 3 month, 6 month]
 - 5. year [No, Yes]
 - If clinically indicated [No, Yes]
 - Routinely [No, Yes]
 - Frequency every [12 month, 3 month, 6 month]
- PET-CT [No, Yes]
 - 1. year [No, Yes]
 - If clinically indicated [No, Yes]
 - Routinely [No, Yes]
 - Frequency every [12 month, 3 month, 6 month]
 - 2. year [No, Yes]
 - If clinically indicated [No, Yes]
 - Routinely [No, Yes]
 - Frequency every [12 month, 3 month, 6 month]
 - 3. year [No, Yes]
 - If clinically indicated [No, Yes]
 - Routinely [No, Yes]
 - Frequency every [12 month, 3 month, 6 month]
 - 4. year [No, Yes]
 - If clinically indicated [No, Yes]
 - Routinely [No, Yes]
 - Frequency every [12 month, 3 month, 6 month]
 - 5. year [No, Yes]
 - If clinically indicated [No, Yes]
 - Routinely [No, Yes]
 - Frequency every [12 month, 3 month, 6 month]

- Pap smear [No, Yes]
 - 1. year [No, Yes]
 - If clinically indicated [No, Yes]
 - Routinely [No, Yes]
 - Frequency every [12 month, 3 month, 6 month]
 - 2. year [No, Yes]
 - If clinically indicated [No, Yes]
 - Routinely [No, Yes]
 - Frequency every [12 month, 3 month, 6 month]
 - 3. year [No, Yes]
 - If clinically indicated [No, Yes]
 - Routinely [No, Yes]
 - Frequency every [12 month, 3 month, 6 month]
 - 4. year [No, Yes]
 - If clinically indicated [No, Yes]
 - Routinely [No, Yes]
 - Frequency every [12 month, 3 month, 6 month]
 - 5. year [No, Yes]
 - If clinically indicated [No, Yes]
 - Routinely [No, Yes]
 - Frequency every [12 month, 3 month, 6 month]
- Physical examination [No, Yes]
 - 1. year [No, Yes]
 - If clinically indicated [No, Yes]
 - Routinely [No, Yes]
 - Frequency every [12 month, 3 month, 6 month]
 - 2. year [No, Yes]
 - If clinically indicated [No, Yes]
 - Routinely [No, Yes]
 - Frequency every [12 month, 3 month, 6 month]
 - 3. year [No, Yes]
 - If clinically indicated [No, Yes]
 - Routinely [No, Yes]
 - Frequency every [12 month, 3 month, 6 month]
 - 4. year [No, Yes]
 - If clinically indicated [No, Yes]
 - Routinely [No, Yes]
 - Frequency every [12 month, 3 month, 6 month]
 - 5. year [No, Yes]
 - If clinically indicated [No, Yes]
 - Routinely [No, Yes]
 - Frequency every [12 month, 3 month, 6 month]
- Other regular tests/procedures [No, Yes]
 - Description
- Late serious adverse events ≥ 2 CTCAE grading (associated with the treatment, since the 31st postoperative day)

- 1. adverse event [No, Yes]
 - Type
[Blood, Gastrointestinal, Infections, Other, Renal, Respiratory, Skin, Surgical, Vascular]
 - Grade [2,3,4,5]
 - Date of 1st diagnosis (month/year)
- 2. adverse event [No, Yes]
 - Type
[Blood, Gastrointestinal, Infections, Other, Renal, Respiratory, Skin, Surgical, Vascular]
 - Grade [2,3,4,5]
 - Date of 1st diagnosis (month/year)
- 3. adverse event [No, Yes]
 - Type
[Blood, Gastrointestinal, Infections, Other, Renal, Respiratory, Skin, Surgical, Vascular]
 - Grade [2,3,4,5]
 - Date of 1st diagnosis (month/year)
- 4. adverse event [No, Yes]
 - Type
[Blood, Gastrointestinal, Infections, Other, Renal, Respiratory, Skin, Surgical, Vascular]
 - Grade [2,3,4,5]
 - Date of 1st diagnosis (month/year)
- 5. adverse event [No, Yes]
 - Type
[Blood, Gastrointestinal, Infections, Other, Renal, Respiratory, Skin, Surgical, Vascular]
 - Grade [2,3,4,5]
 - Date of 1st diagnosis (month/year)
- Date of last FU visit (month/year)
- Status at the time of the last FU visit [Alive with disease (AWD), Death, No evidence of disease (NED)]
- Date of death (month/year)
- Cause of death [Disease progression, Intercurrent disease, Other, Other cancer, Treatment complications]
- Recurrence
 - Cancer recurred [No, Yes]
 - Recurrence date (month/year)
 - Site
 - Pelvis [No, Yes]
 - Central [No, Yes]
 - Lateral [No, Yes]
 - Preserved uterus involved [No, Yes]
 - Abdomen [No, Yes]
 - Thorax [No, Yes]

- Other distant [No, Yes]
- Symptoms at the time of diagnosis [No, Yes]
- Recurrence was treated [No, Yes]
- Treatment of recurrence
 - Chemotherapy [No, Yes]
 - Experimental [No, Yes]
 - Immunotherapy [No, Yes]
 - Radiochemotherapy [No, Yes]
 - Radiotherapy [No, Yes]
 - Secondary surgery [No, Yes]
 - Targeted [No, Yes]
 - Other [No, Yes]
 - Description
- Treatment response
 - Response of the 1st recurrence [Complete remission, Partial remission/stable disease, Progression]
 - 2nd recurrence [No, Yes]
 - Third line treatment
 - Chemotherapy [No, Yes]
 - Experimental [No, Yes]
 - Immunotherapy [No, Yes]
 - Radiochemotherapy [No, Yes]
 - Radiotherapy [No, Yes]
 - Surgery [No, Yes]
 - Targeted [No, Yes]
 - Other [No, Yes]
 - Description
 - None [No, Yes]
 - Third line treatment
 - Chemotherapy [No, Yes]
 - Experimental [No, Yes]
 - Immunotherapy [No, Yes]
 - Radiochemotherapy [No, Yes]
 - Radiotherapy [No, Yes]
 - Surgery [No, Yes]
 - Targeted [No, Yes]
 - Other [No, Yes]
 - Description
 - None [No, Yes]