

# EMBRACE-II Variable Description

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**Author:** Stefan Ecker, PhD

## Quick Reference: All Added Variables EMBRACE-II

This document describes the custom variables added to the EMBRACE-II dataset during data processing. Variables are organized by functional categories.

### 1. Patient and Study Information

Variable	Details
age	<ul style="list-style-type: none"><li>Patient age at diagnosis</li><li><b>Calculation:</b> histology_assessment_date – year_of_birth</li><li><b>Implementation:</b> add_age()</li><li><b>Unit:</b> Years</li></ul>
included_in_study	<ul style="list-style-type: none"><li>Indicates whether a patient is included in the final study cohort</li><li><b>Calculation:</b> Based on the study's inclusion/exclusion criteria documented in the official study flowchart</li><li><b>Implementation:</b> load_embrace_ii()</li><li><b>Values:</b> TRUE = included in study, FALSE = excluded from study</li></ul>
withdrew_consent	<ul style="list-style-type: none"><li>Indicates if a patient withdrew consent from the study</li><li><b>Calculation:</b> Based on followup_*m columns</li><li><b>Implementation:</b> add_lost_to_fu()</li><li><b>Values:</b> TRUE = consent withdrawn, FALSE = consent maintained</li></ul>
is_lost_to_fu	<ul style="list-style-type: none"><li>Indicates if a patient was lost to follow-up during the study</li><li><b>Calculation:</b> Based on followup_*m columns</li><li><b>Implementation:</b> add_lost_to_fu()</li><li><b>Values:</b> TRUE = patient lost to followup, FALSE = patient not lost to followup</li></ul>

## 2. Diagnostic Measurements

Variable	Details
max_tumor_dimension_sta_d	<ul style="list-style-type: none"> <li>• Maximum tumor dimension at diagnosis</li> <li>• <b>Calculation:</b> Overall maximum value across both MRI and gynecological exam measurements (<code>mri_tumor_*_sta_d</code> and <code>gyn_tumor_*_sta_d</code>)</li> <li>• <b>Implementation:</b> <code>add_max_tumor_dimension()</code></li> <li>• <b>Unit:</b> Millimeters</li> </ul>
gyn_max_parametrium_sta_d	<ul style="list-style-type: none"> <li>• Maximum parametrial involvement from gynecological examination at diagnosis</li> <li>• <b>Calculation:</b> Maximum value between left and right parametrial involvement (<code>gyn_left_parametrium_sta_d</code> and <code>gyn_right_parametrium_sta_d</code>)</li> <li>• <b>Implementation:</b> <code>add_parametrial_involvement()</code></li> <li>• <b>Values:</b> 0 = Not involved, 1 = Proximal, 2 = Distal, 3 = To pelvic wall</li> </ul>
gyn_max_tumor_dimension_sta_d	<ul style="list-style-type: none"> <li>• Maximum tumor dimension from gynecological examination</li> <li>• <b>Calculation:</b> Maximum value across all gynecological tumor measurements (width, height, thickness)</li> <li>• <b>Implementation:</b> <code>add_max_tumor_dimension()</code></li> <li>• <b>Unit:</b> Millimeters</li> </ul>
mri_max_parametrium_sta_d	<ul style="list-style-type: none"> <li>• Maximum parametrial involvement from MRI at diagnosis</li> <li>• <b>Calculation:</b> Maximum value between left and right parametrial involvement (<code>mri_left_parametrium_sta_d</code> and <code>mri_right_parametrium_sta_d</code>)</li> <li>• <b>Implementation:</b> <code>add_parametrial_involvement()</code></li> <li>• <b>Values:</b> 0 = Not involved, 1 = Proximal, 2 = Distal, 3 = To pelvic wall</li> </ul>
mri_max_tumor_dimension_sta_d	<ul style="list-style-type: none"> <li>• Maximum tumor dimension from MRI</li> <li>• <b>Calculation:</b> Maximum value across all MRI tumor measurements (width, height, thickness)</li> <li>• <b>Implementation:</b> <code>add_max_tumor_dimension()</code></li> <li>• <b>Unit:</b> Millimeters</li> </ul>

### 3. Brachytherapy Treatment and Technique

Variable	Details
icis	<ul style="list-style-type: none"> <li>Intracavitary/Interstitial classification</li> <li><b>Calculation:</b> Based on <code>fraction_*_technique_tdvh</code> columns</li> <li><b>Implementation:</b> <code>add_icis()</code></li> <li><b>Values:</b> Binary (1 = ICIS, 0 = IC)</li> <li><b>Note:</b> Derived from technique values across fractions</li> </ul>
icis_parallel_oblique	<ul style="list-style-type: none"> <li>Detailed ICIS needle classification</li> <li><b>Calculation:</b> Based on <code>fraction_*_technique_tdvh</code> columns</li> <li><b>Implementation:</b> <code>add_parallel_oblique_needles()</code></li> <li><b>Values:</b> “no needles”, “parallel needles”, “oblique needles”, “other”</li> </ul>
average_nr_active_needles	<ul style="list-style-type: none"> <li>Average number of active needles</li> <li><b>Calculation:</b> Mean of <code>fraction_*_active_needles</code> columns</li> <li><b>Implementation:</b> <code>add_average_active_needles()</code></li> <li><b>Unit:</b> Number of needles</li> </ul>
time_to_bt	<ul style="list-style-type: none"> <li>Time from EBRT start to first BT fraction</li> <li><b>Calculation:</b> <code>fraction01date_tdvh - ebrt_start_date_tdvh</code></li> <li><b>Implementation:</b> <code>add_time_to_bt()</code></li> <li><b>Unit:</b> Days</li> </ul>
time_to_bt_percent	<ul style="list-style-type: none"> <li>Relative timing of brachytherapy</li> <li><b>Calculation:</b> <code>time_to_bt / ott_ebrt</code></li> <li><b>Implementation:</b> <code>add_time_to_bt()</code></li> <li><b>Unit:</b> Proportion</li> </ul>
ott_ebrt	<ul style="list-style-type: none"> <li>Overall treatment time of EBRT</li> <li><b>Calculation:</b> <code>ebrt_end_date_tdvh - ebrt_start_date_tdvh</code></li> <li><b>Implementation:</b> <code>add_time_to_bt()</code></li> <li><b>Unit:</b> Days</li> </ul>
ott	<ul style="list-style-type: none"> <li>Overall Treatment Time from start of EBRT to last treatment</li> <li><b>Calculation:</b> Time interval between <code>ebrt_start_date_tdvh</code> and <code>last_treatment_date</code> (which is the latest of EBRT end date and all fraction dates)</li> <li><b>Implementation:</b> <code>emii_add_ott()</code></li> <li><b>Unit:</b> Days</li> </ul>
last_treatment_date	<ul style="list-style-type: none"> <li>Date of the last treatment received</li> <li><b>Calculation:</b> Maximum date among EBRT end date (<code>ebrt_end_date_tdvh</code>) and all brachytherapy fraction dates (<code>fraction*date_tdvh</code>)</li> <li><b>Implementation:</b> <code>emii_add_ott()</code></li> <li><b>Unit:</b> Date</li> </ul>

Variable	Details
<code>fraction01hrctv_volume_bins</code>	<ul style="list-style-type: none"> <li>• CTV-HR volume categories</li> <li>• <b>Calculation:</b> Based on <code>fraction01hrctv_volume_tdvh</code></li> <li>• <b>Implementation:</b> <code>add_hrctv_volume_bins()</code></li> <li>• <b>Values:</b> 0: &lt; 30 cm<sup>3</sup>, 1: 30-45 cm<sup>3</sup>, 2: &gt; 45 cm<sup>3</sup>, NA: missing</li> </ul>
<code>trak_total_sum</code>	<ul style="list-style-type: none"> <li>• Total Reference Air Kerma (TRAK) summed across all brachytherapy fractions</li> <li>• <b>Calculation:</b> Sum of all <code>fraction*trak_tdvh</code> values</li> <li>• <b>Implementation:</b> <code>emii_add_trak_absolute()</code></li> <li>• <b>Unit:</b> cGy at 1m</li> </ul>
<code>trak_needles_sum</code>	<ul style="list-style-type: none"> <li>• Total TRAK contribution from needles across all brachytherapy fractions</li> <li>• <b>Calculation:</b> Sum of <code>fraction*_needles_abs</code> values, which are derived from percentage contributions (<code>trak * trak_needles_pct / 100</code>)</li> <li>• <b>Implementation:</b> <code>emii_add_trak_absolute()</code></li> <li>• <b>Unit:</b> cGy at 1m</li> </ul>
<code>trak_vaginal_applicator_sum</code>	<ul style="list-style-type: none"> <li>• Total TRAK contribution from vaginal applicator across all fractions</li> <li>• <b>Calculation:</b> Sum of <code>fraction*_vaginal_applicator_abs</code> values, which are derived from percentage contributions (<code>trak * trak_vaginal_applicator_pct / 100</code>)</li> <li>• <b>Implementation:</b> <code>emii_add_trak_absolute()</code></li> <li>• <b>Unit:</b> cGy at 1m</li> </ul>
<code>trak_tandem_applicator_sum</code>	<ul style="list-style-type: none"> <li>• Total TRAK contribution from tandem applicator across all fractions</li> <li>• <b>Calculation:</b> Sum of <code>fraction*_tandem_applicator_abs</code> values, which are derived from percentage contributions (<code>trak * trak_tandem_applicator_pct / 100</code>)</li> <li>• <b>Implementation:</b> <code>emii_add_trak_absolute()</code></li> <li>• <b>Unit:</b> cGy at 1m</li> </ul>
<code>imp1gyn_max_parametrium_sta_b</code>	<ul style="list-style-type: none"> <li>• Maximum parametrial involvement from gynecological examination at first implant</li> <li>• <b>Calculation:</b> Maximum value between left and right parametrial involvement (<code>imp1gyn_left_parametrium_sta_b</code> and <code>imp1gyn_right_parametrium_sta_b</code>)</li> <li>• <b>Implementation:</b> <code>add_parametrial_involvement()</code></li> <li>• <b>Values:</b> 0 = Not involved, 1 = Proximal, 2 = Distal, 3 = To pelvic wall</li> </ul>

Variable	Details
imp1image_max_parametrium_sta_b	<ul style="list-style-type: none"><li>• Maximum parametrial involvement from imaging at first implant</li><li>• <b>Calculation:</b> Maximum value between left and right parametrial involvement (imp1image_left_parametrium_sta_b and imp1imaging_right_parametrium_sta_b)</li><li>• <b>Implementation:</b> add_parametrial_involvement()</li><li>• <b>Values:</b> 0 = Not involved, 1 = Proximal, 2 = Distal, 3 = To pelvic wall</li></ul>

#### 4. External Beam Radiotherapy (EBRT)

Variable	Details
<code>ebrt_elective_target_algorithm</code>	<ul style="list-style-type: none"> <li>Algorithm-recommended treatment target volume for elective nodal irradiation</li> <li><b>Calculation:</b> Determined based on EMBRACE-II protocol</li> <li><b>Implementation:</b> <code>emii_add_elective_targets()</code></li> <li><b>Values:</b> ‘Small Pelvis’, ‘Large Pelvis’, ‘Large Pelvis + Para-aortic’, ‘Large Pelvis + Inguinal’, ‘Large Pelvis + Para-aortic + Inguinal’</li> </ul>
<code>elective_high_risk</code>	<ul style="list-style-type: none"> <li>Indicates if high-risk criteria for nodal treatment are met</li> <li><b>Calculation:</b> TRUE if pathological nodes present AND <math>\geq 3</math> nodes found, OR if any common iliac or para-aortic nodes present</li> <li><b>Implementation:</b> <code>emii_add_elective_targets()</code></li> <li><b>Values:</b> TRUE/FALSE</li> </ul>
<code>elective_inguinal</code>	<ul style="list-style-type: none"> <li>Indicates if inguinal node irradiation criteria are met</li> <li><b>Calculation:</b> TRUE if maximum vaginal involvement = 3 (distal third) OR any inguinal nodes present in right or left groin</li> <li><b>Implementation:</b> <code>emii_add_elective_targets()</code></li> <li><b>Values:</b> TRUE/FALSE</li> </ul>
<code>elective_low_risk</code>	<ul style="list-style-type: none"> <li>Indicates if low-risk criteria for nodal treatment are met</li> <li><b>Calculation:</b> TRUE if NO pathological nodes, tumor <math>\leq 40\text{mm}</math>, TNM stage 1/2/3/5, squamous cell histology, and no corpus uteri involvement on MRI</li> <li><b>Implementation:</b> <code>emii_add_elective_targets()</code></li> <li><b>Values:</b> TRUE/FALSE</li> </ul>
<code>any_node_ci_pa</code>	<ul style="list-style-type: none"> <li>Indicates presence of any common iliac or para-aortic lymph nodes at diagnosis</li> <li><b>Calculation:</b> TRUE if any node has anatomical position of “R com iliac”, “L com iliac”, or “Para Aortic”</li> <li><b>Implementation:</b> <code>emii_add_elective_targets()</code></li> <li><b>Values:</b> TRUE/FALSE</li> </ul>

## 5. Lymph Nodes and Metastases

Variable	Details
nodal_classification	<ul style="list-style-type: none"> <li>Classification of nodal involvement status</li> <li><b>Calculation:</b> Based on pathological nodes present (<code>pathological_nodes_present</code>) and Para-Aortic lymph node involvement at diagnosis</li> <li><b>Implementation:</b> <code>emii_add_nodal_classification()</code></li> <li><b>Values:</b> ‘N0’ (no pathological nodes), ‘N1PAN’ (pathological nodes with Para-Aortic involvement), ‘N1pelvic’ (pathological nodes without Para-Aortic involvement)</li> </ul>
number_common_iliac_ln_stat_d	<ul style="list-style-type: none"> <li>Count of common iliac lymph nodes at diag.</li> <li><b>Calculation:</b> Sum of left and right common iliac lymph nodes from staging data</li> <li><b>Implementation:</b> <code>emii_add_number_common_iliac_ln_stat_d()</code></li> <li><b>Unit:</b> Count</li> </ul>
number_paraaortic_ln_stat_d	<ul style="list-style-type: none"> <li>Count of para-aortic lymph nodes at diag.</li> <li><b>Calculation:</b> Count of lymph nodes with “Para Aortic” anatomical position from staging data</li> <li><b>Implementation:</b> <code>add_number_paraaortic_ln_stat_d()</code></li> <li><b>Unit:</b> Count</li> </ul>
has_*_followup	<ul style="list-style-type: none"> <li>Indicates lymph node involvement during follow-up by specific anatomical location</li> <li><b>Calculation:</b> Checks if any lymph node documented during follow-up has this specific anatomical position</li> <li><b>Implementation:</b> <code>emii_add_recurrent_nodes()</code></li> <li><b>Example variables:</b> <code>has_L.ext.iliac_followup</code>, <code>has_Para.Aortic_followup</code>, etc.</li> <li><b>Values:</b> TRUE/FALSE</li> </ul>
has_*_diagnosis	<ul style="list-style-type: none"> <li>Indicates lymph node involvement at diagnosis by specific anatomical location</li> <li><b>Calculation:</b> Checks if any lymph node documented at diagnosis has this specific anatomical position</li> <li><b>Implementation:</b> <code>emii_add_diagnostic_nodes()</code></li> <li><b>Example variables:</b> <code>has_L.ext.iliac_diagnosis</code>, <code>has_Para.Aortic_diagnosis</code>, etc.</li> <li><b>Values:</b> TRUE/FALSE</li> </ul>
has_*_metastases	<ul style="list-style-type: none"> <li>Indicates presence of specific metastatic disease sites</li> <li><b>Calculation:</b> Checks if any follow-up visit reports metastasis at this site</li> <li><b>Implementation:</b> <code>add_metastases()</code></li> <li><b>Example variables:</b> <code>has_liver_metastases</code>, <code>has_bone_metastases</code>, <code>has_brain_metastases</code>, <code>has_lung_metastases</code>, <code>has_other_metastases</code></li> <li><b>Values:</b> TRUE/FALSE</li> </ul>

Variable	Details
<code>has_*_nodes</code>	<ul style="list-style-type: none"> <li>• Indicates presence of distant nodal metastases</li> <li>• <b>Calculation:</b> Checks if any follow-up visit reports nodes at these sites</li> <li>• <b>Implementation:</b> <code>add_metastases()</code></li> <li>• <b>Example variables:</b> <code>has_paraaortic_nodes_above_12</code>, <code>has_supraclavicular_nodes</code>, <code>has_mediastinal_nodes</code></li> <li>• <b>Values:</b> TRUE/FALSE</li> </ul>
<code>has_abdominal_carcinomatosis</code>	<ul style="list-style-type: none"> <li>• Indicates presence of abdominal carcinomatosis</li> <li>• <b>Calculation:</b> Checks if any follow-up visit reports abdominal carcinomatosis</li> <li>• <b>Implementation:</b> <code>add_metastases()</code></li> <li>• <b>Values:</b> TRUE/FALSE</li> </ul>

## 6. Event Endpoints

Variable	Endpoint	Details
<code>event_localfailure</code>	Local Control	<ul style="list-style-type: none"> <li><b>Calculation:</b> Triggered when any followup <code>disease_local_status_*</code> column has a value of 2, indicating recurrence/progression</li> <li><b>Implementation:</b> <code>add_local_failure_event()</code></li> <li><b>Values:</b> 1 = failure (event occurred), 0 = no failure (no event)</li> </ul>
<code>event_nodalfailure</code>	Nodal Control (lower PAO)	<ul style="list-style-type: none"> <li><b>Calculation:</b> Triggered when any followup <code>disease_nodal_status_*</code> column has a value of 2, indicating nodal recurrence or progression</li> <li><b>Implementation:</b> <code>add_nodal_failure_event()</code></li> <li><b>Values:</b> 1 = failure (event occurred), 0 = no failure (no event)</li> </ul>
<code>event_nodalcontrol_incl_pao</code>	Nodal control (incl. all PAO)	<ul style="list-style-type: none"> <li><b>Calculation:</b> Triggered when either nodal failure (<code>event_nodalfailure</code>) OR para-aortic nodal failure (<code>event_paraaortic_nodal</code>) occurs</li> <li><b>Implementation:</b> <code>emii_add_nodalcontrol_incl_pao()</code></li> <li><b>Values:</b> 1 = failure (event occurred), 0 = no failure (no event)</li> </ul>
<code>event_systemicfailure</code>	Systemic Control (incl. upper PAO)	<ul style="list-style-type: none"> <li><b>Calculation:</b> Triggered when any followup <code>disease_systemic_status_*</code> column has a value of 2, indicating systemic recurrence or progression</li> <li><b>Implementation:</b> <code>add_systemic_failure_event()</code></li> <li><b>Values:</b> 1 = failure (event occurred), 0 = no failure (no event)</li> </ul>
<code>event_systemic_excl_pao</code>	Systemic control (excl. PAO)	<ul style="list-style-type: none"> <li><b>Calculation:</b> All systemic failures   (<code>event_systemicfailure</code>) MINUS cases where   para-aortic nodes above L2 are the ONLY   systemic failure. Cases with para-aortic nodes above L2 plus any other systemic   metastasis remain included</li> <li><b>Implementation:</b>   <code>emii_add_systemic_excl_pao()</code>  </li> <li><b>Values:</b> 1 = failure (event occurred),   0 = no failure (no event)  </li> </ul>

Variable	Endpoint	Details
event_vitalstatus	Overall Survival	<ul style="list-style-type: none"> <li><b>Calculation:</b> Uses the value from <code>vital_status</code> when available; otherwise sets to 0 (alive) if a disease assessment date exists (<code>latest_assessment_date_disease</code>)</li> <li><b>Implementation:</b> <code>add_vitalstatus_event()</code></li> <li><b>Values:</b> 1 = death (event occurred), 0 = alive (no event)</li> </ul>
event_pelvic_nodal	Pelvic Nodal control	<ul style="list-style-type: none"> <li><b>Calculation:</b> Triggered when nodal failure (<code>event_nodalfailure</code>) occurs AND at least one node is positive in any pelvic location: external iliac, internal iliac, common iliac, or parametrial/paracervical regions (left or right), Other</li> <li><b>Implementation:</b> <code>emii_add_pelvic_nodal_event()</code></li> <li><b>Values:</b> 1 = failure (event occurred), 0 = no failure (no event)</li> </ul>
event_pelvic	Pelvic control (local + nodal)	<ul style="list-style-type: none"> <li><b>Calculation:</b> Triggered when either local failure (<code>event_localfailure</code>) OR pelvic nodal failure (<code>event_pelvic_nodal</code>) occurs</li> <li><b>Implementation:</b> <code>emii_add_pelvic_event()</code></li> <li><b>Values:</b> 1 = failure (event occurred), 0 = no failure (no event)</li> </ul>
event_paraaortic_nodal	Para-aortic nodal control	<ul style="list-style-type: none"> <li><b>Calculation:</b> Triggered when either para-aortic nodes above L2 (<code>has_paraaortic_nodes_above_l2</code>) OR para-aortic nodes below L2 (<code>has_Para.Aortic_followup</code>) is detected</li> <li><b>Implementation:</b> <code>emii_add_paraaortic_nodal()</code></li> <li><b>Values:</b> 1 = failure (event occurred), 0 = no failure (no event)</li> </ul>
event_locoregional	Locoregional (Pelvic/PAO)	<ul style="list-style-type: none"> <li><b>Calculation:</b> Triggered when either local failure (<code>event_localfailure</code>) OR nodal control including para-aortic (<code>event_nodalcontrol_incl_pao</code>) occurs</li> <li><b>Implementation:</b> <code>add_locoregional_event()</code></li> <li><b>Values:</b> 1 = failure (event occurred), 0 = no failure (no event)</li> </ul>

Variable	Endpoint	Details
event_locoregional_alone	Locoregional alone (no metastases)	<ul style="list-style-type: none"> <li><b>Calculation:</b> Triggered when a locoregional failure occurs (<code>event_locoregional=1</code>) WITHOUT any concurrent distant metastases (<code>event_systemic_excl_pao=0</code>)</li> <li><b>Implementation:</b> <code>add_locoregional_event()</code></li> <li><b>Values:</b> 1 = isolated locoregional recurrence, 0 = no recurrence or recurrence with distant metastases</li> </ul>
event_cancer_specific	Cancer-Specific Survival	<ul style="list-style-type: none"> <li><b>Calculation:</b> Triggered when death occurs (<code>event_vitalstatus=1</code>) AND the main cause of death is primary cancer (codes 1 or 3 in <code>vital_status_cause_of_death_vital_status</code>)</li> <li><b>Implementation:</b> <code>emii_add_cancer_specific()</code></li> <li><b>Values:</b> 1 = cancer death, 0 = alive or non-cancer death</li> </ul>
event_disease_control	Disease Control	<ul style="list-style-type: none"> <li><b>Calculation:</b> Triggered when any failure occurs at any site: local failure OR nodal failure OR systemic failure</li> <li><b>Implementation:</b> <code>emii_add_disease_control()</code></li> <li><b>Values:</b> 1 = any disease failure, 0 = disease controlled at all sites</li> </ul>
event_progression_free	Progression-Free Survival	<ul style="list-style-type: none"> <li><b>Calculation:</b> Triggered when any disease event (<code>event_disease_control=1</code>) OR death occurs (<code>event_vitalstatus=1</code>)</li> <li><b>Implementation:</b> <code>emii_add_progression_free_survival()</code></li> <li><b>Values:</b> 1 = progression or death, 0 = alive without progression</li> </ul>
event_distant_alone	Distant Metastases Alone	<ul style="list-style-type: none"> <li><b>Calculation:</b> Triggered when systemic failure excluding para-aortic nodes (<code>event_systemic_excl_pao=1</code>) occurs AND   no locoregional failure (<code>event_locoregional=0</code>)  </li> <li><b>Implementation:</b> <code>emii_add_distant_alone()</code></li> <li><b>Values:</b> 1 = isolated distant metastases, 0 = no distant metastases or concurrent locoregional disease</li> </ul>

Variable	Endpoint	Details
<code>timetoevent_disease</code>	Time to Disease Event	<ul style="list-style-type: none"> <li><b>Calculation:</b> Time interval in months from histology assessment date to either the first disease event date or the latest assessment date if no event occurred</li> <li><b>Implementation:</b> <code>add_time_to_diseaseevent()</code></li> <li><b>Values:</b> Number of months</li> </ul>
<code>timetoevent_vitalstatus</code>	Time to Last Vital Status	<ul style="list-style-type: none"> <li><b>Calculation:</b> Time interval in months from histology assessment date to the latest vital status date</li> <li><b>Implementation:</b> <code>add_time_to_last_vitalstatus()</code></li> <li><b>Values:</b> Number of months</li> </ul>
<code>latest_vital_status_date</code>	Latest Vital Status Date	<ul style="list-style-type: none"> <li><b>Description:</b> The date of the latest available information on vital status, calculated from assessment dates, last info date, and date of death when available</li> <li><b>Implementation:</b> <code>add_time_to_last_vitalstatus()</code></li> <li><b>Values:</b> Date format</li> </ul>

## 7. Late Toxicity and Morbidity (only followup assessments)

Variable	Details
max_value_*	<ul style="list-style-type: none"> <li>• Maximum grade of a specific toxicity or morbidity across all follow-up time points</li> <li>• <b>Calculation:</b> Maximum CTCAE grade value observed for the specific toxicity across all follow-up assessments</li> <li>• <b>Implementation:</b> <code>get_max_side_effects()</code></li> <li>• <b>Values:</b> 0-5 (CTCAE grade scale)</li> <li>• <b>Example variables:</b> <ul style="list-style-type: none"> <li>– <code>max_value_bladder_cystitis</code></li> <li>– <code>max_value_vagina_stenosis</code></li> <li>– <code>max_value_fistula</code></li> <li>– <code>max_value_gastro_proctitis</code></li> </ul> </li> </ul>
max_timepoint_*	<ul style="list-style-type: none"> <li>• Follow-up timepoint at which the maximum grade of toxicity was observed</li> <li>• <b>Calculation:</b> Time point (e.g., “3m” for 3 months) at which maximum CTCAE grade was observed for each specific toxicity</li> <li>• <b>Implementation:</b> <code>get_max_side_effects()</code></li> <li>• <b>Values:</b> Time point indicators (e.g., “3m”, “6m”, “12m”, etc.)</li> <li>• <b>Example variables:</b> <ul style="list-style-type: none"> <li>– <code>max_timepoint_bladder_cystitis</code></li> <li>– <code>max_timepoint_vagina_stenosis</code></li> <li>– <code>max_timepoint_fistula</code></li> <li>– <code>max_timepoint_gastro_proctitis</code></li> </ul> </li> </ul>
overall_max_morbidity_grade	<ul style="list-style-type: none"> <li>• Overall maximum morbidity grade across all toxicity endpoints and all time points</li> <li>• <b>Calculation:</b> The maximum value across all <code>max_value_*</code> variables for each patient</li> <li>• <b>Implementation:</b> <code>emii_add_max_morbidity()</code></li> <li>• <b>Values:</b> 0-5 (CTCAE grade scale)</li> <li>• <b>Purpose:</b> Represents the highest toxicity experienced by a patient regardless of specific type or timepoint</li> </ul>

The toxicity and morbidity data include various organ systems and toxicity types:

1. **Bladder toxicity:** Cystitis, frequency, incontinence, urgency, stenosis/stricture, bleeding
2. **Gastrointestinal toxicity:** Abdominal pain/cramping, constipation, diarrhea, incontinence, proctitis, bleeding (at different sites), stenosis/stricture
3. **Vaginal toxicity:** Bleeding, discharge, dryness, mucositis, stenosis
4. **Fistula:** Grading and localization (bladder, rectum, vagina, etc.)
5. **Lymphatic complications:** Edema (limb, trunk/genital), lymphocele, thromboembolic events
6. **Muscle/skeletal toxicity:** Fibrosis, fracture, back/pelvic pain
7. **Other toxicities:** Fatigue, hot flashes, insomnia, and other patient-specific issues