



What's New MedDRA Version 25.0

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ACKNOWLEDGEMENTS

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Table of Contents

Table of Contents

1. DOCUMENT OVERVIEW	1
2. VERSION 25.0 CHANGE REQUESTS	2
2.1 TERMINOLOGY CHANGES	2
2.2 COMPLEX CHANGES	3
3. NEW DEVELOPMENTS IN VERSION 25.0	6
3.1 ADDITIONAL COVID-19 RELATED TERMS	6
3.2 STANDARDISED MedDRA QUERIES (SMQs)	6
3.3 PROACTIVITY REQUESTS	7
3.4 SNOMED CT – MedDRA MAPPING UPDATE	7
3.5 NEW MedDRA LANGUAGES UNDER DEVELOPMENT	9
4. SUMMARY OF CHANGES	10
4.1 SUMMARY OF IMPACT ON THE TERMINOLOGY	10
4.2 SUMMARY OF IMPACT ON RECORDS IN MedDRA FILES	11
4.3 MedDRA TERM COUNTS BY SOC	12
4.4 LLT CURRENCY STATUS CHANGES	15

LIST OF FIGURES

Figure 2-1 Net Changes of Terms per SOC	3
Figure 3-1 MapCR Change Request Tool	8
Figure 3-2 SNOMED CT – MedDRA Package and Supplemental Release	8

LIST OF TABLES

Table 2-1 New HLGTs	4
Table 2-2 Merged HLGTs	4
Table 2-3 New HLTs	4
Table 2-4 Merged HLTs	5
Table 3-1 COVID-19 Term Examples	6
Table 4-1 MedDRA Term File Counts	10
Table 4-2 Summary of Impact on LLTs	11
Table 4-3 Summary of Impact on SMQs	11
Table 4-4 Summary of Impact on Records in MedDRA Files	12
Table 4-5 MedDRA Term Counts by SOC	15
Table 4-6 LLT Currency Changes	16

1. DOCUMENT OVERVIEW

This *What's New* document contains information on the origins and types of changes made to the Medical Dictionary for Regulatory Activities (MedDRA) between Versions 24.1 and 25.0.

Section 2, Version 25.0 Change Requests, provides a summary of information on the number of change requests processed for the version.

Section 3, New Developments in Version 25.0, highlights changes in Version 25.0 related to change request submissions, new initiatives, information on Standardised MedDRA Queries (SMQs), and any recent updates to software tools provided by the MSSO.

Section 4, Summary of Changes, contains details on:

- The impact of this version on the terminology (in tables)
- Impact on the records in MedDRA files
- MedDRA term and SMQ counts
- LLTs in MedDRA that had a currency status change

All updated documentation associated with this version is located in the distribution file in Adobe® Portable Document Format (PDF) or, for some documents, Microsoft Excel. Please refer to the Readme.txt file for a complete listing.

The Maintenance and Support Services Organization (MSSO) Help Desk can be reached at mssohelp@meddra.org.

2. VERSION 25.0 CHANGE REQUESTS

2.1 TERMINOLOGY CHANGES

Changes to MedDRA result from user change requests, from proactivity requests submitted by MedDRA users, and from internal change requests. Internal change requests result from MSSO maintenance activities and from special working group activities in which the MSSO participates.

MedDRA Version 25.0 is a complex change version which means changes may be made at any level of the MedDRA hierarchy.

Change requests involve both MedDRA updates and SMQ changes. There was a total of 1,832 change requests processed for this version; 1,508 change requests were approved and implemented, and 299 change requests were not approved. There are, in addition, 25 change requests suspended for further consideration and resolution beyond this version.

Information on specific changes (e.g., new terms added, LLT promotions, PT demotions, PT primary SOC changes, etc.) which occurred since the prior MedDRA release can be obtained via the Version Report included with each respective MedDRA download. In addition, users may wish to use the [MedDRA Version Analysis Tool](#) (MVAT) which is an online tool that compares any two MedDRA versions— including non-consecutive versions – to identify changes. The output of MVAT is similar to the Version Report. MVAT is provided free of charge to MedDRA users as part of their subscription.

Between MedDRA releases, the MSSO makes available English [weekly supplemental update](#) files, which are approved changes that will be implemented for the next MedDRA version. Additionally, supplemental changes may be viewed in MedDRA Web-Based Browser via the “supplemental view” feature. Supplemental information may be helpful for users to identify changes that will be implemented in the next release.

An explanation of all changes considered (approved and not approved) for MedDRA Version 25.0 is accessible as a cumulative Detail Report included in the MedDRA English version download. Users may review all change requests considered by the MSSO from MedDRA Version 5.1 to the present in [WebCR](#).

Figure 2-1 (shown below) summarizes all changes made per System Organ Class (SOC) and may be useful to gauge the impact of changes to a specific area of MedDRA. The data are derived from the difference in counts of primary and secondary PT/LLTs, HLTs, and HLGs for Version 25.0 (shown in Table 4-5) and the corresponding information for Version 24.1. Additionally, LLT currency status changes are included in Figure 2-1.

Please see Section 4 for a summary of the changes in MedDRA Version 25.0.

Version 25.0 Change Requests

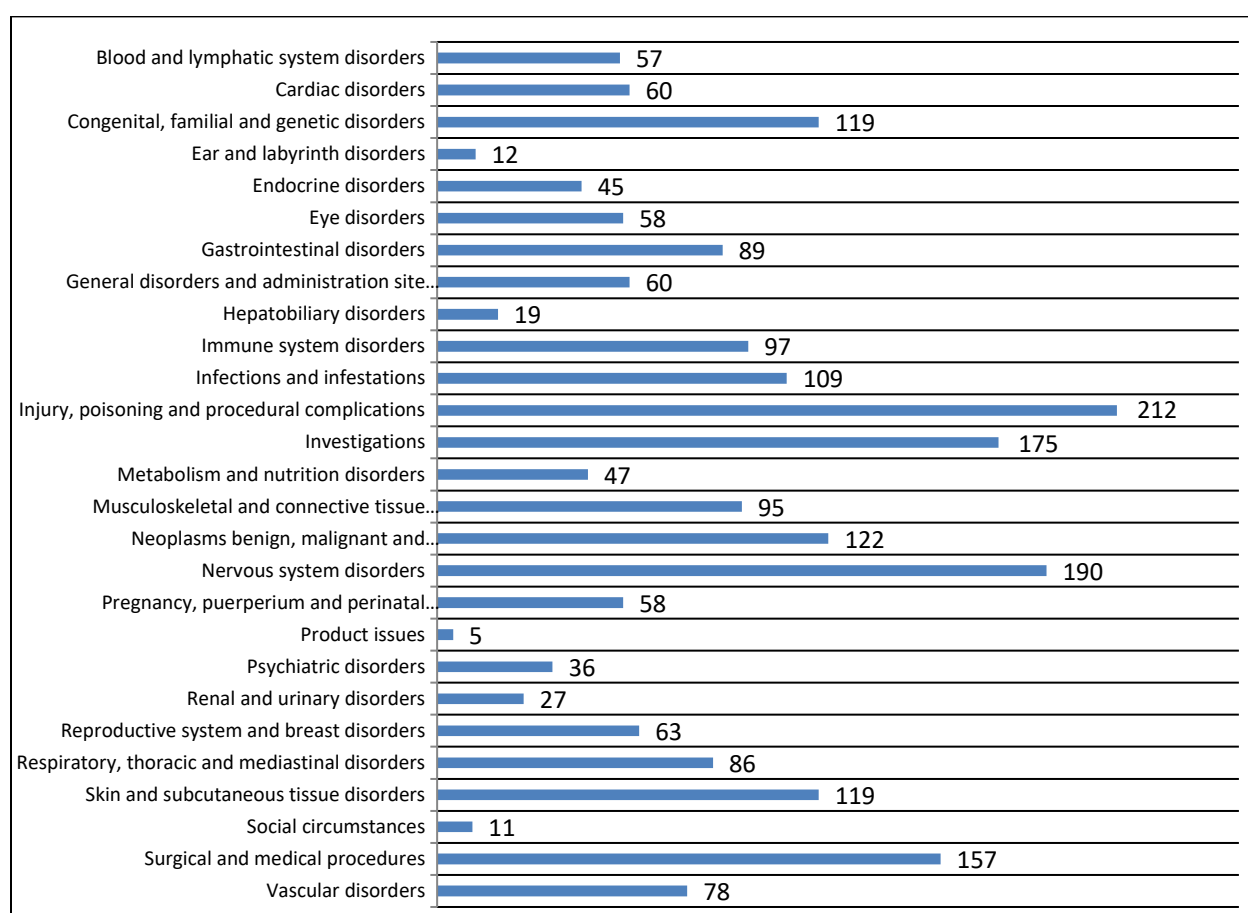


Figure 2-1 Net Changes of Terms per SOC

2.2 COMPLEX CHANGES

The proposals for complex changes considered during Version 25.0 included those submitted by users, special initiatives, and those internally identified by the MSSO during change request processing.

Complex change proposals were posted on the MedDRA website for feedback from the MedDRA user community from 29 July 2021 to 24 September 2021. Complex changes were followed by further internal review and consensus discussions which resulted in the final approved set of 8 complex changes.

The complex changes implemented in Version 25.0 are summarized below. Please see the “Related Documents” on the [Change Request section](#) of the MedDRA website for specific details.

At the SOC level: No changes were made to existing SOC.

Version 25.0 Change Requests

At the HLGT level: There were two High Level Group Terms (HLGTs) added and two HLGTs merged as a result of complex changes in Version 25.0. The changes are as follows:

New HLGT	To SOC
Cytogenetic investigations and genetic analyses	Investigations
Skin and subcutaneous tissue infections and infestations NEC	Skin and subcutaneous tissue disorders

Table 2-1 New HLGTs

Merged HLGTs

HLGT	To HLGT	SOC
Cytogenetic investigations	Cytogenetic investigations and genetic analyses	Investigations
Skin and subcutaneous tissue infections and infestations	Skin and subcutaneous tissue infections and infestations NEC	Skin and subcutaneous tissue disorders

Table 2-2 Merged HLGTs

At the HLT level: There were two High Level Terms (HLTs) added and two HLTs merged as a result of complex changes in Version 25.0. The changes are as follows:

New HLTs

New HLT	To SOC
Hepatobiliary function diagnostic procedures	Investigations
Skin histopathology and skin investigations NEC	Investigations

Table 2-3 New HLTs

Merged HLTs

HLT	To HLT	SOC
Liver function analyses	Hepatobiliary function diagnostic procedures	Investigations
Skin histopathology procedures	Skin histopathology and skin investigations NEC	Investigations

Table 2-4 Merged HLTs

3. NEW DEVELOPMENTS IN VERSION 25.0

3.1 ADDITIONAL COVID-19 RELATED TERMS

The MSSO continued to add COVID-19 related terms in MedDRA Version 25.0 based upon MedDRA user requests. A total of 54 new COVID-19 related LLTs/PTs were added including terms related to vaccines which may be applicable in the context of COVID-19. See the table below for several examples:

LLT	PT	HLT	Primary SOC
SARS-CoV-2 infection post vaccine	Breakthrough COVID-19	Coronavirus infections	Infections and infestations
SARS-CoV-2 Omicron variant infection	COVID-19	Coronavirus infections	Infections and infestations
Vaccine preparation error	Product preparation error	Product preparation errors and issues	Injury, poisoning and procedural complications
Vaccination hesitancy	Refusal of vaccination	Social issues NEC	Social circumstances
Heterologous prime-boost vaccination	Immunisation	Immunisations	Surgical and medical procedures

Table 3-1 COVID-19 Term Examples

3.2 STANDARDISED MedDRA QUERIES (SMQs)

One new SMQs has been added for MedDRA Version 25.0 - SMQ *Noninfectious myocarditis/pericarditis*. The focus of this SMQ is to identify cases of noninfectious myocarditis and/or pericarditis possibly related to exposure to drugs, vaccines, and biologics. It has relevance for cardiac adverse events following immunization (AEFIs) with mRNA COVID-19 vaccines. There are now 110 level 1 SMQs in production as of this version. In addition, there were 309 approved PT changes to existing SMQs. To view changes to existing SMQs, please review the MedDRA Version 25.0 Version Report.

Please see the MedDRA Version 25.0 SMQ Introductory Guide for detailed information on new SMQ *Noninfectious myocarditis/pericarditis*.

3.3 PROACTIVITY REQUESTS

The proactive maintenance process allows MedDRA users to propose general changes to MedDRA outside of the established change request process. These proactivity requests may address inconsistencies, make corrections, or suggest improvements. During the Version 25.0 change request processing period, there were no open or implemented proactivity requests. The MSSO publishes and updates a list of all proposals received and their status on the [Change Request](#) section of the MedDRA website.

The MSSO is interested in learning about any ideas that users may have about “proactive” improvements to MedDRA. Please email your ideas for “proactive” MedDRA improvements to the MSSO Help Desk. Be as specific as possible in describing your suggestion(s), and include a justification which explains why you think your proposal should be implemented.

3.4 SNOMED CT – MedDRA MAPPING UPDATE

On 30 April 2021, ICH and SNOMED International announced the first production release of important new maps between SNOMED CT and MedDRA. This collaborative agreement between SNOMED International and ICH has produced two independent maps (MedDRA to SNOMED CT and SNOMED CT to MedDRA) which are intended to facilitate the exchange of data between regulatory databases and healthcare databases/electronic health records.

Licensed users of either MedDRA or SNOMED CT can obtain the maps free of charge from either the MSSO or SNOMED International. Users can also contribute to the ongoing maintenance of the maps by submitting requests for new mappings or changes to existing mappings by using a mapping change request submission tool, MapCR, on the MedDRA website (<https://mapcr.meddra.org>).

New Developments in Version 25.0

The screenshot shows the 'Mapping Change Request Tool (MapCR)' interface. At the top, there's a navigation bar with links: 'Add Mapping' (highlighted), 'Revise Mapping', 'Search Change Request', and 'Logout'. Below this is the 'Add Mapping' section. It contains several input fields: 'Name *' (with placeholder 'Enter your name'), 'Email address *' (with placeholder 'Enter your email'), 'Confirm email address *' (with placeholder 'Enter your email again'), and 'Organization *' (with placeholder 'Enter your organization'). There's also a 'Source terminology *' dropdown menu. A large text area for 'Rationale for this request (Maximum 2000 characters) *' is present. At the bottom, there are two columns for 'Proposed target code' and 'Proposed target term', each with an 'Enter code' placeholder. A blue 'Add CR' button is to the right of these fields. At the very bottom left, there are 'Submit' and 'Cancel' buttons.

Figure 3-1 MapCR Change Request Tool

Since the first production release in April 2021, approximately 250 requests for new term mappings have been received and will be implemented in the next production release in April 2022. A preview set of these supplemental mappings for the upcoming production release is available on the Downloads page of the MedDRA website.

The screenshot shows the 'Downloads' page of the MedDRA website. The page title is 'Downloads' with a home icon. Below the title, it states: 'The MSSO download page provides access to the following types of information:'. There are three main sections: 'MedDRA Release packages' (with a link to 'MSSO Help Desk'), 'MedDRA Desktop Browsers' (with a link to 'MedDRA Desktop Browsers'), and 'MedDRA supplemental releases' (with a link to 'Supplemental Changes'). A red box highlights the 'SNOMED CT – MedDRA Mapping' section, which contains two links: '30 April 2021 Release Package' and '2 November 2021 Supplemental Release'.

Figure 3-2 SNOMED CT – MedDRA Package and Supplemental Release

The April 2022 production release will be based on MedDRA Version 24.1 (September 2021) and the January 2022 release of SNOMED CT International Edition. In addition, the updated release will include relevant COVID-19 terms and changes resulting from version updates of the two terminologies.

3.5 NEW MedDRA LANGUAGES UNDER DEVELOPMENT

In 2020, the MedDRA Management Committee (MC) approved additional MedDRA translations for the European Economic Area (EEA) official languages. This includes up to a total of 17 additional European languages to support the electronic product information initiative. Note that this initiative includes the translation of MedDRA terms only and does not include MedDRA user documentation.

Presently, Greek, Latvian, Maltese, Polish, and Swedish translations are in development and are expected to be completed in the first half of 2022. The MSSO will begin development of four new European languages in 2022 – Estonian, Finnish, Icelandic, and Norwegian. The remaining languages in the EEA region will be translated and made available between the years of 2023 to 2024. The MSSO will provide estimated release dates for these languages as they become available.

Additionally, in July 2021 the MedDRA Management Committee approved an Arabic MedDRA translation. This translation began development in 2022 and will include all MedDRA user documentation. The MSSO expects to deploy Arabic MedDRA before the end of 2022.

4. SUMMARY OF CHANGES

4.1 SUMMARY OF IMPACT ON THE TERMINOLOGY

The tables below (Tables 4-1 through 4-5) summarize the impact on MedDRA in Version 25.0. For detailed information on the changes to Version 25.0, please see the MedDRA Version Report in MVAT.

File Name	Number of Records in V24.1	Number of Records in V25.0	Change
hlgt.asc	337	337	0
hlgt_hlt.asc	1,755	1,755	0
hlt.asc	1,737	1,737	0
hlt_pt.asc	36,633	37,186	553
llt.asc	84,139	85,091	952
meddra_history_english.asc*	132,027	133,409	1,382
meddra_release.asc*	1	1	0
mdhier.asc	38,767	39,352	585
pt.asc	25,077	25,412	335
soc.asc	27	27	0
soc_hlgt.asc	354	354	0
intl_ord.asc	27	27	0
smq_list.asc	229	230	1
smq_content.asc	90,597	92,226	1,629

Table 4-1 MedDRA Term File Counts

MedDRA Version 25.0 is a complex change version which means changes may be made at any level of the MedDRA hierarchy. In this case, there were two additions and two merges of HLGTS and HLTs. See section 2.2 Complex Changes above. As a result, the net number of changes to the HLT and HLGT record counts remain the same as last release.

* The meddra_history_english.asc and meddra_release.asc files are optional files for use with the MedDRA Desktop Browser (MDB) release 3.0.2 Beta and up. These files are not part of the MedDRA schema.

Summary of Changes

The table below identifies the number of current vs. non-current terms.

LLT Changes

Level	Currency Status	v24.1	v25.0
LLT	Current Terms	74,838	75,787
LLT	Non-current Terms	9,301	9,304
LLT	Total LLTs ¹	84,139	85,091

Table 4-2 Summary of Impact on LLTs

¹Total LLTs include PTs as they are also in the LLT distribution file.

New SMQs

Level	Net Change	v24.1	v25.0
1	1	109	110
2	0	82	82
3	0	20	20
4	0	16	16
5	0	2	2

Table 4-3 Summary of Impact on SMQs

4.2 SUMMARY OF IMPACT ON RECORDS IN MedDRA FILES

The table below lists the consecutive files, associated MedDRA tables and the number of records contained in each consecutive file. A zero indicates that the file has not changed since the prior consolidated MedDRA release. The table below summarizes the impact on MedDRA in Version 25.0. Please see the MedDRA Version Report in MVAT for details.

Summary of Changes

File Name	Number of Records in Table
hlgt.seq	4
hlgt_hlt.seq	20
hlt.seq	4
hlt_pt.seq	985
llt.seq	1,209
mdhier.seq	1,749
pt.seq	421
soc.seq	0
soc_hlgt.seq	4
intl_ord.seq	0

Table 4-4 Summary of Impact on Records in MedDRA Files

4.3 MedDRA TERM COUNTS BY SOC

The table below shows term counts by SOC for HLGTS, HLTs, primary and secondary PTs and LLTs, and primary PTs and LLTs. Note that the number of LLTs also includes PTs.

SOC	LLTs (Primary) ¹	PTs (Primary) ¹	LLTs (Primary and Secondary) ²	PTs (Primary and Secondary) ²	HLTs ³	HLGTS ³
<i>Blood and lymphatic system disorders</i>	1,241	318	4,543	1,113	87	17
<i>Cardiac disorders</i>	1,553	381	2,571	683	36	10
<i>Congenital, familial and genetic disorders</i>	4,304	1,716	4,304	1,716	100	19

Summary of Changes

SOC	LLTs (Primary)¹	PTs (Primary)¹	LLTs (Primary and Secondary)²	PTs (Primary and Secondary)²	HLTs³	HLGTs³
<i>Ear and labyrinth disorders</i>	453	100	914	242	17	6
<i>Endocrine disorders</i>	719	202	1,971	603	38	9
<i>Eye disorders</i>	2,655	669	4,076	1,146	63	13
<i>Gastrointestinal disorders</i>	4,105	950	8,025	1,888	105	21
<i>General disorders and administration site conditions</i>	2,534	1,017	3,530	1,381	35	7
<i>Hepatobiliary disorders</i>	722	221	1,582	471	19	4
<i>Immune system disorders</i>	576	165	3,086	871	26	4
<i>Infections and infestations</i>	7,633	2,133	8,055	2,258	150	12
<i>Injury, poisoning and procedural complications</i>	7,156	1,345	10,183	2,664	78	9
<i>Investigations</i>	14,590	6,111	14,590	6,111	106	23
<i>Metabolism and nutrition disorders</i>	1,032	306	2,969	873	63	14
<i>Musculoskeletal and connective tissue disorders</i>	2,771	518	7,090	1,482	59	11

Summary of Changes

SOC	LLTs (Primary)¹	PTs (Primary)¹	LLTs (Primary and Secondary)²	PTs (Primary and Secondary)²	HLTs³	HLGTs³
<i>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</i>	8,916	2,067	9,774	2,411	201	39
<i>Nervous system disorders</i>	3,969	1,065	7,964	2,212	108	20
<i>Pregnancy, puerperium and perinatal conditions</i>	1,706	248	3,068	671	48	8
<i>Product issues</i>	907	179	937	193	21	2
<i>Psychiatric disorders</i>	2,467	566	3,454	864	77	23
<i>Renal and urinary disorders</i>	1,292	384	2,773	806	32	8
<i>Reproductive system and breast disorders</i>	1,837	527	4,502	1,289	52	16
<i>Respiratory, thoracic and mediastinal disorders</i>	1,894	591	4,612	1,285	49	12
<i>Skin and subcutaneous tissue disorders</i>	2,293	560	5,821	1,552	56	10
<i>Social circumstances</i>	667	287	667	287	20	7
<i>Surgical and medical procedures</i>	5,670	2,446	5,670	2,446	141	19

Summary of Changes

SOC	LLTs (Primary) ¹	PTs (Primary) ¹	LLTs (Primary and Secondary) ²	PTs (Primary and Secondary) ²	HLTs ³	HLGTs ³
<i>Vascular disorders</i>	1,429	340	7,316	1,834	68	11
Total	85,091	25,412				

Table 4-5 MedDRA Term Counts by SOC

¹Primary count only includes the number of terms that are primarily linked to the designated SOC at either the LLT level or the PT level. The sums of primary LLTs and PTs match those in Tables 4-1 and 4-2.

²Total count includes the number of terms that are both primarily and secondarily linked to the designated SOC at either the LLT level or the PT level. Therefore, the sums of total LLTs and PTs are greater than those in Tables 4-1 and 4-2.

³The HLT and HLGT counts are not necessarily unique values given MedDRA's multi-axiality (see Section 2.2 of the Introductory Guide for a discussion of multi-axiality). There are some HLTs that are counted in more than one SOC. For example, HLT *Connective tissue disorders congenital* and HLGT *Musculoskeletal and connective tissue disorders congenital* are counted in both SOC *Congenital, familial and genetic disorders* and SOC *Musculoskeletal and connective tissue disorders*. The sums of HLTs and HLGTs are greater than those found in Table 4-1.

4.4 LLT CURRENCY STATUS CHANGES

The following table reflects three terms at the LLT level in MedDRA Version 25.0 that had a change in currency status along with the rationale for the change.

Lowest Level Term	Currency Status Changed to	Rationale
Hypoglossal nerve stimulator	Non-current	LLT <i>Hypoglossal nerve stimulator</i> (under PT <i>Hypoglossal nerve stimulation</i>) was changed to a status of non-current because the concept represents the name of a device which is out of scope of MedDRA.
Infusion related hypotension	Non-current	LLT <i>Infusion related hypotension</i> (under PT <i>Infusion related reaction</i>) was changed to a status of non-current because the concept represents a combination of infusion related reaction and a systemic event.

Summary of Changes

Lowest Level Term	Currency Status Changed to	Rationale
Red man	Non-current	Vancomycin infusion reaction, a new PT added in Version 25.0, is now the currently accepted nomenclature for this specific drug reaction and is intended to provide an alternative term for the concept of “Red Man Syndrome” which carries racist connotations and implies a white male reference.

Table 4-6 LLT Currency Changes